_____ SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 FORM 10-K ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES [X] EXCHANGE ACT OF 1934 (FEE REQUIRED) FOR THE FISCAL YEAR ENDED DECEMBER 31, 1996 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (NO FEE REQUIRED) FOR THE TRANSITION PERIOD FROM ТΟ 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 (I.R.S. EMPLOYER INCORPORATION OR ORGANIZATION) IDENTIFICATION NO.) 951 CALLE AMANECER SAN CLEMENTE, CALIFORNIA 92673 (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE) (REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE): (714) 366-2183 Securities registered pursuant to Section 12(b) of the Act: None Securities Registered Pursuant to Section 12 (g) of the Act: Common Stock, \$.10 par value Indicate by check mark whether Registrant: (1) has filed all reports required to be filed by Section 13 or 15(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, 1997 was 63,081,000. *

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of February 28, 1997 was \$,169,861.

Portions of the Proxy Statement for Registrant's 1997 Annual Meeting of Stockholders, filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 1996, are incorporated by reference into Part III of this Report.

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

ITEM 1. BUSINESS.

PART I

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 which has become the Company's fastest growing, and largest selling product. The Company believes that the CLAVE offers healthcare providers a combination of safety, ease of use, reliability and cost effectiveness that is superior to any other protective IV connection system on the market.

Heightened awareness of the risk of infection from needlesticks and the substantial expense to healthcare providers of complying with regulatory protocols when needlesticks occur have led to growing demand for safe medical devices such as the Company's protective IV connectors. In addition, healthcare regulations promulgated by OSHA mandate that "universal precautions" be observed to minimize exposure to blood and other body fluids.

BACKGROUND

The Company's first products, the Click Lock and Piggy Lock, feature protected needles to prevent accidental contact with needles and include locking mechanisms to prevent accidental disconnections. These products were designed to replace conventional products and methods, such as IV connectors with exposed needles that are secured by tape or open luer lock connections. Such conventional products typically do not provide the protection from needlesticks, accidental disconnection and contamination that are provided by the Company's products. Although protected needle products manufactured by the Company and by others significantly reduce the risk of needlesticks, they nevertheless employ steel needles which require special disposal procedures.

Recognizing the inherent risks associated with needle handling and disposal, even with protected needle systems, the Company developed the CLAVE, a needleless IV connection system which was introduced in 1993. The CLAVE IV connection system allows protected, secure and sterile IV connections without needles and without failure prone mechanical valves used in the IV connection systems of some competitors. The CLAVE was designed to eliminate needles from certain applications by acute care hospitals, home healthcare providers, ambulatory surgical centers, nursing homes, convalescent hospitals, physicians' offices, medical clinics, and emergency services. Reduction in the use of needles will not only decrease needlesticks but will also reduce the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal. While the Company continues to manufacture and sell protected needle products, sales of those products are declining as the market penetration of needleless systems such as the CLAVE and other competitive needleless products increases.

IV USAGE AND INFECTION CONTROL

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

In conventional practice, primary IV system connections are made by inserting an exposed steel needle attached to the primary IV line into an injection port connected to the catheter. Conventional secondary IV connections, so called piggyback connections, are made by inserting an exposed steel needle attached to a secondary IV line into an injection port or other IV connector. In a conventional IV connection the needle, which typically is secured only with tape, can detach from the catheter or injection port resulting in disconnection and a serious and sometimes fatal interruption of the flow of the IV solution to the patient. The exposed needles can easily be contaminated by contact with unsterile objects or through contact with fluid in the IV lines. A contaminated needle can result in infection to healthcare workers and, less frequently, patients, as a result of accidental needlesticks.

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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 provider is required to perform a series of tests on the healthcare worker for both Hepatitis B and HIV as well as track and record each needlestick incident. Thus, needlesticks result in time lost from work and substantial expense regardless of whether an infectious disease is transmitted. The Company's protective IV connectors are designed to prevent accidental needlesticks from needles originating from primary and secondary IV connections.

PRODUCTS

CLAVE Products

A conventional IV line terminates with a male luer connector to which a needle would be attached to penetrate a latex-covered injection port to make a primary or secondary IV connection. With the CLAVE system, instead of attaching a needle to the male luer, a CLAVE is used in place of the injection port and the male luer, without a needle, is simply threaded into the CLAVE with a half turn. The CLAVE consists of a cylindrical housing which contains a silicone compression seal and a recessed plastic piercing element. As the luer tip enters the CLAVE housing, it depresses the silicone seal back into the housing and slides over the piercing element which penetrates through the compressed silicone. Fluid channels in the piercing element create a continuous fluid pathway from the IV line, through the CLAVE into the primary IV line and into the catheter. The luer tip creates a tight seal against the top of the silicone thereby preventing contaminants from entering the fluid pathway. When the IV line is disconnected from the CLAVE, the silicone compression seal expands to again fill the housing and reseal the opening. When the CLAVE is not in use, the silicone compression seal fills the opening in the housing and covers the plastic piercing element, thus completely sealing the connector and presenting a flush surface which can be cleansed with an alcohol swab.

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 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, 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 integrated CLAVE 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 Y site and twists to make the connection. The CLAVE Y site will not replace CLAVE products used in nonpiggyback connections. Unlike the original CLAVE site, the CLAVE Y site is marketed exclusively to IV set manufacturers, such as McGaw Inc. ("McGaw") and Abbott Laboratories ("Abbott"). These manufacturers plan to build the CLAVE Y site directly into their IV sets. Sales of the CLAVE Y site to date have only been to Abbott and accounted for approximately 4% of the Company's net sales in 1996.

The CLAVE is the Company's fastest growing and largest selling product line, and accounted for 68% of the Company's net sales in 1996.

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

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

With the availability of the CLAVE and other needleless products sold by competitors, the market is shifting rapidly away from protected needle products to needleless connection systems. Sales of Click Lock and Piggy Lock products are declining both absolutely and as a percentage of net sales.

McGaw Protected Needle and Safeline Products

The Company has a Manufacture and Supply Agreement with McGaw (the "McGaw Agreement") extending to July 2000, which grants the Company exclusive rights to perform certain assembly of the McGaw Protected Needle which is marketed and distributed by McGaw. See Marketing and Distribution, below. The McGaw Protected Needle is similar to the Click Lock, and competes with the Company's IV connection systems. The McGaw 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 Agreement, so long as the McGaw Agreement is in effect, and permanently once McGaw purchases a specified quantity of McGaw Protected Needles. The Company began assembly of the McGaw Protected Needle during 1994. Sales of the McGaw Protected Needle to McGaw under the McGaw Agreement accounted for approximately 9%, 14%, and 9% of the Company's net sales in 1994, 1995 and 1996, respectively. With the continuing shift in demand from protected needle to needleless products, the Company expects sales of McGaw Protected Needles will eventually decline. Pursuant to a May 1995 amendment to the McGaw Agreement, McGaw also agreed to pay the Company a share of McGaw's revenues on Safeline, a new needleless IV connector designed and manufactured by McGaw for use with pre-slit injection ports. Such payments commenced in 1996 and accounted for approximately 3% of the Company's net sales.

Lopez Valve

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

RF100 and RF150

The Company has developed a family of inexpensive single-use needleless connectors for use in both piggyback and non-piggyback applications. The RF100, designed for use in piggyback applications, is a one-piece, needleless IV connector comprised of a small plastic piercing element that is recessed into a plastic housing. The

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RF100 locks onto any standard Y site reducing the potential for accidental disconnection. The RF150 is similar to the RF100 in that it is comprised of a small plastic piercing element that is recessed into a plastic housing. The RF150 was developed specifically for Abbott for use with pre-slit injection

ports in piggyback and non-piggyback applications. Once the injection port is pierced, the protective housing opens much like a clothes pin, and locks over the pre-slit injection port thus reducing the potential for accidental disconnections. Although the Company believes that the CLAVE has significant functional advantages over the RF100 and RF150, these products could compete with the CLAVE as less expensive needleless IV connectors.

Budget Medical Products, Inc.

During late 1995, the Company created BMP as a wholly owned subsidiary. BMP was established to service the low end of the safe medical connector market by distributing custom IV sets manufactured by the Company which incorporate lower priced safe medical connectors, and custom IV sets incorporating the CLAVE. During 1995, BMP had no revenue and nominal expenses. During 1996, BMP's revenues were approximately \$400,000. The Company expects to continue to expand the operations of BMP in 1997.

New Products

The Company is developing a number of new products and enhancements to the CLAVE that it intends to introduce in 1997. 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 McGaw and Abbott, two major IV product suppliers, each of whom has a significant share of the IV set market under contract. The McGaw Agreement, which extends to July 2000, gives McGaw exclusive and nonexclusive rights to distribute certain CLAVE products to certain categories of customers. Under the Abbott Agreement which extends to April 2002, Abbott also has rights to market certain CLAVE products together with its own products. The McGaw Agreement and the Abbott Agreement establish the minimum prices that $\ensuremath{\mathsf{McGaw}}$ and Abbott will pay for the Company's products, which are lower than the Company's current average selling prices and which the Company negotiated in anticipation of significant sales to McGaw and Abbott. The McGaw Agreement provides for automatic reductions in minimum prices based on volume increases, and the Abbott Agreement provides for annual renegotiation of minimum prices. The Company could receive more than the minimum prices under formulae in the agreements based on incremental increases in selling prices of McGaw and Abbott IV sets incorporating the Company's products. Although the Company could experience declines in gross margins at the minimum price levels, the Company believes that any such declines would be offset in part by improved absorption of manufacturing overhead as a result of increased production volumes anticipated from sales to McGaw and Abbott.

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

The Company currently has approximately 23 independent distributors in the United States who employ approximately 150 salespeople in the aggregate. In addition, the Company employs 25 product specialists who support the Company's distributors' salespeople, calling on prospective customers, demonstrating products and

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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 McGaw of McGaw Protected Needles and CLAVE products accounted for approximately 20%, 30% and 28% of the Company's net sales in 1994, 1995 and 1996, respectively. Sales to Abbott accounted for approximately 7% of net sales in 1996. Two independent distributors, Professional Hospital Supply and New England Medical Specialties accounted for 13% and 9%, respectively, of 1996 net sales. All other customers account for smaller percentages of net sales. Although the loss of one or more of the distributors named above 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 McGaw or Abbott as a customer would be more significant because these customers have full-line contracts with numerous hospitals and homecare providers to supply all IV products and solutions to those customers.

The Company's products are distributed in several European countries, Canada, the Middle East, Australia, Japan and other parts of Asia. During 1996, 1995 and 1994, foreign sales accounted for approximately 3%, 2% and 2%, respectively, of the Company's net sales. During the second quarter of 1996, the Company entered into a distribution agreement with BOC OHMEDA AB ("Ohmeda"), a major distributor of medical products, for distribution of CLAVE in Europe. Full launch of exclusive distribution in the United Kingdom, France and the Benelux countries commenced in the fourth quarter of 1996, and distribution in most other countries in Europe will be added in phases. In late 1996, the Company employed a product specialist and a clinical specialist resident in Europe. Management expects that its sales to foreign distributors will continue to increase in the future.

MANUFACTURING

Manufacturing of the Company's products involves injection molding of plastic parts, manual and automated assembly of the molded plastic parts, needles and other components, quality control inspection, packaging and sterilization. The Company molds the majority of its requirements for components, performed 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, run by a team of experienced manufacturing management personnel. A mold maintenance shop supports the repair and maintenance needs of the Company's molding operation. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment. The state-of-the-art medical device molding facility includes an 8,000 square foot class 100,000 clean room in which all molding of the Company's proprietary medical components is performed. The clean room is equipped with 22 injection molding machines and ancillary equipment including robots designed to minimize human intervention. The Company uses sophisticated, highly automated assembly systems to assemble the CLAVE, Click Lock, RF150 and the McGaw Protected Needle products. The assembly systems are custom designed and manufactured for the Company. The Company's new CLAVE Y site was initially assembled in a semi-automated mode until automated assembly equipment was completed and installed in early 1997. The Piggy Lock, Lopez Valve and IV sets are assembled manually.

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

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

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 premarket 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 premarket 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. FDA regulatory processes are time consuming and expensive. Uncertainties as to time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. All of the regulated products currently manufactured by the Company are classified as Class II medical devices by the FDA. Class II medical devices are subject to performance standards relating to one or more aspects of the design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

The Company must comply with FDA regulations governing medical device manufacturing practices. The FDA and the California Department of Health Services ("DHS") require manufacturers to register and subject them to periodic FDA and DHS inspections of their manufacturing facilities. The Company is an FDA registered medical device manufacturer, and must demonstrate that the Company and its contract manufacturers comply with the FDA's current Good Manufacturing Practices ("GMP") 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 GMP requirements 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

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management standards of EN ISO 9001(08/94)/EN 46001 (10/93). Those quality standards are similar to the GMP regulations but incorporate the quality requirements for product design and development.

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

The Company has demonstrated conformity to the regulations of both EN ISO 9001 (08/94)/EN 46001 (10/93) and the Medical Device Directive. Upon identifying an EC representative and developing the associated technical files for its products, the Company can affix the CE Mark to its device labeling.

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 with its high-end products like the CLAVE depends on its ability to differentiate them based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as the Company's ability to perceive and respond to changing customer needs. In the long term, the Company's ability to compete may be affected by its ability to reduce unit manufacturing costs of the CLAVE through higher volume production. In October 1996, in response to competitive pressure, the Company announced a price reduction to independent distributors with the objective of protecting and expanding its market.

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

Manufacturers of products with which the Company currently competes, or might compete in the future, include large companies with an established presence in the healthcare products market and substantially greater financial, marketing and distribution, managerial and other resources. In particular, Baxter, Abbott and 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 McGaw and Abbott.

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

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PATENTS

The Company has United States and certain foreign patents on the Click Lock and Piggy Lock IV connectors and has United States patents on the Lopez Valve connector. The Company has applications pending for United States and foreign patents on the CLAVE, Click Lock and Piggy Lock IV connectors. The expiration dates of the Company's patents range from 2005 to 2011.

