SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2004 or

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

For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0022692**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
951 Calle Amanecer San Clemente, California	**9267**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

None

Securities Registered Pursuant to Section 12 (g) of the Act:

Common Stock, $.10 par value
Preferred Stock Purchase Rights

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. [X] Yes [ ] 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. [ ]

Indicate by checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). [X] Yes [ ] No

The aggregate market value of the voting stock held by non-affiliates of Registrant as of June 30, 2004, the last business day of Registrant's most recently completed second fiscal quarter, was $421,707,145*.

The number of shares outstanding of Registrant's Common Stock, $.10 par value, as of January 31, 2005 was 13,574,969.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for Registrant's 2005 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 2004, are incorporated by reference into Part III of this Report.

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

PART I

Item 1. Business.

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous ("I.V.") therapy applications. Our devices are designed to protect healthcare workers and their patients from exposure to infectious diseases such as Hepatitis B and C and Human Immunodeficiency Virus ("HIV") through accidental needlesticks. We are also a leader in the production of custom I.V. systems and low cost generic I.V. systems and we incorporate our proprietary products on many of those custom I.V. systems.

In 1993, we launched the CLAVE®, an innovative one-piece, needleless I.V. connection device that accounts for approximately 47% of our revenue in 2004, exclusive of CLAVEs incorporated into custom I.V. systems. We believe that the CLAVE offers healthcare providers a combination of safety, ease of use, reliability and cost effectiveness that is superior to any other protective I.V. connection system on the market. It allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE is a successor to our protected needle products first introduced in 1984. We designed the CLAVE to eliminate needles from certain applications in acute care hospitals, home healthcare, ambulatory surgical centers, nursing homes, convalescent facilities, physicians' offices, medical clinics, and emergency centers. Reduction in the use of needles not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal.

We are taking steps to reduce our dependence on our current proprietary products. The initiative involves a planned transition from being primarily a manufacturer of I.V. system components to producing and distributing complete I.V. systems, both custom and low-cost, generic systems, blood collection devices and other products. Many of the I.V. systems include our I.V. proprietary component products.

We have been manufacturing and distributing custom and generic I.V. systems since late 1995. In 1999, we decided to substantially increase our emphasis on marketing and selling custom I.V. systems. A key element of our strategy to expand our custom I.V. system business has been the development and implementation of our proprietary software for custom product design, customer orders and order tracking, combined with an innovative system to coordinate the manufacture of components in the U.S., assembly of components into sets in Mexico and Italy and distribution of finished products. We believe that we offer customers substantially shorter delivery times and lower costs than other manufacturers of I.V. systems can currently offer.

The principal products that we have introduced in recent years are the CLC2000®, the 1o2 Valve®, and, with the acquisition of Bio-Plexus, Inc. ("Bio-Plexus") in late 2002, the Punctur-Guard® line of blood collection needles. In January 2005, we introduced the TEGO ™ Connector product, a new connector for use in Hemodialysis. We expect to be introducing a new CLAVE Y Site connector with integral check valve, a diabetes infusion set and a novel male luer connection device in 2005.

We currently sell substantially all of our products to I.V. product manufacturers and independent distributors. Our largest customer is Hospira, Inc. ("Hospira", formerly the Hospital Products Division of Abbott Laboratories ("Abbott")), which accounted for 53% of our revenues in 2004.

On February 25, 2005, we entered into a twenty-year Manufacturing, Commercialization and Development Agreement ("MCDA") with Hospira. Under the MCDA and related agreements, we will acquire Hospira's Salt Lake City, Utah manufacturing facility, related capital equipment and certain inventories for approximately $35 million in cash, and produce for sale to Hospira on an exclusive basis substantially all the products manufactured at that plant. Hospira will retain commercial responsibility for the products we will be producing, including sales, marketing, distribution, customer contracts, customer service and billing. The majority of the products we will be producing under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. We have also committed to fund certain research and development to improve critical

care products and develop new products for sale to Hospira, and have committed to provide certain sales specialist support. Our prices and our gross margins on the products we sell to Hospira under the MCDA are based on cost savings that we are able to achieve in producing those products over Hospira's current cost to manufacture those same products. We expect to move the production to our current facilities or other lower-cost locations over the next several years. Initially, we expect our gross margins under the MCDA to be small, but we expect them to expand as we achieve cost savings. We estimate that sales under this agreement will exceed $50 million in 2005, with only small profits in 2005, with increasing sales and profits in future years. However, this sales estimate is subject to a variety of factors and there can be no assurance that the prospective results will be indicative of future performance or that results will not vary materially from this estimate. We expect the MCDA to commence early in the second quarter of 2005

First person pronouns used in this Report, such as "we, " "us, " and "our, " refer to ICU Medical, Inc. and its subsidiaries unless context requires otherwise.