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 either on the CLAVE or on other products, 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 and Lopez Valve products or the inability to obtain patent protection on the CLAVE could adversely affect the Company's ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on the Company's financial results.

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

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

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

EMPLOYEES

At February 28, 1997, the Company had 121 full-time employees, consisting of 55 engaged in sales, marketing and administration, and 66 in manufacturing, molding, product development and quality control. The Company contracts with two independent temporary agencies to provide its production personnel; none of the personnel provided through those agencies are employed by the Company. At February 28, 1997, the number of temporary production personnel was approximately 114.

ITEM 2. PROPERTIES.

The Company owns two adjacent 39,000 square foot buildings in San Clemente, California. The Company believes that its current facilities are of sufficient size for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

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

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

District of California, the Company alleges patent infringement by defendant's protected needle connector. The Company is seeking an injunction, and monetary damages in an amount to be determined. On February 8, 1996, the Court denied Tri-State's motion for summary judgment of non-infringement

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of one of the Company's patents. On February 28, 1997, the Court ruled on a number of motions filed by the parties, denying summary judgment on most of the motions and issuing rulings on matters of enforceability of the Company's patents that were generally favorable to the Company. The case remains pending and a number of motions remain to be determined by the Court. There is currently no scheduled trial date.

In an action entitled Allen E. Petty dba Carmel Development International v. ICU Medical, Inc. pending in Superior Court for Orange County, State of

California, Plaintiff alleges breach of contract and seeks at least \$500,000 in commissions allegedly related to sales of the CLAVE to various O.E.M. manufacturers. The Company believes the claim is without merit and intends to defend the action vigorously.

In an action entitled Hinck Medical, Inc. v. ICU Medical, Inc,. pending in

the United States District Court for the District of Oregon, the plaintiff alleges that the Company breached a distribution agreement by imposing different payment terms on the plaintiff, Hinck Medical, Inc. ("Hinck") than were required of other distributors, and makes several other allegations. The Company has denied the allegations of the complaint and has asserted counterclaims against Hinck for breach of the distribution agreement and is seeking damages.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS. Not Applicable

EXECUTIVE OFFICERS OF REGISTRANT.

The following table lists the names, ages, positions and offices with the Company held by the executive officers and certain 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.	49	Chairman of the Board, President and Chief Executive Officer
Evelyn Foss Francis J. O'Brien	41 54	Vice President of Marketing Chief Financial Officer, Secretary and Treasurer
KEY EMPLOYEES:		
Robert Brown	39	President, Budget Medical Products, Inc.
Richard Costello	33	National Sales Manager

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.

Ms. Foss became Vice President of Marketing in January 1992, after having been the Manager of Sales and Marketing since October 1988.

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

Young LLP.

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

Mr. Costello became National Sales Manager in August, 1996, after having been a product specialist since February 1992.

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PART II

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

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

1996	High 	Low
First Quarter Second Quarter Third Quarter Fourth Quarter	\$17 5/8 23 1/2 13 5/8 9	\$ 14 13 8 1/4 6 5/8
1995		
First Quarter	\$16 3/8	\$14 1/4
Second Quarter	17	12 3/4
Third Quarter	16 1/2	13
Fourth Quarter	17	10 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, 1997 the Company had 202 stockholders of record and believes it has approximately 4,000 beneficial stockholders.

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ITEM 6. SELECTED FINANCIAL DATA

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

YEAR ENDED DECEMBER 31,

1996	1995	1994	1993	1992
(In	thousands,	except	per share	data)

Net sales Cost of goods sold	\$24,599 10,443	\$21,282 10,286	\$16,542 8,818	\$11,381 4,407	\$10,153 3,219
Gross profit Operating expenses	14,156 8,236	10,996 5,600	,	6,974 2,784	6,934 2,301
Income from operations Other income (expense) Provision for income taxes	5,920 1,294	5,396 723 1,958	3,847	4,190 (12)	4,633 166 848
Income from continuing operations	\$ 4,739 	\$ 4,161	\$ 2,907 =====		\$ 3,951 ======
Income from continuing operations per share	\$0.54 =====	\$0.50 =====	\$0.39 =====	\$0.41	\$0.57 =====
Weighted average number of common and common equivalent shares outstanding	8,842	8,270	7,494	7,431	6,965
CASH FLOW DATA:					
Cash flows from operations	\$ 6,513	\$ 6,997	\$ 938	\$ 3,263	\$ 3,048
BALANCE SHEET DATA					
Cash and liquid investments Working capital Total assets Long-term debt Stockholders' equity	\$31,760 35,587 49,639 - 46,749	\$29,665 33,762 47,850 - 45,658		23,594	\$ 2,787 16,308 18,964

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

OVERVIEW

Following the Company's launch of CLAVE products in 1993, the Company's net sales have increased and the Company has experienced a significant shift in demand towards the needleless CLAVE system and away from its Click Lock and Piggy Lock protected needle products. The Company believes that the shift to needleless IV connection systems is taking place throughout the safe connector market, and will continue for the foreseeable future. The Company believes that its ability to increase its revenues and profits will depend, in large part, on the success of its marketing and distribution strategies for CLAVE products, its ability to reduce unit manufacturing costs for CLAVE, and its ability to develop, produce and sell new, innovative products.

The following table sets forth, for the periods indicated, net sales by product as a percentage of total net sales:

Product Line	1996	1995	1994
~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	600	61.0	
CLAVE	68%	61%	45%
Click Lock	12%	20%	41%
McGaw Protected Needle	8 %	13%	9%
Lopez Valve	4%	4 %	5%
RF100-RF150 ("Rhino")	3%	28	-
Budget Medical Products	2%	-	-
McGaw SafeLine revenue			
sharing	3%	-	-
Total	100%	100%	100%

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. To gain additional access to large hospitals and major buying organizations, the Company negotiated the McGaw Agreement and the Abbott Agreement. Those agreements establish minimum prices that McGaw and Abbott will pay for the Company's products, which are lower than the Company's current average selling prices and which the Company negotiated in anticipation of significant sales to McGaw and Abbott. The McGaw Agreement, provides for automatic reductions in minimum prices based on volume increases, and the Abbott Agreement provides for annual re-negotiation of minimum prices. Although the Company could experience declines in gross margins at the minimum price levels, the Company believes that any such declines would be offset in part by improved absorption of manufacturing overhead as a result of increased production volumes anticipated from sales to McGaw and Abbott.

The Company's marketing and distribution strategy may result in a significant share of the Company's revenues being concentrated among a small number of customers. The loss of a strategic supply and distribution agreement with a customer or the loss of a large contract by such a customer, could have a material adverse effect on operating results.

COMPARISON OF 1996 TO 1995

In 1996, the Company reported net sales of \$24,599,000, which was \$3,317,000, or 16%, higher than the net sales of \$21,282,000 reported in 1995. The increase was primarily attributable to a \$3,648,000, or 28%, increase in CLAVE sales, including revenue sharing from McGaw on sales of CLAVE products, and \$829,000 of revenue sharing on McGaw's sales of its SafeLine products, which payments were initiated 1996. Also contributing to the increase were sales by the Company's Budget Medical Products subsidiary formed in late 1995, sales of the low-priced Rhino and a modest increase in Lopez valve sales. Those increases were partially offset by a 32% decrease in

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Click Lock and Piggy Lock sales and a 25% decrease in McGaw Protected Needle sales. The Company's independent distributors accounted for 65% of the Company's net sales in 1996, with McGaw accounting for 28% and Abbott the remaining 7%. In 1995, the comparable percentages were 68%, 30% and 2%, respectively.

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

Net sales to McGaw, including revenue sharing, amounted to \$6,875,000 in 1996, as compared to \$6,301,000 in 1995. CLAVE sales to McGaw increased approximately 14%, principally because of an increase in unit shipments. Net sales of the McGaw Protected Needle declined 25% and management expects those to continue to decline as the market for safe connectors continues its shift to needleless technology. Under a non-exclusive strategic supply and distribution agreement with McGaw, the Company is entitled to share in certain incremental increases in McGaw's CLAVE selling prices. The Company recorded approximately \$377,000 of revenue sharing on CLAVE products in 1996, but at McGaw's current price levels, Management does not expect to receive significantly greater amounts of revenue sharing on CLAVE products sold to McGaw, and there is no assurance that McGaw's pricing in the future will result in any revenue sharing in the future. Based on McGaw's forecasts, Management expects increases in unit shipments to McGaw in 1997, although there is no assurance that this expectation will be realized. Under that same agreement, the Company receives revenue sharing payments on McGaw's sales of its SafeLine products; such payments commenced in 1996, and the Company recorded estimated revenue sharing of approximately \$829,000. Although Management anticipates that such revenue sharing will continue, the actual amount will depend on the volume and selling prices of McGaw's SafeLine products, which Management has no means of forecasting accurately.

Net sales to Abbott amounted to \$1,755,000 in 1996, as compared to \$406,000 in 1995. CLAVE sales were \$1,156,000, as compared with none in 1995, with the balance of the sales in the low-priced Rhino. Under its non-exclusive supply and distribution agreement with Abbott, Abbott pays minimum prices for CLAVE and

Rhino products and the Company is entitled to receive revenue sharing under a formula based on Abbott's selling prices. The minimum prices were negotiated in anticipation of significant sales to Abbott; however, the agreement with Abbott neither requires the purchase of minimum quantities nor prevents Abbott from marketing competitive products, and there is no assurance that Abbott will be successful in promoting and selling the Company's products against its other products or against other competitors' current or future products. Net sales in 1996 include \$124,000 of revenue sharing recorded in the fourth quarter of 1996 related to sales through the third quarter of 1996, principally related to the Rhino product; Abbott had not reported the fourth quarter revenue share in time to be recorded in the 1996 financial statements, and Management did not believe that it has adequate history under the Abbott Agreement to estimate the amount. Management expects only a moderate increase in sales volume with Abbott in 1997, although the amount and timing will depend on Abbott's sell-through of products sold to it by the Company and Abbott's ability to expand its market for those products, and there is no assurance that such increases will be realized.

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 at least five such products. In response to competitive pressure felt in the third quarter of 1996, the Company in mid-October announced to its distributors a new aggressive pricing strategy to protect and expand its market. Prices to independent distributors will eventually be reduced up to approximately 40%. The average price reduction in the fourth quarter of 1996 was far less than the maximum 40%, although Management expects that the average price of its CLAVE products will decline over the next several quarters. Management expects that the price decline will be more than offset by increased volume. However, there is no assurance that such increased volume will be achieved, or that the Company's current or future products will be able to successfully compete with products developed by others.

Management expects that unit sales of CLAVE to its independent distributors will increase in 1997, although the size of such increase may be impacted by competition from existing and new competitive products or acquisition of CLAVE

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market share by Abbott and McGaw. Management expects to encounter continued pricing pressure from individual end users, but believes that its new pricing strategy will improve its competitive position.

Net sales of Click Lock and Piggy Lock decreased 32% in 1996 as compared to 1995, again because of the safe connector market's continued shift to needleless technology, and Management expects that decline to continue.

The Lopez Valve and Swiss System showed a 23% growth in 1996 revenue as compared to 1995 because of increased unit shipments. Management expects continued modest increases in Lopez Valve sales in 1997.

During the second quarter of 1996, the Company entered into a distribution agreement with BOC OHMEDA AB ("Ohmeda"), a major distributor of medical products, for distribution of CLAVE in Europe. Full launch of exclusive distribution in the United Kingdom, France and the Benelux countries commenced in the fourth quarter of 1996, and distribution in most other countries in Europe will be added in phases. Total sales to foreign distributors were \$693,000 in 1996. Management expects that its sales to foreign distributors will continue to increase in the future.

Gross margin for 1996 improved to 58% from the 52% registered in 1995. The shift in sales mix toward a higher percentage of the relatively higher-margin CLAVE products, continued increases in the benefits of the Company's extensive production automation, and the McGaw SafeLine revenue sharing first recorded in 1996 more than offset the effect of lower average unit selling prices.

The Company's Budget Medical Products subsidiary ("BMP") recorded approximately \$400,000 net sales in 1996, its first year of operations. BMP markets custom I.V. sets, production of which is relatively labor-intensive, resulting in a generally lower gross profit margin than for the Company's other products. BMP had a small negative gross profit margin in 1996. It expects to achieve a small positive gross profit margin in 1997, as volume increases and improvements in production efficiency are achieved, although there can be no assurance that such increases and improvements will be achieved. 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.

The Company expects that its unit production costs will continue to decrease in 1997 as unit volumes increase, but that the gross margin percentage will stay at or slightly lower than that achieved in 1996 as average unit sales prices decrease.

Selling, general and administrative costs ("SG&A") increased by approximately \$2,009,000 to \$7,446,000 in 1996, as compared to \$5,437,000 in 1995. As a percentage of sales, SG&A costs were 30% in 1996 and 26% in 1995. The increase was primarily due to the continuing costs of patent litigation in which the Company is the plaintiff; such costs were \$1,615,000 in 1996 and \$168,000 in 1995 (see Item 3, "Legal Proceedings"). Other SG&A expenses increased at a somewhat lower rate than the increases in sales except for those related to BMP, which were not incurred in 1995. Management expects SG&A costs, exclusive of the patent litigation costs, to increase in 1997, both in absolute terms and also slightly as a percentage of sales, because of growth in the Company and marketing and promotional costs of new products expected to be introduced in 1997.

Management expects the patent litigation costs to decrease somewhat from the level experienced in 1996, but the amount and timing of the costs will depend on the progress of the litigation, and no assurances can be given in this regard.

Research and development ("R&D") costs increased in 1996 by approximately 626,000 to 790,000, or 3% of net sales, as compared with approximately 164,000, or less than 1% of sales, in 1995. The increase accelerated during the year as the Company increased efforts to complete development on a number of new products. Those efforts will continue into 1997, and Management expects R&D costs to continue at or higher than the level in the second half of 1996 until the principal product development efforts are completed in mid-1997. However, no assurance can be given that such costs will not differ from those estimates or that the R&D will be completed as expected.