Our website address is http://www.icumed.com. We make available our Annual Reports on Form 10-K, Quarterly Reports on 10-Q and Current Reports on Form 8-K free of charge on our website as soon as reasonably practicable after filing them with the Securities and Exchange Commission. The information on our website is not incorporated into this annual report.

I.V. Usage and Infection Control

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

Prior to the introduction of needlesafe connectors, conventional practice was to make, primary I.V. system connections by inserting an exposed steel hollow-bore needle attached to the primary I.V. line into an injection port connected to the catheter. Conventional secondary I.V. connections, so called piggyback connections, were made by inserting an exposed steel hollow-bore needle attached to a secondary I.V. line into an injection port or other I.V. connector. In those I.V. connections, the needles, which typically were secured only with tape, could detach from the catheter or injection port resulting in disconnection and a serious and sometimes fatal interruption of the flow of the I.V. solution to the patient. The exposed needles could easily be contaminated by contact with unsterile objects or through contact with fluid in the I.V. lines. Accidental needlesticks from contaminated needles can result in infection to healthcare workers and, less frequently, patients. 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 our protective I.V. connectors.

Hepatitis B and C and HIV are transmitted through blood and other body fluids, and workers who come in contact with such infectious materials are at risk of contracting these diseases. Transmission may occur from needlesticks by contaminated needles or exposure of mucous membranes to infectious body fluids containing blood traces. Following each needlestick, the healthcare employer is required to perform a series of tests on the healthcare worker for both Hepatitis B and C and HIV, as well as track and record each needlestick incident. Thus, needlesticks result in time lost from work and substantial expense regardless of whether transmission of an infectious disease is detected. By eliminating needles from primary and secondary I.V. connections, our protective I.V. connectors prevent accidental needlesticks in those applications.

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 our needleless I.V. connectors. This awareness has also lead

to significant federal and state legislation. In addition, the federal Needlestick Safety and Prevention Act, enacted in 2000, modified standards promulgated by the Occupational Safety and Health Administration ("OSHA"), to require employers to use needle-safe systems where appropriate to reduce risk of injury to employees from needlesticks. This is a significant expansion of the previous OSHA mandate that "universal

precautions" be observed to minimize exposure to blood and other body fluids. In September 1998, the State of California enacted the bloodborne pathogen standard under the state's occupational safety and health statute. This standard mandates use of needlestick prevention controls, including needleless systems. California was the first state to enact such legislation, and since then many other states have enacted similar legislation. Our devices will allow a healthcare provider to be compliant with any of these standards.

Products

CLAVE Products

Prior to the introduction of needlesafe connectors, a conventional I.V. line terminated with a male luer connector to which a hollow-bore needle would be attached to penetrate a latex or non-latex rubber covered injection port to make a primary or secondary I.V. connection. With the CLAVE system, instead of attaching a hollow-bore needle to the male luer, a CLAVE is used in place of the injection port and the male luer, without a needle, is simply threaded into the CLAVE with a half turn. The CLAVE consists of a cylindrical housing, which contains a silicone compression seal and a recessed plastic piercing element. As the luer tip enters the CLAVE housing, it depresses the silicone seal back into the housing and slides over the piercing element, which penetrates through the compressed silicone. Fluid channels in the piercing element create a continuous fluid pathway from the I.V. line, through the CLAVE into the primary I.V. line and into the catheter. The luer tip creates a tight seal against the top of the silicone thereby preventing contaminants from entering the fluid pathway or fluid from escaping the connection. When the I.V. line is disconnected from the CLAVE, the silicone compression seal expands to again fill the housing and reseal the opening. When the CLAVE is not in use, the silicone compression seal fills the opening in the housing and covers the plastic piercing element, thus completely sealing the connector and presenting a flush surface that can be cleansed with an alcohol swab. The CLAVE contains no natural rubber latex.

Emergency medications can be administered through the CLAVE by using a standard syringe without a hypodermic needle attached. The CLAVE can be used with any conventional peripheral or central vascular access systems, both for venous and arterial applications. 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 I.V. sets, thus eliminating the need for special adapters, pre-slit injection ports, or metal needles when making piggyback I.V. connections. Currently, many popular I.V. connection systems that compete with our 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. We believe the 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 I.V. 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 non-piggyback connections. Unlike the original CLAVE site, the CLAVE Y site is marketed exclusively to I.V. set manufacturers, such as Hospira, to build directly into their I.V. sets or used by us in our custom I.V. sets.

The CLAVE is our largest selling product line, and accounted for 47% of our net revenue in 2004 and 59% of our revenue in 2003. Custom I.V. systems including one or more CLAVEs accounted for 71% and 73% of our net revenue in 2004 and 2003, respectively.

In October 2001, we commenced production of the "MicroCLAVE®." It is smaller than the standard CLAVE but is functionally similar. We are marketing it as an extension of the CLAVE product line for use where its smaller size is advantageous, such as pediatric care.

Custom I.V. Systems

During late 1995, we entered the low end of the safe medical connector market by manufacturing and distributing I.V. sets which incorporated lower priced safe medical connectors, and also commenced

manufacturing and distributing custom I.V. sets incorporating the CLAVE. In 1999, we substantially increased our emphasis on marketing and selling custom I.V. systems. To promote the growth of the business, we have developed innovative software systems and manufacturing processes that permit us to design a custom I.V. set to a hospital's or clinician's exact specifications, commence production within less than a day after we receive the customer order and ship smaller orders of the custom I.V. sets to the customer within three days of receipt for smaller orders. While we are capable of meeting customer demand on this accelerated three-day schedule, in normal circumstances we ship within twenty-one to thirty days of receipt of the customers' order. This is a fraction of the time required by other custom set manufacturers. The use of sophisticated design, ordering and order tracking systems and streamlined assembly and distribution processes allows us to sell custom I.V. sets at prices substantially lower than those charged by other producers of custom I.V. sets.

We have also developed proprietary Internet-based electronic ordering, order tracking, invoicing and payment systems. Hospitals and other healthcare providers have been slow to change from traditional methods of ordering products and supplies to ordering over the internet, and to date we receive most of our orders by facsimile or telephone. We believe, however, that customers will gradually make the transition from traditional ordering methods to internet ordering.

In February, 2001, we signed an agreement with Hospira under which we manufacture all new custom I.V. sets for sale by Hospira, and the two companies jointly promote the products under the name SetSource™. Sales of custom I.V. systems continue to increase as a result of the agreement and we expect further significant increases in sales of custom I.V. systems, although there is no assurance that such increase will be achieved.

We have committed significant resources to the strategic initiative to expand our custom I.V. system businesses and expect to incur additional expenses for continuing software development and enhancements in the manufacturing process. To date, most of the I.V. set sales volume is in custom I.V. systems, and we expect this to continue.

During 2004, 2003 and 2002, net sales of custom I.V. systems were approximately $26.2 million, $22.8 million and $15.2 million, respectively. Approximately 63% of the growth in 2004 custom I.V. systems net sales was from sales to Hospira. The remaining increase was through domestic and

international distributors.

Punctur-Guard

We acquired the Punctur-Guard product line and technology with the purchase of Bio-Plexus on October 31, 2002. The Punctur-Guard products are based on a patented technology that internally blunts a needle while still in the patient's vein, and are the only products which allow the procedure to continue while the needle is rendered safe. We currently use the technology to make Blood Collection Needles (BCN) and Winged Sets, primarily for use by phlebotomists and other medical personnel in hospitals and independent clinical laboratories.

Our internal needle blunting technology is licensed to Medex, (successor to Johnson & Johnson Medical) and to TFX Medical, a division of Teleflex Incorporated, for use in various types of catheters. None of the applications of the patented technology under those licenses compete with our Punctur-Guard line of blood collection products. Sales of Punctur-Guard products and royalties from licenses of the related technology for 2004 were $3.9 million and $1.1 million, respectively. Sales of Punctur-Guard products and royalties from licenses of the related technology for 2003 were $7.3 million and $1.1 million, respectively.

Since the acquisition of the Punctur-Guard product line, we have made significant improvements to the products and the manufacturing processes. Although we have reduced prices in attempting to achieve wider distribution, such efforts have not been successful to date. We are currently concentrating our sales and marketing efforts for the Winged Sets on outpatient provider contracts and the lab market. We are not

currently making any significant efforts to sell and market the BCN. There is no assurance as to future sales of Punctur-Guard products.