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

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Investment income increased in 1996 to \$1,289,000 from \$713,000 in 1995 because of increased funds invested. Funds increased because of the net proceeds of approximately \$16,000,000 from the Company's July 1995 public offering of Common Stock and cash provided by operations. Management expects that there may be a decrease in investment income in 1997 because of the use of funds to acquire treasury stock, but the amount of decrease, if any, will depend on the amount of stock acquired. Investment income would also be affected by any change in short-term interest rate levels.

The Company's effective income tax rate in 1996 was 34% as compared with 32% in 1995. A state manufacturing tax credit, recorded in the fourth quarter of both years, was lower in 1996 than in 1995, and that effect was partially offset by a higher portion of income being tax-exempt investment income in 1996. Management expects its effective tax rate in 1997 to be equal to or slightly higher than the 1996 rate.

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

COMPARISON OF 1995 TO 1994

Net sales increased 29% to \$21,282,000 compared to \$16,542,000 in 1994. The primary reason for this increase was higher CLAVE unit sales. Total CLAVE unit sales increased approximately 100% compared to 1994. The Company's independent distributors and McGaw accounted for approximately 39% and 61% of this unit growth, respectively. The aggregate average sales price on CLAVE products decreased approximately 10% in 1995 compared to 1994. This decrease was due to shifts in both customer and product mixes. McGaw purchases primarily lower cost bulk non-sterile product versus higher priced packaged and sterilized products purchased by independent distributors. CLAVE unit shipments to McGaw

represented approximately 42% of total CLAVE unit shipments in 1995 compared to only 23% in 1994. In addition, a larger percentage of CLAVE units purchased by McGaw in 1995 were lower cost bulk CLAVEs compared to 1994 resulting in lower average selling prices to McGaw. Total CLAVE sales dollars increased approximately 76% to approximately \$13,075,000 in 1995 compared to \$7,411,000 in 1994.

Click Lock sales continued to decrease at a steady rate. Click Lock sales decreased from approximately 6,843,000 in 1994 to approximately 4,236,000 in 1995.

McGaw Protected Needle sales increased from approximately \$1,529,000 in 1994 to approximately \$2,833,000 in 1995. Demand for McGaw's Protected Needle in 1995 was essentially the same as that in 1994. The dollar increase realized by the Company in 1995 was due to the fact that the Company increased its production of this product mid-way through 1994 and throughout 1995 to supply all of McGaw's requirements.

Lopez Valve and Swiss System sales increased approximately 5% to approximately \$778,000 in 1995 compared to approximately \$743,000 in 1994.

The Company designed and manufactured the RF150 during 1995 at the request of Abbott. RF150 sales to Abbott in 1995 were approximately \$363,000.

Gross margins improved in 1995 to 52% compared to 47% in 1994. The Company dramatically increased its production capacity in 1994. The increased capacity was not fully utilized in 1994. Higher production volumes in 1995 resulted in a greater absorption of overhead. In addition, certain start-up costs associated with CLAVE in 1994 did not recur in 1995. Due to higher production volumes and various cost cutting measures employed in 1995, manufacturing overhead as a percentage of sales decreased from 31% in 1994 to 27% in 1995. By the fourth quarter of 1995 manufacturing overhead as a percentage of sales decreased to 24% of net sales and the gross margin was 60%.

SG&A expenses increased approximately \$1,761,000 to approximately \$5,437,000 in 1995 from approximately \$3,676,000 in 1994. As a percentage of net sales, SG&A expenses increased to 26% compared to 22% in 1994. The primary reason for the increase related to significantly higher advertising and promotion of CLAVE in

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1995 compared to 1994. Sales and marketing expenses increased approximately \$1,426,000 in 1995 compared to 1994.

Legal fees related the Company's is patent litigation (see above and Item 3, "Legal Proceedings") decreased to approximately \$168,000 in 1995 from approximately \$347,000 in 1994.

Research and development expenses decreased somewhat in 1995 compared to 1994.

Operating margin increased in 1995 to 25% from 23% in 1994 due to higher gross margins offset slightly by higher sales and marketing expenses as noted above. During the fourth quarter of 1995, operating margins reached 33% due to higher gross margins.

The Company's effective tax rate in 1995 was 32% compared to 33% in 1994. The effective tax rate in 1995 was lower than statutory rates due to a state manufacturing tax credit recorded in the fourth quarter. In 1994, the Company also received a tax benefit related to a reduction in the valuation allowance established against the Company's deferred tax asset.

Net income increased 43% primarily due to higher sales and higher operating margins.

Net income per share increased 28% due to the factors noted above, offset somewhat by the issuance of 1,460,000 shares in the secondary public offering completed in July 1995.

LIQUIDITY AND CAPITAL RESOURCES

During 1996, working capital increased approximately \$1,825,000 to \$35,587,000 from \$33,762,000. The Company's cash and cash equivalents and

investment securities, including liquid investments, increased to \$31,759,000 from \$30,172,000. Those increases were due primarily to \$6,513,000 of cash flows from operating activities and \$1,460,000 from stock options exercised (principally tax benefits), offset by \$5,108,000 used to acquire treasury stock.

During 1995, working capital increased approximately \$21,050,000 to \$33,762,000 from \$12,712,000. The Company's cash and cash equivalents and investment securities position increased to \$30,172,000 from \$8,073,000. Those increases were due primarily to approximately \$6,997,000 cash flow from operating activities and \$16,000,000 in net proceeds raised in a Common Stock offering which closed July 5, 1995 in which 1,460,000 new shares were issued.

Capital expenditures were reduced significantly in 1996 and 1995 compared to 1994. During 1994, the Company made significant investments to increase production capacity to facilitate the agreements with McGaw and Abbott. Management believes it now has adequate production capacity to meet demand for the foreseeable future, although it expects to add some machinery and equipment and molds in 1997 for production of new products.

Management expects that sales of the Company's products will continue to grow in 1997. If sales continue to increase, accounts receivable and inventories are expected to increase as well. In addition, the Company intends to continue to expand its sales force by adding more product specialists and marketing support personnel. As a result of these and other factors, the Company expects the use of working capital to fund its operations to continue to increase.

Management has announced that it expects to spend \$1 million to \$3 million beyond amounts spent through December 31, 1996 to repurchase its Common Stock. Through February 28, 1997, the Company has spent an additional \$1,275,000 to acquire 138,000 shares. Future acquisitions, if any, will depend on market conditions and other factors and their amount could change significantly from the announced expectation.

The Company believes, however, that its existing working capital, supplemented by income from operations, will be sufficient for the foreseeable future.

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FORWARD LOOKING STATEMENTS

The foregoing statements in this Management's Discussion and Analysis and elsewhere in this Report concerning beliefs or expectations for the future with respect to market shifts, competitive conditions, timing and success of new product offerings, trends, production capacity, improvement in production efficiency, sales growth, gross sales to particular customers, product pricing, revenue sharing, factors affecting gross margins, overhead absorption, product mix, product sales and demand, selling, general and administrative expenses generally and specific expenses, research and development progress and expenses, investment income, income tax rates, capital expenditures, working capital, expenditures to repurchase Common Stock, and other financial factors are forward looking statements that involve a number of risks and uncertainties. The Company cautions that, in addition to the factors described in such statements, actual future results of operations are subject to other important factors, including among others the following: general economic and business conditions; the effect of price and safety considerations on the healthcare industry, such as product innovation, new technologies, marketing and distribution strength and price erosion; unanticipated market shifts and trends; production problems; changes in product mix; changes in marketing strategy; the availability of patent protection and the cost of enforcing of defending patent claims; and other risks described from time to time in the Company's registration statements and reports filed with the Securities and Exchange Commission, including those described under "Risk Factors" in the Company's Current Report on Form 8-K dated November 14, 1996. Results of operations actually achieved in the future may thus differ materially from Management's current expectations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

following page.

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, 1996 and 1995, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1996. 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, 1996 and 1995, and the consolidated results of its operations and its consolidated cash flows for each of the three years in the period ended December 31, 1996, 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 29, 1997

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ICU MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

ASSETS

December	31,
1996	1995

CURRENT ASSETS: Cash and cash equivalents Liquid investments	\$ 2,059,663 29,700,000	\$ 2,013,770 27,650,844
Cash and liquid investments Investment securities held-to-maturity Accounts receivable, net of allowance for doubtful accounts	31,759,663 -	29,664,614 507,580
of \$293,032 in 1996 and \$254,987 in 1995 Inventories Prepaid expenses and other Deferred income taxes		2,733,329 1,503,822 888,425 451,000
Total current assets	38,249,577	35,748,770
PROPERTY AND EQUIPMENT, at cost: Machinery and equipment Furniture and fixtures Molds Construction in process Land, building and building improvements	1,319,920 2,679,014 417,327	6,222,556 899,953 3,128,740 502,638 4,988,036
LessAccumulated depreciation	, ,	15,741,923 (4,092,855)
	10,928,570	11,649,068
OTHER ASSETS	460,490 \$49,638,637 ========	452,535 \$47,850,373

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ICU MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

LIABILITIES AND STOCKHOLDERS' EQUITY

	December 31,		
	1996	1995	
CURRENT LIABILITIES: Accounts payable Accrued liabilities	\$1,902,217 760,516	\$1,048,412 937,920	
Total current liabilities	2,662,733	1,986,332	
DEFERRED INCOME TAXES	227,000	206,000	

<pre>STOCKHOLDERS' EQUITY: Convertible preferred stock, \$1.00 par value Authorized500,000 shares; Issued and outstandingnone Common stock, \$0.10 par value- Authorized20,000,000 shares; Issued 8,867,162 shares at 1996 and</pre>	-	-
8,662,837 shares at 1995, respectively Additional paid-in capital Treasury stock 566,711 shares at 1996 Retained earnings	886,716 39,447,125 (4,848,465) 11,263,528	866,284 38,016,465 - 6,775,292
Total stockholders' equity	46,748,904 \$49,638,637	45,658,041

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF INCOME

	Years ended December 31,				
	1996	1995	1994		
NET SALES	\$24,599,005	\$21,281,995	\$16,542,293		
COST OF GOODS SOLD	10,442,986	10,286,052	8,818,286		
Gross profit	14,156,019	10,995,943	7,724,007		
OPERATING EXPENSES: Selling, general and administrative Research and development	7,445,694 790,353		3,676,122 200,742		
Income from operations	5,919,972	5,395,471	3,847,143		
OTHER INCOME: Investment income Other	4,920		153,797		
	1,294,218	723,089	516 , 259		
Income before income taxes	7,214,190	6,118,560	4,363,402		
PROVISION FOR INCOME TAXES	2,475,000	1,958,000			
NET INCOME		\$ 4,160,560	\$ 2,907,402		
NET INCOME PER SHARE		\$0.50 =======			
WEIGHTED AVERAGE NUMBER OF COMMON AND COMMON EQUIVALENT SHARES OUTSTANDING	8,841,562	8,269,523	7,494,179		

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Number of Shares Outstanding			Treasury Stock	Retained Earnings (Accumulated Deficit)	Total
BALANCE, January 1, 1994	7,003,637	\$700,364	\$21,086,135	ş –	\$ (292,670)	\$21,493,829
Exercise of stock options and related income tax benefits Net Income	62,100	6,210			- 2,907,402	
BALANCE, December 31, 1994	7,065,737	706,574	21,338,190		2,614,732	24,659,496
Issuance of common stock Exercise of stock options and	1,460,000	146,000	15,861,697	-	-	16,007,697
-	137,100	13,710	816,578	-	4,160,560	830,288 4,160,560
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 Net Income	234,325	20,432	1,430,660	259,703		1,459,841 4,739,190
BALANCE, December 31, 1996	8,300,451	\$886,716	\$39,447,125	\$(4,848,465)	\$11,263,528	\$46,748,904

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

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,			
	1996 1995		1994	
CASH FLOWS FROM OPERATING				
ACTIVITIES:				
Net income	\$ 4,739,190	\$ 4,160,560	\$ 2,907,402	
Adjustments to reconcile net income to net cash				
provided by operating activities				
Depreciation and amortization	1,969,310	1,798,700	1,123,776	
Deferred income taxes, non-current	21,000	288,300	(36,000)	
(Increase) decrease in:				
Accounts receivable	(289,821)	(578,972)	(588,480)	
Inventories	(729,797)	1,366,342	(1,673,136)	
Prepaid expenses and other assets	125,279	(568,426)	(356,007)	
Increase(decrease) in:				
Accounts payable	853,805	290,878	37,102	
Accrued liabilities	(177,404)	134,920	(577,211)	
Deferred income taxes, current	1,000		101,000	

Net cash provided by operating activities	6,512,562	6,997,302	
CASH FLOWS FROM INVESTING ACTIVITIES: Purchases of property and equipment Purchases of investment securities		(1,739,877)	(E 101 110)
Proceeds from sales of investment securities Net change in liquid investments		4,000,000 (24,775,844)	
Net cash (used in) investing activities	(2,818,342)	(22,515,721)	
CASH FLOWS FROM FINANCING ACTIVITIES: Proceeds from exercise of stock			
options and related income tax benefits Proceeds from sale of common stock	-	830,288 16,007,697	,
Purchase of treasury stock	(5,108,168)	-	
Net cash provided by (used in) financing activities	(3,648,327)	16,837,985	,
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	45,893	1,319,566	(1,223,594)
CASH AND CASH EQUIVALENTS, beginning of year	2,013,770	694,204	1,917,798
CASH AND CASH EQUIVALENTS, end of year	\$ 2,059,663	\$ 2,013,770	
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the period for income taxes	\$ 1,406,620	\$ 1,304,677	

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ICU MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 1996, 1995 AND 1994

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. General

ICU Medical, Inc. (the Company - a Delaware Corporation) operates in one business segment engaged in the development and marketing of proprietary disposable medical devices designed to protect healthcare workers and patients from the spread of infectious diseases. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States. A wholly owned subsidiary, Budget Medical Products, Inc., formed late in 1995 is included in the Consolidated Financial Statements.

b. Inventories

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

Inventories, net of reserves, at December 31, consist of the following:

	1996	1995
Raw materials Work in process Finished goods	\$1,179,126 457,885 596,608	\$684,438 531,638 287,746
	\$2,233,619	\$1,503,822

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 vears

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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Effective January 1, 1996, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of." The statement requires that impairment losses for long-lived assets and identifiable intangibles to be held and used be based on the fair value of the asset. The statement also requires that these assets be reported at the lower of carrying amount or fair value less cost to sell. Adoption of SFAS No. 121 did not have a material effect on the Company's financial position or results of operations.