CLC2000

The CLC2000 is a one piece, swabbable connector used to connect I.V. lines to catheters, which is engineered to prevent the back-flow of blood into the catheter. The CLC2000 does not permit the use of needles, thereby ensuring compliance with needle-free policies of healthcare providers. The CLC2000 also contains no natural rubber latex.

The CLC2000 is typically used on central venous catheters where catheter occlusion is most prevalent. Generally, when an I.V. line is disconnected, there is a back-flow of blood into the catheter that is in the patient's vein. That blood in time coagulates and occludes the catheter. Occlusion ("clotting off") of catheters requires expensive drugs and procedures to "flush" the catheter, or if those procedures are not effective, replacement of the catheter.

The CLC2000 was developed to reduce clotting of catheters because of "back-flow" when the I.V. line is disconnected. The CLC2000 consists of a "T" shaped cylindrical housing, which contains a poppet that is depressed as the luer tip enters the CLC2000. Fluid flows around the poppet and through the housing and into the catheter. When the luer is removed from the CLC2000, a portion of the fluid remaining in the housing is expelled out through the tip of the catheter while a constant positive pressure is maintained to prevent any back-flow into the catheter.

We began marketing the CLC2000 in November 1997. We are concentrating the marketing of the CLC2000 where its "no back-flow" features are of maximum benefit in patient care. These are generally therapies that use long-term indwelling catheters such as oncology and long-term infusion of medication. We commenced production on automated assembly equipment in the fourth quarter of 2002. CLC2000 accounted for 4% of our net revenue in 2004 and 2003.

1o2 Valve

The 1o2 Valve is the first one-way or two-way drug delivery system. It functions as a single unit or in multiple "ganged" units as a manifold, for use throughout a hospital. It provides the safety features of an automatic one-way valve, yet allows aspiration, or two-way function by simply pushing a button. The 1o2 Valve can be used in place of products such as stopcocks and check valve manifolds. We actively commenced sales in April 2000. Our initial manufacturing focus has been on anesthesia and critical care usage and we are selling the 1o2 Valve only as part of I.V. sets that we manufacture. In the third quarter of 2002, we commenced production on automated assembly equipment. Sales of I.V. sets containing 1o2 Valves were approximately $4.4 million and $3.6 million in 2004 and 2003.

Other Products and Revenues

The Lopez Enteral Valve® is a small "T" valve designed to be connected into nasogastric, gastric or jejunostomy tube systems. The valve permits intermittent injection of medications, irrigation or suction without having to disconnect the line and thereby opening the system. By eliminating the need to open the system, the Lopez Valve helps prevent the splashing of and risk of contact with potentially infectious stomach fluids and also saves valuable time.

We have developed a family of inexpensive single-use needleless connectors for use in piggyback and non-piggyback applications. The RF100 is designed for use in piggyback applications. We developed the RF150, called the "Rhino," specifically for Hospira for use with pre-slit injection ports in piggyback and non-piggyback applications. Although we believe that the CLAVE has significant functional advantages over the RF100 and RF150, these products are alternative and less expensive needleless I.V. connectors.

We have a significant number of patents on the technology in our products and methods used to manufacture them. We have continuing royalty, license fee and revenue share income from our technology and from time to time may receive license fees or royalties from other entities for the use of our technology.

New Products

We are developing several new products that we intend to introduce in 2005 and later. We believe innovative products continue to be important to maintaining and increasing our sales levels.

In September 2004, we invested approximately $2.5 million cash for 57% of a company developing a new medical device for screening for heart disease. The device is in the early stage of design, uses new technology, and completion of a marketable device is expected to take at least several years at a cost

somewhat in excess of our current funding commitment. We have agreed to invest an additional $1.5 million if certain milestones are achieved by November 30, 2005. There is no assurance as to the timing of or cost of completing a marketable device or whether it will be completed.

New products that we expect to introduce in 2005 include: TEGO, a new connector that can fill a long-standing need to reduce infection in dialysis therapy; a new CLAVE Y Site connector with integral check value for sale to I.V. set manufacturers and use in products we manufacture; the Orbit 90 diabetes set, a subcutaneous administration set for use with personal portable insulin administration pumps; and another new connection device designed to eliminate hazardous oncolytic exposure and reduce infection. There is no assurance as to the levels of sales we will achieve with these new products.

Marketing and Distribution

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

As of January 31, 2005, we employed 39 product specialists in the United States and Canada to support the salespeople employed by the medical product manufacturers and independent domestic distributors. Our product specialists call on prospective customers, demonstrate products and support programs to train the salespeople and customers' staffs in the use of our products.

Medical Products Manufacturers

We have a strategic supply and distribution relationship with Hospira, a major I.V. product supplier, which has a significant share of the I.V. set market under contract. The agreement runs to 2014 and confers to Hospira conditional exclusive and nonexclusive rights to distribute certain of our CLAVE and other products to certain categories of customers both in the United States and foreign countries.

On April 30, 2004, Abbott spun off its core Hospital Products Division to its stockholders as an independent company named Hospira, Inc. The Hospital Products Business accounted for virtually all of our sales to Abbott. Abbott has assigned our agreements with Abbott to Hospira. We believe the spin-off is a positive development for us and will result in new business opportunities with the new Hospira. For clarity, all historical references to Abbott and its Hospital Products Division have been changed to Hospira.

Hospira purchases CLAVE products packaged separately for distribution to healthcare providers and in bulk for assembly into Hospira's full range of I.V. products. MicroCLAVE, 1o2 Valve, CLC2000, Punctur-Guard, Lopez Valve and Rhino products are purchased packaged separately.

Under another agreement with Hospira that extends to December 2014, we have the exclusive right to manufacture all new custom I.V. sets for sale by Hospira, and Hospira and we will jointly promote the products under the name SetSource. Hospira is the exclusive and non-exclusive distributor and co-promoter of SetSource products to certain categories of customers, including SetSource products containing both companies' proprietary products.

Sales to Hospira accounted for approximately 53%, 67% and 57% of net sales in 2004, 2003, and 2002 respectively. The loss of Hospira as a customer could have a significant adverse effect on our business and operating results.

Independent Domestic Distributors

As of January 31, 2005, we had approximately 26 independent distributors in the United States and Canada who employ approximately 150 salespeople in the aggregate and which accounted for approximately 30% of our net revenues in 2004. We include Canada as "domestic" for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

No single independent distributor accounts for more than 4% of net sales in 2004. Although the loss of one or more of our larger distributors could have an adverse affect on our business, we believe we could readily locate other distributors in the same territories who could continue to distribute our products to the same customers.

International

We distribute products principally in Western Europe, the Pacific Rim, Latin America and in South Africa. Foreign sales (excluding Canada) accounted for approximately 12%, 6%, and 8% of our net sales in each of the years 2004, 2003, and 2002, respectively. The International Division currently has approximately 41 distributors. Customers in Europe are served by our distribution operation in Italy. We serve the rest of the world from our facilities in the U.S. and Mexico. We have three business development managers in Europe and three who, together, serve the entire Pacific Rim, Southeast Asia, the Middle East, Africa and Latin America. We expect to add several more business development managers in 2005. Administrative operations are in Roncanova in northern Italy (at the site of our assembly plant) and San Clemente. Currently, all shipments from the United States are invoiced in U.S. dollars and sales from Italy are invoiced in Euros.

Manufacturing

Manufacturing of our products involves injection molding of plastic and silicone parts, manual and automated assembly of the molded plastic parts, needles and other components, quality control inspection, packaging and sterilization. We mold all of our proprietary components, and perform all assembly, quality control, inspection, packaging, labeling and shipping of our products. Our manufacturing operations function as a separate group, producing products for the marketing and sales groups.

We own a fully integrated medical device manufacturing facility in two adjacent buildings totaling 78,000 square feet in San Clemente, California. A mold maintenance shop supports the repair and maintenance needs of our molding operation and manufactures some of our production molds. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment. The state-of-the-art medical device molding facility includes a 24,425 square foot class 100,000 clean room in which all molding and automated assembly of our proprietary medical components is performed. The clean room is equipped with 42 injection molding machines and ancillary equipment including robots designed to minimize human intervention, and sophisticated, highly automated assembly systems to assemble the CLAVE, CLAVE Integrated Y site, MicroCLAVE, CLAVE vial access spike, CLC2000, 1o2 Valve, RF150, B. Braun Protected Needle products. The assembly systems

are custom designed and manufactured for us.

We assemble our Punctur-Guard products in our 37,500 square foot manufacturing facility in Vernon, Connecticut, which includes two clean rooms. The assembly processes for both the BCN and the Winged Set use custom made automated assembly systems. Molding of Punctur-Guard components, which had been done by outside custom molding companies, was transferred to our San Clemente facility in 2004.