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, 1996 and 1995, the net book value of patents and licenses was \$371,131 and \$343,176, respectively; net of accumulated amortization of \$166,214 and \$111,214, respectively.

e. Research and Development

The Company expenses research and development costs as incurred.

f. Cash Equivalents

Cash equivalents include certificates of deposit and money market funds

with initial maturities of three months or less.

g. Net Income Per Share

Net income per share is computed by dividing net income by the weighted average number of shares of common stock and common stock equivalents outstanding during the years. Common stock equivalents consist of the number of shares issuable on exercise of the outstanding common stock options (excluding any options which are antidilutive), 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

In May 1993, the Financial Accounting Standards Board issued 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. This statement 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. The Company adopted SFAS No. 115 on January 1, 1994. Adoption of SFAS No. 115 did not have a material impact on the Company's consolidated financial position or results of operations.

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.

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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 based on historical experience. Revenue sharing payments are estimated and recorded in the period earned, and adjusted to actual amounts when reports are received from payers; if there is insufficient data to make such estimates, the revenue sharing is not recorded until reported by the payers.

k. Post-retirement and Post-employment Benefits

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

1. Stock Options

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

m. Accounting Estimates

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

n. Reclassifications

Certain reclassifications have been made to the 1995 financial statements in order to conform with the 1996 presentation.

2. INVESTMENTS

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

	1996	1995
Corporate preferred stocks Federal tax-exempt debt securities	\$17,500,000 12,200,000	\$ 27,650,844
	\$29,700,000	\$27,650,844

Investment securities held-to-maturity securities at December 31, 1995 consisted of municipal bonds that are stated at amortized cost, which approximated market and which the Company intended to hold until maturity in 1996.

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

	1996	1995	1994
Corporate dividends Tax-exempt interest Other interest	\$ 71,176 1,072,711 145,411	\$ 58,465 524,431 129,755	\$ - 340,726 21,736
	\$1,289,298	\$712,651	\$362,462

3. ACCRUED LIABILITIES

Accrued liabilities consists of the following:

	1996	1995
Accrued legal expenses	\$ 24,728	\$ 49,609
Accrued incentive compensation	210,849	261,225
Accrued vacation	152,407	118,906
Taxes payable	229 , 776	300,000
Other accruals	142,756	208,180
Total accrued liabilities	\$760 , 516	\$937 , 920

4. COMMON STOCK AND COMMON STOCK OPTIONS GRANTED

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

In 1993, the Company terminated a previous stock option plan and adopted

the 1993 Stock Incentive Plan and Directors' Stock Option Plan (the Plans). In 1996, the Plans were amended to increase from 1,500,000 to 3,500,000 the number of shares reserved for issuance to employees and directors. Options granted under the 1993 Stock Incentive Plan expire eleven years from issuance and are time-accelerated options which vest upon the earlier of the Company attaining specific operating performance levels or ten years from the date of grant. The 1993 Directors' Stock Option Plan calls for options to be granted to nonemployee Directors every three years; fifty percent of each Director's options vest on the date of the first annual shareholders meeting following the grant and the other fifty percent on the date of the second such meeting. The Plans include a condition whereby options not vested are cancelled 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.

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

	Exercise Price		
	Shares	Range	Weighted Average
Outstanding at January 1, 1994	634,875	\$ 0.29 -\$14.63	\$ 4.25
Granted Exercised Forfeited	62,100	10.63 - 16.25 0.29 - 7.17 9.50 - 14.63	1.12
Outstanding at December 31, 1994	1,295,775	0.29 - 16.25	10.49
Granted Exercised Forfeited	137,100	11.44 - 16.63 0.29 - 6.96 9.50 - 15.13	0.37
Outstanding at December 31, 1995	1,175,225	0.29 - 16.63	11.76
Granted Canceled Exercised Forfeited	105,000 234,325 55,050	7.19 - 23.00 15.35 - 16.25 0.29 - 14.63 9.50 - 18.81	16.13 2.00 14.01
Outstanding at December 31, 1996	1,739,150	\$ 5.75 - \$23.00	\$13.82
Exercisable at December 31: 1994 1995 1996	375,675 255,825 26,500	0.29 - 14.00 0.29 - 14.00 5.75 - 14.00	\$ 1.31 2.75 10.98
Available for grant at December 31, 1996	1,756,900		

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).

Of the options outstanding at December 31, 1996, 1,682,650 are timeaccelerated options, almost all of which were issued under the 1993 Stock Incentive Plan. Of those options, 136,350 issued in 1993 at an average exercise price of \$9.56 expire in 2004; 609,000 issued in 1994 at an average exercise price of \$15.13 expire in 2005; 31,000 issued in 1995 at an average exercise price of \$13.77 expire in 2006; and, 906,300 issued in 1996 at an average exercise price of \$13.60 expire in 2007. Of the remaining 56,500 options that are not time-accelerated, 11,500 at an average exercise price of \$7.05 expire in 1997, 15,000 at an exercise price of \$14.00 expire in 1998 and 30,000 at an exercise price of \$16.13 expire in 2001. In January 1997, an additional 750,000 options with exercise prices ranging from \$15.38 to \$16.25 per share (weighted average \$15.92) were canceled and replaced with options with an average exercise price of \$8.23 per share. The exercise prices on options for an additional 80,000 shares with exercise prices ranging from \$9.19 to \$23.00 per share (weighted average \$13.22 per share) were reduced to \$ 8.31 per share, equal to the fair market value of the Company's stock at the date of the reduction. These January 1997 actions narrowed the price range of options outstanding at December 31, 1996, from \$5.75 to \$16.13 per share, and reduced the weighted average to \$10.28 per share.

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

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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 1995 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 6.0 and 6.4 percent, respectively; expected option life of 2.5 and 3.4 years, respectively; expected volatility of 44 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.

For purposes of the following required pro forma information, the weighted average fair value of stock options granted in 1995 and 1996 was \$4.50 and \$5.84, respectively. The total estimated fair value is amortized to expense over the vesting period.

	1996	1995
Proforma:		
Net income	\$3,968,000	\$4,147,000
Net income per share	\$0.47	\$0.50
Weighted average number of shares outstanding	8,378,000	8,254,244

5. INCOME TAXES

The provision for income taxes for the years ended December 31, 1996, 1995 and 1994, is as follows:

	1996	1995	1994
Current:			
Federal State	\$1,992,000 461,000	\$1,110,700 454,000	\$1,064,000 327,000
State	401,000	434,000	
	2,453,000	1,564,700	1,391,000

Deferred:

Federal State	(3,000) 25,000	279,300 114,000	47,000 18,000
	22,000	393,300	65,000
	\$2,475,000	\$1,958,000 ======	\$1,456,000

The current tax provision includes the tax expense that results from allocating to stockholders' equity the tax benefit that the Company receives upon exercise of stock options by employees and directors. Because of that benefit, current income taxes payable were reduced from the amounts in the above table by \$1,032,000, \$780,000 and \$188,000 in 1996, 1995 and 1994, respectively.

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

	19	96	1995		1994	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected						
statutory rate	\$2,453,000	34.0%	\$2,080,000	34.0%	\$1,483,000	34.0%
State income tax	443,000	6.1	373,000	6.1	266,000	6.1
Tax-exempt interest						
and dividends	(382,000)	(5.3)	(145,000)	(2.4)	(110,500)	(2.5)
Change in valuation						
allowance	-	-	-	-	(182,500)	(4.2)
Tax credits	(39,000)	(0.5)	(350,000)	(5.7)	-	-
Provision	\$2,475,000	34.3%	\$1,958,000	32.0%	\$1,456,000	33.4%
		=====		====		====

The components of the Company's deferred income tax provision for the years ended December 31, 1996, 1995 and 1994 are as follows:

	1996	1995	1994
Allowance for doubtful accounts	\$(25 , 000)	\$(24,000)	\$ 1,500
Inventory reserves	(23,000)	37,800	47,200
Accruals	122,000	159,500	(3,000)
State income taxes	(73,000)	115,000	(46,000)
Depreciation	21,000	105,000	247,800
Valuation allowance	-	_	(182,500)
	\$ 22,000	\$393,300	65,000
		========	

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

1996	1995

Allowance for doubtful accounts Inventory reserves Accruals State income taxes	\$ 127,000 195,000 70,000 58,000	\$ 102,000 172,000 192,000 (15,000)
beate mediae caxes		(10,000)
	\$ 450,000	\$ 451,000
Long-term deferred tax liability:		
Depreciation	\$(227 , 000)	\$(206,000)

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6. MAJOR CUSTOMERS AND CONCENTRATIONS OF CREDIT RISKS

The Company manufactures disposable medical devices which are sold on credit terms principally throughout the United States to wholesale medical supply distributors, and in selected cases to hospitals and homecare providers. The distributors, in turn, sell the Company's products to hospitals and homecare providers. For the years ended December 31, 1996, 1995 and 1994, the Company had sales of 10 percent or greater to three distributors as follows:

		1996	1995	1994
Distributor	A	*	12	11
Distributor	В	*	*	13
Distributor	С	13	12	12

* less than 10 percent

The Company has entered into a sales and supply agreement with a medical supply manufacturer which accounted for 28 percent, 30 percent and 20 percent of sales for the years ended 1996, 1995 and 1994, respectively.

7. EMPLOYMENT CONTRACTS

The Company has employment contracts with certain key employees which include an incentive compensation agreement. Under contracts that expired on December 20, 1996, a cash bonus pool was provided equal to 10 percent of aftertax profits through 1995. Fifty percent of each period's incentive compensation was payable on December 20 of that period and the remaining 50 percent was paid on December 20 of the subsequent period. Incentive compensation expense for the years ended December 31, 1995 and 1994, was approximately \$465,000 and \$324,000, respectively. Under new contracts effective January 1, 1997, incentive compensation will be awarded if certain operating performance goals are met.

8. COMMITMENTS AND CONTINGENCIES

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

9. RELATED PARTY TRANSACTION

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

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

Quarter Ended

	March 31	June 30 S	Sept. 30	Dec. 31
1996 				
Net Sales	\$6,008	\$6,147	\$5 , 972	\$6,472
Gross Profit	3,704	3,472	3,200	3,780
Net Income	1,591	1,267	964	917
Net Income Per Share	\$ 0.18	\$ 0.14	\$ 0.11	\$ 0.11
1995 				
Net Sales	\$5,427	\$5 , 966	\$4,617	\$5 , 272
Gross Profit	2,411	3,118	2,310	3,157
Net Income	731	890	891	1,649
Net Income Per Share	\$ 0.10	\$ 0.12	\$ 0.10	\$ 0.18

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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, 1996, and such information is incorporated herein by this reference. Pursuant to Instruction G(3) to Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K, information about Registrant's executive officers called for by Item 10, Part III of Form 10-K is set forth in Part I of this Report in a separate item captioned "Executive Officers of Registrant."

ITEMS 11 THOUGH 13.

The information called for by Part III of Form 10-K (Item 11 - Executive Compensation, Item 12 - Security Ownership of Certain Beneficial Owners and Management and Item 13 - Certain Relationships and Related Transactions) is set forth in Registrant's definitive Proxy Statement filed or to be filed pursuant to Regulation 14A within 120 days of Registrant's fiscal year ended December 31, 1996, 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 Consolidated Balance Sheets at December 31, 1996 and 1995 Consolidated Statements of Income for the Years Ended December 31, 1996,	
1995 and 1994	22
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 1996, 1995 and 1994 Consolidated Statements of Cash Flows for the Years Ended December 31, 1996,	23
1995 and 1994 Notes to Consolidated Financial Statements	24 25-33

2. Financial Statement Schedules

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

	FORM 10-K PAGE NO.
Schedule II - Valuation and Qualifying Accounts	38

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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

product.(6)

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 10.2	Form of Indemnity Agreement with Executive Officers(1) Registrant's Amended 1985 Stock Option Plan(1)
10.3	Form of Stock Option Agreement(1)
10.4	Registrant's Amended and Restated 1993 Incentive Stock Plan
10.5	Registrant's Directors' Stock Option Plan(2)
10.6	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and McGaw, Inc. relating to the CLAVE product(3)
10.7	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and McGaw, Inc. relating to the Protected Needle product(3)
10.8	Supply agreement dated January 1, 1995 between MAGNET, Inc. and Registrant.(5)
10.9	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE

- 10.10 Second Amendment to Manufacture and Supply Agreement dated May 31, 1995 between Registrant and McGaw, Inc.(7)
- 10.11 Distribution Agreement dated June 1, 1996 between Registrant and BOC OHMEDA AB
- 10.12 Underwriting Agreement dated June 28, 1995 among Registrant, Rodman & Renshaw, Inc. and Pacific Growth Equities.(8)
- 10.13 Amendment to Underwriting Agreement dated July 5, 1995 among Registrant, Rodman & Renshaw, Inc. and Pacific Growth Equities.(7)

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- 21.1 Subsidiaries of Registrant.
- 23.1 Consent of Arthur Andersen LLP.
- 27.1 Financial Data Schedule
- Filed as an exhibit to Registrant's Registration Statement Form S-1 (Registration No. 33-45734) filed on February 14, 1992, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 22, 1993 and incorporated herein by reference.
- (3) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.
- (4) Reference not used.
- (5) Filed as an Exhibit to Registrant's Annual Report on Form 10K for the Year ended December 31, 1994, and incorporated herein by reference.
- (6) 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.
- (7) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 1995, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Registration Statement (Registration No. 33-92482) filed on June 23, 1995.
 - (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 14, 1996

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.