Most of our manual assembly is done at our facilities in Ensenada, Baja California, Mexico. Those facilities include approximately 60,000 square feet of production and warehousing space and an electron beam sterilizer. Principal products assembled manually are I.V. therapy systems, the Lopez Valve, and CLAVE ancillary products and accessories. We also assemble I.V. therapy systems in our approximately 17,000 square foot facility in northern Italy that we acquired in June 2003.

Our 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, we mold our entire requirements of proprietary molded components. The raw materials for our molding operation are principally resins and silicones, and these materials are available from several sources. Generic, "off-the-shelf" items are purchased from outside vendors unless significant cost savings can be achieved by molding in-house. We are not dependent on any individual vendor for purchased parts and have no contracts with our suppliers beyond the terms of purchase orders issued.

Our products are sterilized in processes which use either gamma or electron beam ("e-beam") radiation. Most of the sterilization is by e-beam, which is less expensive and quicker than gamma radiation sterilization. All sterilization was performed by independent companies through the January 2004. In February 2004, we commenced operation of our own sterilization facility at our plant in Mexico and we sterilize all of our products that are assembled in Mexico and most of our products made in San Clemente at that facility. We continue to use independent contractors to sterilize some of the products assembled in San Clemente and all products assembled in Italy.

We have an ongoing program to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. In 2002 and 2003 we expanded our automated assembly capabilities and capacity. In late 2003 and early 2004, we moved plastic injection molding for our Punctur-Guard products to our San Clemente facility to ensure more consistent quality in our molded components and decreased costs. Ongoing steps also include automation of the production of new products and other products for which volume is growing. We continue to consider establishment of additional production facilities outside of North America to meet local demand and reduce transportation costs. Because significant innovation is required to achieve these goals, there is no assurance that these steps will achieve the desired results.

Government Regulation

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

procedure. There is no assurance, however, that new products we develop or any manufacturers that we might acquire, or claims that we 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 that we currently manufacture 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.

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

We believe that our products and procedures are in compliance with all applicable FDA and DHS regulations. The company is expecting the formal report by early March 2005. There is no assurance, however, that other products we are developing or products that we may develop in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of our 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 our business.

To market our products in the European Community ("EC"), we 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, we must comply with the quality management standards of EN ISO 9001(1994) / EN 46001 (1996). Those quality standards are similar to the QSR regulations but incorporate the quality requirements for product design and development.

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

We have demonstrated conformity to the regulations of both ISO 9001 (1994) / EN 46001 (1996), ISO 13485 (1996) and the Medical Device Directive and we affix the CE Mark to our device labeling for product sold in member countries of the EC.

We believe our products and systems are in compliance with all EC requirements. There can be no assurance, however, that other products we are developing or products that we may develop in the future will

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

Competition

The market for I.V. products is intensely competitive. We believe that our ability to compete depends upon our continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection, and pricing. We encounter significant competition in this market both from large established medical device manufacturers and from smaller companies. Our ability to compete effectively depends on our ability to differentiate our products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as our ability to perceive and respond to changing customer needs. In the long term, we expect that our ability to compete will continue to be affected by our ability to reduce unit manufacturing costs through higher volume production.

In addition to competing with conventional needle I.V. connection systems and protected needle connection systems marketed by companies such as Baxter Healthcare Corporation ("Baxter") and Hospira, our present and future products compete with needleless I.V. connection systems like those marketed by Baxter, Becton-Dickinson and Company ("BD"), B.Braun, Alaris Corporation and others. Although we believe that our needleless CLAVE has distinct advantages over competing systems, there is no assurance that it will be able to compete successfully with these products.

The blood collection needle market is highly competitive, and a large segment of the market continues to use non-safety devices that are generally less expensive than safety devices such as the Punctur-Guard products. The largest share of the blood collection needle market is held by BD.

Manufacturers of products with which we currently compete, 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, Hospira and B.Braun are leading distributors of I.V. therapy systems, while BD dominates the blood collection 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 substantially all of their I.V. product requirements. In order to penetrate more of these hospitals, we have established a strategic supply and distribution relationship with Hospira.