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

Dated: March 25, 1997

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SIGNATURES

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

Signature	Title	Date

/s/ George A. Lopez, M.D. Chairman of the Board, President, March 25, 1997
- ----- and Chief Executive Officer, (Principal
George A. Lopez, M.D.
Executive Officer)

- /s/ Francis J. O'Brien Chief Financial Officer March 25, 1997
 ------ and Principal Accounting Officer
 Francis J. O'Brien
- /s/ Jack W. Brown Director Jack W. Brown
- /s/ John J. Connors Director March 24, 1997 John J. Connors
- /s/ Michael T. Kovalchik, III Director March 21, 1997
 -----Michael T. Kovalchik, III
- /s/ Richard H. Sherman Director March 24, 1997

Richard H. Sherman

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ICU MEDICAL, INC.

SCHEDULE II

March 20, 1997

VALUATION AND QUALIFYING ACCOUNTS

		Addi	tions		
		Charged			
	Balance at	to Costs	Charged	Balance	
	Beginning	and	to Other	Write-offs/	at End o
Description	of Period	Expenses	Accounts	Disposals	Period

Allowance for doubtful accounts	\$198,262	\$ 4,628	\$ - ======	\$ 7,842	\$195,048 =======
Inventory reserves	202,658	\$730,187	\$264,340	\$876,774	\$320,411
For the year ended December 31, 1995:					
Allowance for doubtful accounts	\$195,048	\$ 82,000 ======	\$ - ======	\$ 22,061	\$ 254,987 ======
Inventory reserves	\$320,411	\$254,700	\$ 83,901 ======	\$357,574 ======	\$301,438
For the year ended December 31, 1996:					
Allowance for doubtful accounts	\$254,987	\$ 40,000 ======	\$ - 	\$ 1,955 ======	\$ 293,032
Inventory reserves	\$301,438	\$ 50,000	\$ – =======	\$ 77,371 ======	\$ 274,067 ======

December 31, 1994:

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EXHIBIT INDEX

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

EXHIBIT 10.11

DATED: JUNE, 1ST, 1996

ICU MEDICAL, INC.

AND

BOC OHMEDA AB

DISTRIBUTION AGREEMENT

BOC Group Legal Department Chertsey Road Windlesham Surrey GU20 6HJ Tel: 01276 477222 Fax: 01276 471333

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THIS AGREEMENT DATED THE 1ST DAY OF JUNE, 1996 BETWEEN

- ICU Medical, Inc., a Delaware corporation with an office and place of business at 951 Calle Amanecer, San Clemente, CA 92673, USA (referred to below as "ICU") and,
- 2) BOC OHMEDA AB, a Swedish company with registered office located at P O Box 631, S-251 06, Helsingborg, Sweden (referred to as "OHMEDA").

IT IS AGREED AS FOLLOWS:

1. DEFINITIONS

1.1 In this Agreement:

- "Affiliate" shall mean any person, firm, company or other legal entity which controls, is controlled by or which is under common control with ICU or OHMEDA.
- "Contract Year" shall mean each sequential twelve (12) month period during the term of this Agreement commencing with the Effective Date.
- "Effective Date" shall mean the date of execution of this Agreement by both parties.
- "Improvements" shall mean changes to or developments in needleless connectors together with accessories and components disclosed by either party to the other and developed by ICU during the term of this Agreement which technically or functionally improve upon Products and which ICU offers to the public to replace one or more of the existing Products.
- "Product' or shall mean ICU's CLAVE needleless injection "Products" valves, to be sold under the Connecta CLAVE trademark, and any similar medical devices in the field of needleless infusion connection (the "Field") which meet the specifications set forth in Appendix 1.1 below as amended by mutual written agreement of the parties and any Improvements.
- "Territory" shall mean one or more of the nations listed in Appendix 1.2.

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2. APPOINTMENT OF DISTRIBUTOR

2.1 As the Products are newly developed and have not previously been marketed in Europe, OHMEDA's representation rights UNDER THIS AGREEMENT ARE TO BE staggered as follows:

2.1.1 TEST LAUNCH PHASE As from the Effective Date, OHMEDA is appointed ICU's exclusive distributor for the Products in each of Great Britain, France, Belgium and Holland for a fixed period of six (6) calendar months. During this Test Launch Phase the terms of this Agreement shall apply to the extent applicable, together with the arrangements comprised in the Test Launch Program set out in Appendix 2.1.1.

2.1.2 FULL LAUNCH PHASE - DIRECT COUNTRIES Not less than 30 days prior to the expiration of the Test Launch Phase, OHMEDA shall have the right to submit to ICU written Business Plans for each of the Territories listed in Part A of Appendix 1, such Business Plans to include the information listed in Appendix 4.5. ICU shall accept or reject each of the Business Plans in writing within 30 days of receipt, unless otherwise agreed. The power to reject is subject to Clause 5.9 below. On the expiration of the Test Launch Phase, OHMEDA shall become the exclusive distributor for the Products with immediate effect, for those Territories listed in Part A of Appendix 1, as to which OHMEDA has received ICU's written acceptance of the Business Plan and subject to the terms of this Agreement.

2.1.3 FULL LAUNCH PHASE - DISTRIBUTOR COUNTRIES

At any time on or after the expiration of the Test Launch Phase, OHMEDA shall have the right to submit to ICU a Business Plan for any

one or more of the Territories listed in Part B of Appendix 1 (and in

the terms provided for in clause 4.5) for which it then wishes to act as distributor of the Products. ICU shall review and accept or reject, in writing, all Business Plans within 60 days of receipt unless otherwise agreed. The power to reject is subject to Clause 5.9 below. Upon written acceptance by ICU of a Business Plan for a particular Territory, (with or without amendment as applicable), OHMEDA shall become exclusive distributor for the Products in such Territory with immediate effect and subject to the terms of this Agreement.

In the event that any such Business Plans are rejected, the applicable nations shall be removed from the definition of Territory for the purposes of OHMEDA's distribution rights.

2.1.4 At any time after the expiration of the Test Launch Phase, ICU shall have the right, on not less than 60 days written notice, to demand from

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OHMEDA, a Business Plan for any Territory for which OHMEDA has not then exercised its rights pursuant to clauses 2.1.2 and 2.1.3. The terms of clause 2.1.2 or as applicable 2.1.3 shall apply to any Business Plan then supplied. If OHMEDA fails or elects not to submit any such Business Plans it shall immediately forfeit any distribution rights for the Products in the applicable Territory.

- 2.2 OHMEDA may appoint sub-distributors to sell the Products in any Territory for which OHMEDA is the exclusive distributor for the Products after written notification to ICU subject to ICU's written approval of the sub-distributor. OHMEDA shall include in each agreement appointing a sub-distributor, provisions to the effect that (i) New York law shall govern with respect to any dispute or litigation between ICU and sub-distributor, (ii) the prevailing party in any such litigation shall be entitled to attorneys fees reasonably incurred, (iii) exclusive jurisdiction and venue shall be the state courts of the State of Illinois located in Cook County, Illinois, USA., (iv) service of process may be effected by telecopier, telex, facsimile, mail or courier such provisions to be substantially the same in substance as set forth in clause 19.
- 2.3 Notwithstanding OHMEDA's above appointments as exclusive distributor, ICU shall have the right to sell the Products direct to a customer without obligation to pay OHMEDA commission, when such customer is an original equipment manufacturer or pharmaceutical company who will sell the Products only as a component part of another product.
- 2.4 Nothing in this Agreement shall preclude ICU from the direct sale or sale through third parties of individual components comprised in the Products without obligation to pay OHMEDA commission.
- 2.5 In the event that ICU sells the Products or individual components as described in Clauses 2.3 and 2.4, ICU will use reasonable efforts to facilitate a liaison between OHMEDA and such other parties for the limited purpose of ensuring that product performance claims and other regulatory matters are dealt with consistently.

3. EFFECTIVE DATE AND TERM

3.1 The initial term of this Agreement shall be five (5) years commencing on the Effective Date. This Agreement shall be automatically extended after the five years, unless and until either party elects to terminate it, upon not less than 12 months prior written notice to the other party to expire on or at any time after the fifth anniversary. Notwithstanding the above termination arrangements, this Agreement may be terminated at any time:

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3.1.1 By mutual consent in writing.

- 3.1.2 By either party sixty (60) days after the giving of written notice to the other that the other is in material breach of any of its obligations under this Agreement and has failed to cure such breach during such sixty (60) day period except that material breach of payment obligations must be cured within thirty (30) days of such written notice.
- 3.1.3 By either party immediately if any proceeding in bankruptcy, or for reorganization or arrangement, or for the appointment of a receiver or trustee, or any other proceeding under any law for the relief of creditors, shall be instituted by or against the other, or the other shall make an assignment for the benefit of its creditors.
- 3.1.4 By ICU where in its reasonable opinion, OHMEDA conducts itself in such a manner as to be detrimental or harmful to the good name, goodwill or reputation of ICU and/or the Products.
- 3.1.5 By ICU if in its reasonable opinion it is unable to comply with clause 8.1 on a commercially reasonable basis.
- 3.1.6 By ICU if OHMEDA, any Affiliate of OHMEDA to which this Agreement has been assigned, or any entity of which OHMEDA or such an Affiliate is a direct or indirect subsidiary or which directly or indirectly controls OHMEDA or such an Affiliate is acquired by means of a merger, consolidation, purchase of assets, purchase of stock or otherwise.
- 3.2 In addition to the rights of complete termination provided for above, either party shall have the right, again on not less than 12 months notice to expire on or at any time after the fifth anniversary, to terminate any one or more of the nations of the Territory, whereupon the provisions of clause 18 shall apply to that Territory only and the rights of any subdistributor appointed by OHMEDA shall terminate as to such Territory.
- 3.3 ICU shall have the right on not less than 90 days written notice to either terminate OHMEDA's distributorship or convert OHMEDA to a non-exclusive distributor in a Territory (a) in which OHMEDA has not substantially achieved the material objectives of its Business Plan for the preceding 12 months or (b) as to which ICU has rejected OHMEDA's annual Business Plan giving reasonable grounds as provided in clause 5.9, whereupon the provisions of clause 18 shall apply to that Territory only and the rights of any sub-distributor appointed by OHMEDA shall terminate as to that Territory. In the event that OHMEDA's status in a Territory changes to that of a non-exclusive distributor this Agreement shall be equitably adjusted to reflect the change of status.

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- 3.4 Either party may terminate this Agreement in respect of a Territory, in the event of the commencement of litigation against either party for infringement of a third party's intellectual property rights in consequence of the sale of the Products in such Territory.
- 4. OHMEDA'S RESPONSIBILITIES AND UNDERTAKINGS
- 4.1 FORECASTS. OHMEDA shall provide ICU each month with a six (6) month rolling

forecast of anticipated Product orders, beginning with the first month for which ICU is expected to supply OHMEDA with Products, in the form attached as Appendix 4.1. OHMEDA shall be free from month to month to modify its forecasts of Product orders.

- 4.2 ORDERS. OHMEDA shall place irrevocable purchase orders for Products with ICU for each month 60 days in advance of the desired delivery date. Purchase orders shall be in writing, and consistent with this Agreement and may be sent by telex or facsimile machine.
- 4.3 PROMOTION. OHMEDA shall develop energetically and satisfactorily the potential for Product sales. OHMEDA shall keep available at all times for demonstration and evaluation purposes, minimum amounts of each Product as specified in Appendix 4.3 which shall be in a condition appropriate for sales promotion. ICU shall review and approve all advertising and marketing materials prepared by OHMEDA, in advance of their use.
- 4.4 TRAINING. At its expense, OHMEDA shall train the employees of its customers to use the Products. OHMEDA sales, customer service and technical service representatives must be fully trained in the use of the Products and must have the specific qualifications specified by ICU at the commencement of this Agreement.
- 4.5 BUSINESS PLANS. OHMEDA shall prepare a written Business Plan for each nation in the Territory annually. All Business Plans shall contain the material listed in Appendix 4.5 and shall be submitted to ICU not less than 90 days prior to the commencement of such Contract Year.
- 4.6 CUSTOMER SERVICE. OHMEDA shall render prompt and willing service with respect to the Products and shall use its best efforts to handle satisfactorily all matters relating to the sale and servicing of the Products in the Territory. To facilitate timely customer service, manufacturer's support may be requested by OHMEDA. If such support is provided by ICU at ICU's sole direction, it shall be free of charge. If it is supplied at OHMEDA's request, ICU may bill OHMEDA at ICU's then current rates for time and/or travel expenses.
- 4.7 PAYMENT. The purchase price for all Product orders and service orders and all expenses incurred by ICU in the shipment and delivery of ordered Products and

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the performance of service orders, including without limitation freight charges, taxes, export and import duties and insurance premiums, shall be payable by OHMEDA to ICU 60 days after delivery of the Products by ICU to a carrier (in case of Product orders) or the date of invoice for services performed. All payments by OHMEDA to ICU shall be made in the currency of the United States of America.

- 4.8 TITLE AND RISK OF LOSS. Risk of loss in the Products shall pass to OHMEDA upon delivery of the Products to the carrier at ICU's manufacturing facility. ICU shall co-operate with OHMEDA in processing all claims for loss or damage to the Products. Ownership of the Products shall pass to OHMEDA upon their acceptance by OHMEDA following receipt.
- 4.9 DELAY AND STORAGE. OHMEDA shall be responsible for and shall pay for any delay in accepting delivery, storage and other charges accruing after the arrival of any shipment at OHMEDA's designated destination where such shipment conforms in all respects with OHMEDA's order. If OHMEDA shall fail or refuse to accept delivery of any of the Products ordered by it, and without good reason, OHMEDA shall pay ICU the amount of all expenses incurred by ICU in returning the Products to the original shipping point.

4.10 RESTRICTIVE COVENANT.

4.10.1 OHMEDA acknowledges that (i) ICU will provide OHMEDA valuable Confidential Information (as defined in clause 16 of this Agreement) and/or trade secrets of ICU, (ii) that the conduct of any Competitive Activity by OHMEDA while OHMEDA is in possession of such information and privy to ICU's product development and marketing strategies could result in the disclosure or use of such Confidential Information and trade secrets and put ICU at a severe competitive disadvantage, and (iii) that ICU would not knowingly disclose such information to any person engaged in any Competitive Activity.

It is the intention and obligation of the parties to comply with the limitations on the use and disclosure of Confidential Information set forth in clause 16 of this Agreement. In order to avoid the intentional or inadvertent use or disclosure of Confidential Information and trade secrets and to ensure that OHMEDA can effectively and credibly promote and represent the Products, OHMEDA agrees that, during the term of this Agreement and for a period ending six months after the termination of this Agreement (such period to be extended to include any period of violation of this clause 4.10.1) by OHMEDA or period which is required for litigation to enforce this Agreement and during which OHMEDA is in violation of this clause 4.10. 1, OHMEDA shall not, without prior written consent of ICU, engage, directly or indirectly, in any Competitive Activity in any Territory, or in any country in Europe in which any aspect of the research.

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design, development, manufacture, clinical testing, marketing, market research (other than general surveys and analysis), demonstration or sale of Products has been carried on by or on behalf of ICU. As used herein the term "Competitive Activity" shall mean engaging in any business, directly or indirectly, whether as a manufacturer, DISTRIBUTOR, manufacturer's representative, dealer, proprietor, partner, joint venturer, employer, agent, employee, consultant, officer, director, or beneficial or record owner (other than as a passive investor owning a minority interest in any entity in which OHMEDA is not involved, directly or indirectly through representation on the board of directors or otherwise, in running the business, and which involves the manufacture, clinical testing, distribution, marketing, demonstration, promotion or sale of Competitive Products. As used herein, the term "Competitive Products" means medical connectors which have all of the following design and performance characteristics: activated by advancing a male Luer into the valve; closed unless activated by a Luer advancing in the valve; easily disinfected by swabbing in the same way as a stretch latex injection site: but expressly excluding those current OHMEDA products listed in Appendix 4.10 hereto and Improvements thereto which do not duplicate all of the foregoing design and performance characteristics. It shall not be a breach of this restriction for OHMEDA or any OHMEDA Affiliate to acquire a business which has as incidental activity a Competitive Product provided OHMEDA demonstrates to ICU that it is taking all reasonable steps to divest it and does divest it within a reasonable time.

4.10.2 In the event OHMEDA proposes to engage in any Competitive Activity in any of the geographic areas specified in clause 4.10.1, OHMEDA shall give ICU 90 days written notice of its intention to do so. Such notice shall constitute the termination by OHMEDA of this Agreement, effective when given, unless ICU, in its sole and absolute discretion, consents to the Competitive Activity. Strict compliance with this clause 4.10.2 shall relieve OHMEDA of the obligation under clause 4.10.1 to refrain from Competitive Activity for six months after any termination of this Agreement and permit OHMEDA to engage in Competitive Activity 90 days after giving such written notice. Notwithstanding the foregoing, if during the aforesaid 90-day period, OHMEDA engages in any Competitive Activity whatsoever, including any promotion of Competitive Products or any communication to any customers or prospective customers of OHMEDA of its intention to engage in Competitive Activity, (except as a permitted incidental activity of an acquisition) (i) the provisions of this clause 4.10.2 shall immediately cease to be of any force and effect, (ii) OHMEDA shall be subject to and deemed to be in violation of the provisions of clause 4.10.1, and (iii) ICU may take action to enforce this Agreement and/or recover damages.

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Notwithstanding any provision of this Agreement, ICU is not waiving

its patent rights in any jurisdiction and is not waiving the obligations of OHMEDA under clause 16 of this Agreement.

- 4.10.3 The conduct by OHMEDA of any Competitive Activity in any Territory, or in any country in Europe shall be a material breach of this Agreement, giving ICU the right to terminate this Agreement under clause 3.1
- 4.10.4 OHMEDA acknowledges and agrees that it would be difficult to compensate ICU fully for damages resulting from the breach or threatened breach of the foregoing provisions and, accordingly, that ICU shall be entitled to temporary and injunctive relief (including temporary restraining orders, preliminary injunctions and permanent injunctions) and specific performance, to enforce such provisions upon proving that ICU suffered or that there is a substantial probability that ICU will suffer irreparable harm and without the necessity of posting any bond or other undertaking in connection therewith. This provision with respect to injunctive relief and specific performance shall not, however, diminish ICU's right to claim and recover damages.
- 4.10.5 The provisions of this clause 4.10 are severable and if any one or more provisions may be determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions, and any partially unenforceable provisions to the extent enforceable, shall nevertheless be binding and enforceable. For the purpose of determining the geographic scope of the covenant such that if the geographic scope shall be determined by a court of competent jurisdiction to be excessive and invalid, such area shall be severed and the covenant relating to the remaining areas shall be deemed enforceable and remain in full force and effect. In addition, if this clause 4.10 or any portion hereof shall be determined by a court of competent jurisdiction to be excessive and invalid by reason of its extending for too great a period of time or over too great a range of activities, it shall be interpreted to extend only over the maximum period of time or range of activities as to which it may be enforceable.
- 4.11 COMPLIANCE WITH US EXPORT REGULATIONS. OHMEDA understands that the Products and Improvements may require a validated export license to be obtained by ICU from the United States Department of Commerce. OHMEDA agrees to assist ICU to obtain any such required license by supplying appropriate documentation requested by ICU. OHMEDA agrees to comply with US Export Administration Regulations as in effect from time to time and will not reexport any Products outside the Territory without first gaining approval from ICU. Until approval is obtained from the United States Department of Commerce, OHMEDA agrees to obtain similar assurances from its customers.

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OHMEDA will also maintain the necessary records to comply with United States Export Administration Regulations.

- 4.12 TERMS OF PURCHASE OF PRODUCTS BY OHMEDA. All purchases of Products by OHMEDA FROM ICU during the term of this Agreement shall be subject to the terms and conditions of this Agreement. No other terms including standard ICU conditions of sale or standard OHMEDA conditions of purchase shall apply unless expressly agreed in writing by authorized representatives of both parties.
- 4.13 TERRITORIAL RESPONSIBILITY. OHMEDA shall refrain from establishing or maintaining any branch, warehouse or distribution depot for the Products, or services outside the Territory and shall not engage in any advertising or promotional activities relating to the Products or services directed primarily to customers located outside the Territory.
- 4.14 SALES TRACKING. OHMEDA shall supply to ICU at its request at reasonable intervals sales tracking information for each Territory in a timely fashion. Such information shall include, but is not limited to, catalog number quantities and prices of Products shipped during the period requested; where possible the facility name and location will also be provided.

- 5. ICU'S RESPONSIBILITIES AND UNDERTAKINGS
- 5.1 CAPACITY. ICU shall maintain manufacturing capacity at the level required to fulfill OHMEDA's forecasted demand for the Products. ICU will maintain reasonable raw material inventory consistent with OHMEDA forecasts and delivery schedules.
- 5.2 LATEST VERSIONS. ICU shall ensure that Products supplied to OHMEDA are its most up to date versions unless otherwise requested by OHMEDA, provided that ICU shall not be required to replace OHMEDA's inventory of earlier versions of Products.
- 5.3 ORDERS AND SPECIFICATIONS. ICU shall use all reasonable efforts to fulfill OHMEDA orders for sterilized Products during the term of this Agreement. ICU undertakes that the processing of OHMEDA orders shall be handled no less favorably than any other customer orders. ICU shall manufacture, assemble, package and label the Products in accordance with the specifications as described in Appendix 1 below. The content of all labeling of Products shall be created by OHMEDA and jointly approved by OHMEDA and ICU.
- 5.4 DELIVERY. ICU shall fulfill all Product orders from OHMEDA so that delivery of the Products to OHMEDA shall be made FOB ICU's Californian facility within 45 days of the placement of the order for that Product with ICU, unless otherwise agreed. If an order cannot be shipped within such time limits after order acceptance, ICU will notify OHMEDA of the anticipated shipping date. ICU will

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take all necessary actions to minimize down-time of any affected major equipment. OHMEDA shall be notified by fax, telephone or similar method of communication promptly as to the date of delivery. In the event that any of the Products are not shipped as of the scheduled date specified, OHMEDA shall be given prompt notice by fax, telephone or similar method of communication. When Products become available, ICU shall ship such delayed Products by the fastest method of delivery, and the excess of the expedited delivery charges over normal delivery charges shall be at ICU's expense when events causing such delay were under ICU control.

ICU shall be responsible for:

- 5.4.1 putting the Products in possession of Ohmeda's designated carrier and contracting for their transit,
- 5.4.2 obtaining any documents necessary to export them from the United States of America and, so far as it can reasonably do so, to enable OHMEDA to take possession upon arrival, and
- 5.4.3 promptly notifying OHMEDA of shipment and delivery to them of any necessary documents of title.
- 5.5 INVOICES. ICU shall send all invoices for Products to OHMEDA at BOC OHMEDA AB, PO Box 631, S-251 06, Helsingborg, Sweden.
- 5.6 SALES LITERATURE. ICU shall provide initial quantities of such technical data, drawings, graphic illustrations, artwork and photography as requested by OHMEDA to enable OHMEDA to prepare adequate selling materials and to service the Products. Shipping charges incurred on delivery of sales literature shall be borne by OHMEDA. Large quantities can be ordered from ICU at ICU's standard prices in effect at the time.
- 5.7 TRAINING. ICU shall undertake a reasonable number of "train the trainers" training courses in Europe free of charge for OHMEDA designated personnel. Such courses shall be in English, shall be of reasonable extent and duration and shall cover the specifications, uses, selling, marketing and operation of the Products including any successor and substitute Products launched from time to time. Both parties shall meet their own travel and accommodation expenses connected with attendance. ICU shall co-operate with the provision of such additional and refresher training as OHMEDA may reasonably require and on terms to be agreed.
- 5.8 TERRITORIAL RESPONSIBILITY. In the event that OHMEDA does not establish a branch, warehouse or distribution depot for the Products in one of the Territories and ICU appoints another distributor in that Territory, ICU

territorial responsibility on that distributor as described in Clause 4.13 imposed on OHMEDA.

- 5.9 BUSINESS PLANS. ICU shall not have the power to reject any Business Plan which conforms to the Appendix 4.5 requirements. Business Plans shall be approved or rejected by ICU not more than 60 days after receipt. The first Business Plan for a Territory shall cover the period up to the next 30th September or such longer period, ending on a 30th September, as agreed between the parties. All subsequent Business Plans shall cover an annual period commencing 1st October.
- 6. PRICE
- 6.1 For the Test Launch Phase of this Agreement, the unit price for each Product shall be as in Appendix 6 attached to this Agreement.

On commencement of the Full Launch Phase and on an annual basis after that date, the parties shall negotiate in good faith as to the need for a price change (increase or decrease) for Products. Any price increase shall be based upon documented total material and direct labor cost increases during the immediately preceding Contract Year, but capped at the percentage increase in the US Consumer Price Index for All Urban Consumers (CPI-U") for Los Angeles-Anaheim-Riverside Average All Items published by the US Bureau of Labor Statistics for the immediately preceding Contract Year.

- 6.2 Prices shall be inclusive of the costs of preparing the Products for shipment FOB California. OHMEDA shall pay for any additional packing and handling charges for other means of shipment and shall also pay all taxes on the export, import, use or sale of the Products and all related insurance.
- 6.3 If the parties fail to agree upon pricing for a following period, they shall request an independent auditor to be agreed between the parties (such auditor acting as an expert and not as an arbitrator) to establish an equitable adjustment to the Purchase Price within thirty (30) days after such request and the auditor's determination, absent bad faith, shall be final and binding. The auditor's fees shall be borne in such proportions as the auditor shall determine. The auditor so appointed shall be entitled to call for and inspect the working papers of each of the parties insofar as they affect the pricing dispute only.
- 7. REGULATORY APPROVALS AND RECALL
- 7.1 ICU shall be responsible for regulatory approval of the Products and any applicable sterilization process. ICU shall inform OHMEDA of any Product data required from the Territory to facilitate any regulatory approvals.

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- 7.2 The Products shall conform to CE marking requirements of European legislation as and when in force in the Territory of Product destination.
- 7.3 ICU may at its sole discretion, institute and fund any recall or field corrective action. In such circumstances, the actual retrieval of Product used in the field will be undertaken by the OHMEDA service organization and reimbursed by ICU. OHMEDA shall maintain adequate records concerning traceability of Product and in the event that recall, field correction, or the like procedures are required, OHMEDA shall co-operate fully with ICU for expeditious completion of the procedure.
- 7.4 ICU agrees that Products supplied under this Agreement are and will be manufactured and/or assembled pursuant to the then current US Food and Drug Administration ("FDA") Good Manufacturing Practices ("GMP") regulations (i.e. GMP's, 121 U.S.C. 360 et seq.), and all OHMEDA current internal

regulatory requirements furnished to ICU in writing by OHMEDA as modified from time to time with ICU's consent. ICU shall be responsible for filing all Medical Devices Reports ("MDR's") with the FDA and any other applicable regulatory authority with respect to the Products and handling all follow-

- 7.5 ICU shall maintain all records and files required by the FDA regulations and any other applicable regulatory authority in respect to the Products and agrees to provide copies of such records and files to OHMEDA as reasonably requested.
- 7.6 Both ICU and OHMEDA shall be responsible for complying with all federal, state and local laws, rules, regulations, guidelines and the like in the United States and in the Territories as they may apply to the Products and to the parties respective obligations to perform under this Agreement. This shall include without limitation, requirements in the United States with respect to registration of establishments, listing of medical devices, reporting of deaths, serious injuries and certain malfunctions under 21 CFR 803 and the potential for any such events, tracking of medical devices, recalls, safety alerts and process controls. In no event shall either party assume any risk arising out of the other party's failure to comply with such laws, rules, regulations, guidelines and the like, and each party shall cooperate with the other in all respects to facilitate and promote strict compliance with the provisions of this clause.
- 7.7 Upon ten (10) days prior notice to ICU, OHMEDA shall have the right to conduct vendor qualification audits and quality audits from time to time at reasonable intervals at ICU's manufacturing and engineering facilities to verify, insofar as feasible, ICU's compliance with the above regulatory requirements. Quality audits will start at the supply phase and be based on and limited to Products. ICU will not be required to disclose trade secrets or proprietary processing know-how. If the review of an area of activity considered proprietary by ICU is regarded as essential by OHMEDA for the performance of an effective audit, a non-disclosure agreement satisfactory to ICU will be signed by OHMEDA. ICU

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shall, in good faith, promptly correct any deficiencies discovered during such audits.