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

In June 2004, Cardinal Health, Inc. ("Cardinal") acquired Alaris Medical Systems, Inc. "Alaris"). Alaris manufactures a connector that competes with the CLAVE. Cardinal is the largest distributor of healthcare products in the United States, and the companies have announced their intent to increase market share growth beyond what Alaris might be able to achieve on its own. We believe the ownership of Alaris by Cardinal could adversely affect our market share and the prices for our CLAVE products.

We believe that our ability to compete in the custom I.V. systems market depends upon the same factors affecting our existing products, but will be particularly affected by cost to the customer and delivery times. While we believe we have advantages in these two areas, there is no assurance that other companies will not be able to compete successfully with our custom I.V. systems.

Patents

We have United States and certain foreign patents on the CLAVE, TEGO, Y-CLAVE with integral check value, Orbit 90 (diabetes infusion set), CLC2000, Punctur-Guard technology, Click Lock, and Piggy Lock I.V. connectors and have United States patents on the Lopez Valve connector. We have applications pending for additional United States and foreign patents on the 1o2 Valve, TEGO, Y-CLAVE with integral check value, Orbit 90, CLC2000, CLAVE, Punctur-Guard, Click Lock and Piggy Lock I.V. connectors. The expiration dates of our patents range from 2006 to 2021. (While we no longer manufacture and sell the Click Lock and Piggy Lock, the patents have considerable value for potential use in other devices.)

Our success may depend in part on our ability to obtain patent protection for our products and to operate without infringing the proprietary rights of third parties. While we have obtained certain patents and applied for additional United States and foreign patents covering certain of our products, there is no assurance that any additional patents will be issued, that the scope of any patent protection will prevent competitors from introducing similar devices or that any of our patents will be held valid if subsequently challenged. We also believe 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 that are as effective as our products. The loss of patent protection on CLAVE, CLC2000, Punctur-Guard, Click Lock or Lopez Valve products could adversely affect our ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on our financial results.

The fact that a patent is issued to us does not eliminate the possibility that patents owned by others may contain claims that are infringed by our 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 us and in diversion of our resources, may be necessary to defend us against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. Adverse determinations in such litigation could subject us to significant liabilities to third parties or could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using our products, any of which could have a material adverse effect on our business. In addition, we have initiated litigation, and will continue to initiate litigation in the future, to enforce our intellectual property rights against those we believe to be infringing on our patents. Such litigation could result in substantial cost and diversion of resources.

ICU Finance

In 2002 we established ICU Finance, Inc., a wholly-owned consolidated subsidiary, to provide financing to healthcare entities. As of December 31, 2004 we had finance loans receivable of approximately $6.2 million that are fully secured by real and personal property. We plan to hold the loans to maturity or payoff. Weighted average maturity (principal and interest) at December 31, 2004 was 1.4 years and the weighted average interest rate was 5.5%. We discontinued new lending activities in October 2003. There were no unfunded commitments at December 31, 2004.

Employees

At January 31, 2005 we had 587 full-time employees, consisting of 114 engaged in sales, marketing and administration, and 473 in manufacturing, molding, product development and quality control, including 329 in Mexico. We contract with an independent temporary agency to provide some San Clemente, California production personnel who are not our employees. At January 31, 2005, the number of temporary production personnel was 33.

Item 2. Properties.

We own two adjacent 39,000 square foot buildings in San Clemente, California, another 28,000 square foot building in the same business park, a 37,500 square foot building in Vernon, Connecticut a 60,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico and a 10,000 square foot building in Roncanova, Italy. We also lease a 17,500 square foot building in Roncanova, Italy.

Item 3. Legal Proceedings.

In an action filed August 21, 2001 entitled ICU Medical, Inc. v. B Braun Medical, Inc. pending in the United States District Court for the Northern District of California, we allege that B. Braun infringes ICU's patent by the manufacture and sale of its UltraSite medical connector. On December 30, 2003, we were awarded an additional patent, and on that day we filed an additional action against B. Braun for patent infringement and moved to amend the 2001 action to include that allegation. The 2001 action has since been amended to include our claim of infringement of the additional patent. Trial is scheduled for August 2005. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. The outcome of this matter cannot be determined at this time.

In an action filed June 16, 2004 entitled ICU Medical, Inc. v. Alaris Medical Systems, Inc. pending in the United States District Court for the Central District of California, we allege that Alaris Medical Systems, Inc. infringes ICU's patent by the manufacture and sale of the SmartSite and SmartSite Plus Needle-Free Valves and Systems. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. On August 2, 2004 the Court denied our request for a preliminary injunction. On December 29, 2004, we amended the action to allege that Alaris infringes three additional patents. The outcome of this matter cannot be determined at this time.