7.8 In the event of any recall of the Products initiated by ICU and conducted by OHMEDA for safety or efficacy reasons which are directly caused by failure of the Products to:

7.8.1 conform in all respects to their specifications, or

7.8.2 be free from defects in design, workmanship or materials,

ICU agrees to accept them for repair or replacement at ICU's sole cost and expense except as provided below.

Except as ordered by a governmental agency or as specified in the above sentence, no recall or field modification action shall be initiated without the mutual agreement of the parties unless the initiating party is prepared to bear the charges on its own. Each party shall notify the other if any recall or field modification action is contemplated and both parties shall co-operate in reaching a consistent response. Neither party shall unreasonably withhold any information involving patient safety or efficacy or required recall or field modification action.

8. INDEMNITY

8.1 ICU hereby promises to indemnify and hold OHMEDA harmless from and against any 3rd party claims, liabilities, damages and costs arising from any sale or use of the Products and Improvements as and when supplied by ICU to OHMEDA, arising through patent, trademark, (other than OHMEDA trademarks), or copyright infringements or misappropriation of trade secrets, provided that ICU is notified promptly in writing and given the necessary authority, information and assistance to defend such action. Any action taken by ICU shall not relieve it of a duty to provide to OHMEDA, at substantially equivalent prices, and otherwise on the same terms as the Products, single use disposable needleless injection valve products which operate in functionally the same way as current Products subject to Clause 3.1.5 above. The above provisions shall not apply to claims based on Products used in a manner for which they were not designed or which were modified by or for OHMEDA, its Affiliates or customers in a manner to become infringing.

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8.2 If either party becomes aware of any infringement or threatened infringement in any Territory of any intellectual property rights in the Products, then such party shall immediately inform the other party. In such event the parties shall at their joint expense refer the matter to legal counsel familiar with the law of the

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Territory concerned, for the purpose of obtaining his/her advice on the chances of success in prosecuting such action. Each party shall make available to the other all information in its possession concerning the subject. ICU may, in its sole discretion (unless the parties agree in writing to the contrary), institute and prosecute such proceedings at its expense. Should ICU elect not to institute and prosecute such proceedings, it shall nevertheless do so if OHMEDA agrees to bear the expense of such proceedings and tenders in advance of each month the estimated cost of prosecuting such proceedings for such month, provided that ICU shall be entitled to withdraw from such prosecution if OHMEDA fails to make all such monthly advances and pay any excess of actual expenses for a month over the amount advanced promptly after receipt of invoice. Nothing in this clause shall affect the other rights and obligations of the parties resulting from such alleged infringement.

- 8.3 ICU shall indemnify and hold OHMEDA or its affiliates harmless from and against any and all loss, damage or cost, including reasonable legal expenses and counsel fees, for which OHMEDA or its affiliates become liable by reason of third party claims relating to defects in Products including design or manufacture thereof except to the extent that such liability arises from conduct described in clauses 8.4.1, 8.4.2, and 8.4.3.
- 8.4 OHMEDA agrees to indemnify and hold ICU and its Affiliates and its officers, directors, and employees free and harmless from any loss, damage or cost, including reasonable legal expenses and counsel fees, incurred by reason of claims of 3rd parties, for which ICU becomes liable by reason of:
 - 8.4.1 acts of OHMEDA or its Affiliates in marketing the Products including, but not limited to (a) misrepresenting the terms of any ICU warranty, (b) misstatements or misrepresentations by OHMEDA's, its Affiliates or their employees or agents concerning the capabilities or performance of the Products or availability, delivery dates or any other related term or condition,
 - 8.4.2 breach of warranties made by OHMEDA, its Affiliates or their employees or agents regarding the Products or their use or performance,
 - 8.4.3 personal injury claims or property damages arising out of the actions of OHMEDA, its Affiliates or their employees or agents in connection with the Products and which is inconsistent with ICU's advice.
- 8.5 A party shall have no liability or responsibility of any kind to the other party or its Affiliates under this clause 8 for any claims, demands, suits, costs or actions unless the indemnifying party shall have been notified within a reasonable time of any such claims, demands, suits, costs or actions and shall have had an adequate opportunity to defend. Should the indemnified party desire to have its own counsel participate in any such action or suit, the costs of such counsel

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shall be borne exclusively by the indemnified party. The obligation of the parties set out in this clause shall continue notwithstanding the cancellation or termination of this Agreement.

- 9. INSURANCE
- 9.1 Each of ICU and OHMEDA shall maintain, at its own expense, general and product liability policies of not less than \$3,000,000. Each party shall provide certificates of insurance to the other party (and in the case of ICU, it shall note OHMEDA's and its Affiliates' interest as a named insured) for information only and such other party shall have no

responsibility to review such policies or to determine their adequacy. Each party shall promptly advise the other party of any and all such actions or suits brought against the advising party or its Affiliates relating to products liability or warranty claims for products sold in the Territories. This clause shall survive the cancellation or termination of this Agreement

10. LIMITED PRODUCT WARRANTY

- 10.1 Limited Product Warranty. Within the expiration date of the Product ICU warrants all Products sold under the Agreement (i) to be free from defects of design, material and workmanship when delivered, (ii) to conform strictly to the applicable published specifications for such Products, as in effect from time to time, and (iii) to be manufactured and packaged in accordance with the FDA's then current GMP's and any other laws and regulations for the time being in force in the United States of America. These warranties shall survive any inspection delivery, acceptance of payment for Products but no later than 60 days after OHMEDA becomes aware of any defect. If any Products sold and delivered by ICU to OHMEDA breach any of these warranties, ICU in its sole discretion will either replace the same including if requested by OHMEDA, carriage CIF (Incoterms 1990) to the end user delivery point of the order being replaced or credit OHMEDA, within 30 days, the invoice price of the same together with OHMEDA's incurred transport expenses in delivering the defective Product to end user if applicable. The design warranty given above shall not apply in respect of Products manufactured to designs provided by or on behalf of OHMEDA.
- 10.2 Disclaimer and Limitation. WITH THE EXCEPTION OF THE WARRANTIES PROVIDED UNDER CALIFORNIA COMMERCIAL CODE SECTION 2312, WHICH ICU AND OHMEDA AGREE IS APPLICABLE TO THE PRODUCTS SOLD BY ICU TO OHMEDA, THE FOREGOING WARRANTIES ARE GIVEN IN LIEU OF ALL OTHER PRODUCT WARRANTIES OR GUARANTIES, EXPRESSED OR IMPLIED, RESPECTING PRODUCTS DELIVERED AND SOLD BY ICU TO OHMEDA, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY FITNESS FOR A PARTICULAR PURPOSE OR COMPLIANCE WITH THE LAWS AND REGULATIONS OF ANY

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JURISDICTION OTHER THAN THE UNITED STATES OF AMERICA. EXCEPT AS PROVIDED IN CLAUSE 10.1 ABOVE, ICU SHALL NOT BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES. THE PRECEDING SENTENCE SHALL NOT RELIEVE ICU FOR TORT LIABILITY FOR PRODUCTS DEFECTS UNDER GOVERNING LAW.

- 10.3 Subject to the limitations in clause 10.2 above, the representations and warranties in clause 10.1 shall survive inspection, testing and acceptance of Products.
- 10.4 ICU agrees that sub-distributors appointed by OHMEDA with ICU's written approval shall be entitled to rely upon the representations, warranties and covenants in clause 10.1 above, subject to the disclaimers and limitations in clause 10.2 above, to the same extent as if made directly to sub-distributors.
- 10.5 ICU shall maintain test records, drawings and serialization lot numbers and a traceability file of Products sold to OHMEDA. ICU shall provide OHMEDA with serialization lot numbers and a Certificate of Release for the Products at shipment as specified in the Vendor Specification shown at Appendix 1.
- 10.6 The parties shall co-operate in the exchange of data on all product complaints in accordance with such complaint handling procedures as agreed. ICU shall co-operate fully with OHMEDA in performing complaint investigations and failure analyses as required by FDA GMP regulations or any regulations applied by regulatory authorities in the countries of the Territory as applicable.
- 10.7 All of the provisions of this clause 10 shall survive the cancellation or termination of this Agreement.
- 11. SPECIFICATION AND DESIGN VARIATIONS
- 11.1 Specifications for Products and accessories are listed in Appendix 1 attached. It is recognized that from time to time ICU may, consistent with

such specifications and with quality performance of Products in their present form, make changes which are deemed Improvements or substitute components of the Products. OHMEDA shall be notified in writing by means of a validation package submitted in accordance with ICU's standard practices prior to the institution of Improvements or substitution of components unless otherwise agreed and OHMEDA reserves the right to reject the Improvements if they fail to meet Product specification or if they adversely affect fit, form, or function or regulatory approvals of the Products. In such case, OHMEDA may elect to continue to receive Products meeting the specifications prior to such Improvements or substitution of components. Should such Improvements or substitution of components or OHMEDA's election to continue to receive Products meeting the specifications prior to such Improvements, then the parties shall

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immediately negotiate in good faith equitable adjustments to the pricing of the Products.

- 11.3 If the parties believe any such revision may require regulatory approval of the FDA or other regulatory agency, any such submission shall be made by ICU after consultation with OHMEDA. If the revision is at the request of OHMEDA, it will bear all costs associated with resubmission to the FDA and other regulatory agencies.
- 11.4 ICU shall maintain design responsibility and shall be responsible for complaint investigation. OHMEDA shall inform ICU of any adverse customer feedback or complaints in a timely manner.
- 12. QUALITY CONTROL AND PRODUCT IMPROVEMENTS
- 12.1 ICU shall maintain a quality assurance program which, without limitation, shall include incoming component and raw material inspection, inspection of work in progress and final kit inspection. All criteria for inspection at each inspection point shall be in writing and kept current with the requirements provided by OHMEDA and the requirements of the FDA GMP regulations. Inspection results shall be documented in writing, dated and maintained as permanent records and subject to audit by OHMEDA.
- 12.2 The parties recognize that as the Products are innovative and have not previously been tried and tested in the Territory, there may be scope for Improvements.
- 12.3 The parties shall share with each other under conditions of confidentiality as provided in Section 16 hereof, ideas they generate during the term hereof that could be used to improve one or more of the Products. With regard to any Improvements generated by OHMEDA which improve both the Products and one of OHMEDA's existing products as set forth in Appendix 4.10 hereto, OHMEDA shall grant to ICU an irrevocable, worldwide, royalty free, exclusive (except as to OHMEDA, its Affiliates and customers) right to use such OHMEDA-generated idea, whether patentable or not, to improve the Products. With regard to OHMEDA-generated ideas which improve the Products, but do not improve at least one of OHMEDA's existing products, as set forth in Appendix 4.10 hereto, OHMEDA shall assign any such OHMEDA-generated idea as well as any intellectual property rights in the idea to ICU. With regard to any intellectual

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property rights so assigned to ICU, ICU shall grant to OHMEDA an irrevocable, worldwide, royalty free, non-exclusive right to use such

OHMEDA-generated ideas in future OHMEDA products. In addition, OHMEDA will execute all documents reasonably necessary to perfect such assignment or prosecute any patent application filed to protect the idea at ICU's expense. Any Improvement assigned from OHMEDA to ICU shall be deemed to be included in the definition of "Products" set forth herein.

13. TRADEMARKS

- 13.1 Products shall be sold under the "Connecta CLAVE" name. "Connecta" is a registered trademark of BOC OHMEDA AB. This name shall appear in a clearly visible place on packaging using the OHMEDA supplied sample labels, packaging and instructions. Supporting materials and manuals shall bear the same marking. Such marking is approved by both parties, provided that no ancillary trademark or service mark rights or licenses are conveyed. Other than the rights specified, and those provided in accordance with commercial codes or other local laws regarding the sale of goods, this Agreement provides no separate rights or licenses for either party to use the trademarks, copyrights, or patents of the other.
- 13.2 ICU will provide OHMEDA with materials for inclusion into OHMEDA's manuals for the Product supplied to OHMEDA, provided that ICU shall have a right to inspect and approve (which approval shall not be unreasonably withheld or delayed) before publication, that portion of such manuals that relate to the Products.
- 13.3 The labels, packaging and instructions for Products shall be incorporated by ICU into its documentation system and included as official ICU documents in all government filings required by this Agreement.

14. INSPECTION AND ACCEPTANCE

- 14.1 OHMEDA shall have the right to inspect Products at the time of their actual receipt. In the event that no notice of defects is provided to ICU within five (5) working days of actual receipt, the associated Products shall be deemed accepted. This acceptance shall not affect the warranty or indemnity provisions of this Agreement. Upon acceptance, ownership of the Products shall pass from ICU to OHMEDA. In the event of rejection, risk of loss shall revert to ICU.
- 14.2 ICU shall conduct analysis of rejected or returned Products. ICU shall provide OHMEDA with a written failure analysis report on any rejected or returned Products within thirty (30) days of return.
- 15. MUTUAL UNDERTAKINGS
- 15.1 OHMEDA and ICU represent and warrant one to the other that:

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- 15.1.1 it is a company duly organized, validly existing, and in good standing under the laws of the state of its incorporation;
- 15.1.2 it has the corporate power to own its assets and to carry on the businesses now being conducted;
- 15.1.3 execution and delivery of this Agreement have been duly authorized in accordance with the applicable laws of its state of incorporation, and its own certificate of incorporation and byelaws; and
- 15.1.4 it is under no legal or equitable restriction or obligation preventing undertaking or discharging its obligations under this Agreement.

16. CONFIDENTIALITY

16.1 The parties recognize the necessity of disclosing to one another not only the basic proprietary technology and information existing at the time of execution of this Agreement, but further, from time to time, additional proprietary developments, improvements and business information. For the purposes of this clause, the term "Confidential Information" shall apply to data suitably identified and not otherwise excluded from the definition pursuant to this section concerning research, design, development, manufacture, use, clinical testing, marketing strategies, market research, pricing information, production capacity and Improvements of or relating to Products. The parties agree to the following obligations of confidentiality, which shall survive expiration of this Agreement.

- 16.2 For the period of this Agreement and for a period of five (5) years following the end of this Agreement, neither party shall use nor permit its Affiliates to use the disclosed Confidential Information except as necessary for the purposes of this Agreement. Each party shall maintain confidential to itself and applicable Affiliates with a need to know, and shall not disclose to third parties, Confidential Information disclosed by the other party, treating it with the same degree of care as that party would treat its own Confidential Information. Both parties shall cause theirs and their Affiliates directors, officers, employees, agents and representatives to observe the terms of this confidentiality provision.
 - 16.2.1 The confidentiality obligations under this clause shall not apply to:
 - a) information which is or becomes part of the public domain through no fault or act of the party receiving the information; or
 - b) information which the receiving party can establish by written documents was in his possession prior to disclosure; or
 - c) information received from a third party which is lawfully in possession thereof not in breach of any obligation of confidentiality to the disclosing party; or

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/

- d) information any receiving party (the "Recipient") is required to disclose by law, order or regulation of a governmental agency or a court of competent jurisdiction; provided, that the Recipient uses its reasonable efforts, which shall include timely notice to the other party and cooperative joint efforts, to obtain protective orders or other available assurances of confidentiality, and provided further that except to the extent of such disclosure contemplated by this sub-paragraph (d) the confidential obligations of this clause 16 shall continue to apply; or
- e) information the Recipient is required to disclose to any governmental agency for purposes of obtaining approval to test or market the Products to the extent that such information thereby becomes part of the public domain. In such event the Recipient shall provide notice to the other party of such disclosure.
- 16.3 In order to implement these confidentiality obligations, both parties submitting information to the other party which it considers confidential shall mark such information with a proprietary, confidential or similar notice. If such Confidential Information is disclosed orally by a party it shall be followed by a writing, within ten (10) days of such oral disclosure, summarizing details of the disclosure and indicating said information was confidential.
- 16.4 ICU and OHMEDA represent and warrant that each has or will have contracts of secrecy and non-use with any employees, consultants and agents who shall have access to any of the Confidential Information and in terms which at least comply with the requirements of this clause. OHMEDA gives the same warranty on behalf of its Affiliates.
- 16.5 Upon the termination of this Agreement for any reason, ICU and OHMEDA shall each deliver to the other (without retaining copies), any and all documents or other written information containing any Confidential Information of the other party.
- 17. FORCE MAJEURE AND EXCESSIVE DEMAND

17.1 In the event that ICU is unable to carry out its obligations under this Agreement due to acts of God or of the public enemy, war, insurrection, mob violence, civil commotion or riots, strike, lockouts, labor disputes, fires, floods, earthquakes, epidemics, quarantine restrictions, freight embargoes, unusual delays in transportation, lack of shipping facilities, unavoidable casualty, accidents, abnormal amounts of inclement weather or unusually severe weather, changes in governmental policy, laws or regulations (including but not limited to impositions or quotas of limitations of shipments), or any other cause or causes beyond the control of ICU or its suppliers, whether herein above specified or not, ICU shall be permitted to extend the time of performance of its obligations to

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such extent as may be necessary to enable ICU and its suppliers to complete performance in the exercise of reasonable diligence after the cause or causes of delay have been removed. In the event any such delay continues for a period of more than six months, either party may terminate this Agreement by so notifying the other party in writing.

- 17.2 If Force Majeure affects ICU's manufacturing capability for the Products, ICU shall, at OHMEDA's request, sub-contract manufacture of the Products to OHMEDA or an OHMEDA Affiliate for the period of the Force Majeure. In such circumstances, ICU shall co-operate fully with OHMEDA and at ICU's expense, in the provision of all necessary technology, technical and regulatory support together with any tooling recoverable from ICU's facility, as may be required.
- 17.3 In the event that world-wide demand for the Products exceeds ICU's manufacturing capacity, ICU shall be excused from supplying OHMEDA's total requirements for the Products, subject to OHMEDA having entitlement to its proportionate share of the Products produced. Such share shall be equal to the ratio that the number of each type of Product purchased by OHMEDA in the previous Contract Year bears to the total number of that type of Product produced at ICU's manufacturing facility during the same period.
- 18. TERMINATION
- 18.1 OHMEDA'S DUTIES UPON TERMINATION. Upon termination of this Agreement for any reason whatsoever, OHMEDA shall:
 - 18.1.1 cease immediately from acting as a distributor for ICU and abstain from making further sales of Products except with the written approval of ICU except that Ohmeda may continue to sell existing inventory to then current customers;
 - 18.1.2 immediately cease making use of any sign, printed material, trademarks or trade name identified with ICU and refrain from holding itself out as having been formerly connected in any way with ICU; and
 - 18.1.3 not dispose of any Products purchased from ICU except to ICU or to a company appointed by ICU, or in a manner approved by ICU.
- 18.2 ICU'S DUTIES UPON TERMINATION SHALL BE AS FOLLOWS:
 - 18.2.1 ICU may accept at its discretion in accordance with ICU's then current published Returned Goods Policy the return of certain Products then held unsold by OHMEDA, in original packaging. The repurchase price shall be the net ex-works price as invoiced by ICU for the goods in question. OHMEDA shall meet the costs of their return CIF ICU facility in California.

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- 18.2.2 ICU shall cease making use of any packaging, printed materials, trademarks or trade names identified with OHMEDA.
- 18.2.3 ICU shall ensure that arrangements are put in place to supply any outstanding customer orders as notified by OHMEDA and in the case of

the Territories listed in Appendix 1, List A, future customer demand for the Products, for not less than 12 months after termination. ICU shall indemnify OHMEDA against all damages, costs and expenses payable by OHMEDA to customers for non fulfillment of customer orders outstanding at termination, through breach of this term.

18.3 OHMEDA and ICU acknowledge and agree that upon termination of this Agreement with due notice, except as provided above, neither party shall be liable to the other for any damages (whether direct, consequential or incidental, and including expenditures, loss of profits or prospective profits of any kind) sustained or arising out of or alleged to have been sustained or to have arisen out of termination with due notice. However, such termination shall not excuse either party from any breach of this Agreement, from amounts owing from one party to the other or from any other obligations surviving termination of this Agreement, and full legal and equitable remedies shall remain available for any breach of this Agreement or any obligation arising from it. This clause 18.3 shall survive the termination of this Agreement.

19. MISCELLANEOUS

- 19.1 Any payments, notices, requests, instructions, or other documents to be given under this Agreement, shall be in writing, and delivered personally or sent by certified or registered mail, prepaid, unless otherwise directed, as follows:
 - If to ICU: President ICU Medical Inc. 951 Calle Amanecer, San Clemente, CA 92673 USA
 - If to OHMEDA: Managing Director BOC OHMEDA AB P O Box 631 S-251 06 Helsingborg Sweden

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WITH COPY TO: The BOC Group pic Chertsey Road Windlesham Surrey GU20 6HJ Great Britain Attention: Legal Department

Either party may change the person or address to which such notices are being sent by giving written notice to the other in the manner provided in this Agreement. Any such payments, notices, requests, instructions or other documents provided for in this Agreement, shall be deemed delivered when hand delivered or posted prepaid airmail or when sent and received by telex or telecopy. In the case of posting, delivery shall be deemed effective 5 business days after the date of posting and in the case of telex and telecopy, 1 business day after the date of transmission.

- 19.2 Neither party may assign this Agreement, or their rights or obligations, without prior consent of the other; provided that upon written notice, OHMEDA shall have the right to assign this Agreement to any of its Affiliates who agrees in writing to be bound by each and all of OHMEDA's obligations.
- 19.3 This Agreement constitutes the entire Agreement between the parties regarding its subject matter and supersedes all prior understandings of the parties. There are no promises, terms conditions or obligations of the parties pertaining to that subject matter other than as contained in this Agreement. No interpretation, change, termination or waiver of any of the provisions shall be binding upon either party unless in writing and signed by its authorized officer. The terms of this clause shall supersede the Confidence Agreement entered into between ICU and OHMEDA Inc., dated 18 October 1995 which shall have no further force and effect.
- 19.4 The relationship of the parties is strictly contractual, and is not that of a joint venture, partnership, agency or employment. Neither party, nor

their agents or Affiliates is authorized to bind the other. No agent of either party is authorized to make any representations, promise, or warranty not contained in this Agreement.

- 19.5 No waiver of any provisions of, or default under this Agreement shall affect the right of either party to enforce that provision or any other provision or to exercise any right or remedy in the event of other default, whether similar or dissimilar.
- 19.6 All disputes between the parties arising out of this Agreement or as to any matters related to but not covered by this Agreement shall be governed by the laws, without regard to the laws as to choice of laws, of the State of New York. Each party hereto on behalf of themselves and their respective Affiliates

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consents to the exclusive jurisdiction and venue of State courts of the State of Illinois located in Cook County, Illinois, USA and/or the United States District Court located in Cook County, Illinois, USA with respect to all disputes arising out of, or related to but not covered by, this Agreement and consents to service of process by written notice given as provided in clause 19.1 of this Agreement.

- 19.7 This Agreement is binding on the successors and assignees of the parties.
- 19.8 In the event this Agreement is required to be registered with any governmental authority, OHMEDA shall cause such registration to be made and bear any expense or tax payable in respect of such registration.
- 19.9 Notwithstanding anything to the contrary contained in this Agreement, neither this Agreement, a modification of any provision of this Agreement, nor a new provision of this Agreement shall be effected by an order, acknowledgment or other form submitted by either party containing different or additional provisions.
- 19.10 This Agreement may be executed in counterparts, each of which will be an original, but both of which together shall constitute one instrument.
- 19.11 The clause and other headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.
- 19.12 Nothing in this Agreement, expressed or implied, is intended to confer on any person or entity other than the parties any right or remedy under or by reason of this Agreement.
- 19.13 The prevailing party shall be entitled to recover all costs and expenses reasonably and properly incurred, including attorneys' fees at the hourly rates usually charged by that party's attorneys, expert witness fees, court costs and all other costs and expenses incurred in any action or proceeding arising out of this Agreement or as to any matters related to but not covered by this Agreement.
- 19.14 The terms of this Agreement are severable and if for any reason any terms should be unenforceable or invalid, the rest of the Agreement shall remain in full force and effect.
- 19.15 This Agreement has been negotiated by the parties and is to be interpreted according to its fair meaning as if the parties had prepared it together and not strictly for or against any party. All reference in this Agreement to "parties" refer to parties to this Agreement unless expressly indicated otherwise. References in this Agreement to Articles and Sections are to Articles and Sections of this Agreement unless expressly indicated otherwise. References in this Agreement to "provisions" of this Agreement refer to the terms, conditions and promises contained in this Agreement. At each place in this Agreement where the context so requires, the masculine, feminine or neuter gender includes the others and

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the singular or plural number includes the other. "Including" means

"including without limitation." "Or" is inclusive and includes "and."

IN WITNESS the parties have caused this Agreement to be executed by their respective duly authorized officers, the day and year written below.

ICU Medical, Inc.

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

Name Title

BOC OHMEDA AB

By: /s/ Joseph W. Pepper JW PEPPER, President Name Title

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APPENDIX 1.2

TERRITORY

Territories shall mean the geographic boundaries of the following nations, existing as of the date of this Agreement and as they may be from time to time altered or modified, whether by treaty, conquest, purchase or otherwise, and all of the political territorial subdivisions within such territories (including any independent nation, republic or other political or legal jurisdiction, which was at the date of this Agreement within any such nations):

PART A - Direct Countries:

Andorra, Belgium, Denmark, Finland, France, Germany, Gibraltar, Great Britain, Ireland, Luxembourg, Monaco, Netherlands, San Marino, Spain, Sweden

PART B - Distributor Countries:

Albania, Austria, Bulgaria, Czech Republic, Greece, Hungary, Iceland, Italy, Liechtenstein, Malta, Norway, Poland, Portugal, Romania, Slovakia, Switzerland, Turkey, the former Union of Soviet Socialist Republics ("USSR") (consisting of Armenia, Azerbaydyhan, Belarus, Estonia, Georgia, Kazakhstan, Kirghizstan, Latvia, Lithuania, Moldavia, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), and the former Yugoslavia (consisting of Bosnia Herzegovina, Serbia, Montenegro, Kosovo, Macadonia, Vojvodina, Croatia and Slovenia).

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EXHIBIT 21.1

SUBSIDIARIES OF REGISTRANT

NAME

STATE OF INCORPORATION

Budget Medical Products, Inc.

California

EXHIBIT 23.1

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report dated January 29, 1997 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, 1996 or performed any audit procedures subsequent to the date of our report.

/s/ Arthur Andersen LLP ARTHUR ANDERSEN LLP

Orange County, California January 29, 1997

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