We are from time to time involved in various other legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

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

Not Applicable.

Executive Officers of Registrant.

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

	Age	Office Held
George A. Lopez, M.D.	57	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	32	Vice President of Marketing
Richard A. Costello	41	Vice President of Sales
Francis J. O'Brien	62	Chief Financial Officer, Secretary and Treasurer
Steven C. Riggs	46	Vice President of Operations

Dr. Lopez and Messrs. Costello and O'Brien have been employed by us in their current positions for more than five years.

Ms. Burcar became Vice President of Marketing in August 2002, after having been Marketing Operations Manager since March 1998. She is the niece of Dr. Lopez.

Mr. Riggs became Vice President of Operations in August 2002, after having been Director of Operations since 1998.

Part II

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

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

2003	High	Low
First Quarter	$ 37.50	$ 25.87
Second Quarter	33.33	26.41
Third Quarter	30.22	22.95
Fourth Quarter	35.55	25.35

2004	High	Low
First Quarter	$ 40.50	$ 27.90
Second Quarter	33.53	31.05
Third Quarter	33.54	25.40
Fourth Quarter	27.64	21.98

We have never paid dividends and do not anticipate paying dividends in the foreseeable future as the Board of Directors intends to retain future earnings for use in our business. Any future determination as to payment of dividends will depend upon our financial condition, results of operations and such other factors as the Board of Directors deems relevant.

As of December 31, 2004 we had 135 stockholders of record and believe we have approximately 7,000 beneficial stockholders.

We have a 2003 Stock Option Plan under which we may grant options to purchase our Common Stock to our employees and have a 2001 Directors' Stock Option Plan under which we may grant options to purchase our Common stock to our Directors. We also had a 1993 Stock Incentive Plan, under which we granted options to purchase Common Stock to the employees which expired in January 2005. We plan to substantially curtail grants of stock options in the future and have suspended further grants under the 2001 Director' Stock Option Plan. We also have an Employee Stock Purchase Plan. All plans were approved by our stockholders. Further information about the plans is in Note 5 to the consolidated financial statements. Certain information about the plans at December 31, 2004, adjusted to reflect the expiration of the 1993 Stock Incentive Plan in January 2005, is as follows:

Number of shares to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (c)
4,420,574	$18.11	2,632,385

Item 6. Selected Financial Data

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2004	2003	2002	2001	2000
INCOME DATA:					
Revenue					
Net Sales	$ 72,704	$102,726	$ 84,218	$ 69,055	$ 56,191
Other	2,846	4,628	3,589	-	-
Total Revenue	75,550	107,354	87,807	69,055	56,191
Cost of Sales	39,853	48,444	36,464	28,932	23,787
Gross profit	35,697	58,910	51,343	40,123	32,404
Selling, general and administrative expenses	26,409	23,029	19,871	16,816	14,302
Research and development expenses	3,376	1,757	1,472	1,188	1,480
Total operating expenses	29,785	24,786	21,343	18,004	15,782
Income from operations	5,912	34,124	30,000	22,119	16,622
Investment income	1,579	1,123	1,432	1,988	2,096
Income before income taxes and minority interest	7,491	35,247	31,432	24,107	18,718
Provision for income taxes	2,600	12,950	11,750	8,720	6,930
Minority interest	(109)	-	-	-	-
Net income	$ 5,000	$ 22,297	$ 19,682	$ 15,387	$ 11,788
Net income per common share					
Basic	$ 0.37	$ 1.62	$ 1.43	$ 1.20	$ 0.94
Diluted	$ 0.33	$ 1.48	$ 1.28	$ 1.06	$ 0.87
Weighted average number of shares					

Basic	13,691	13,753	13,793	12,841	12,495
Diluted	14,960	15,050	15,352	14,454	13,588
CASH FLOW DATA:					
Cash flows from operations, excluding tax benefits from exercise of stock options	$ 23,300	$ 21,987	$ 17,905	$ 20,565	$ 12,760
Total cash flows from operations	$ 25,283	$ 22,829	$ 28,097	$ 24,329	$ 13,462
BALANCE SHEET DATA:					
Cash and liquid investments	$ 87,341	$ 73,137	$ 88,465	$ 73,027	$ 50,786
Working capital	109,590	102,932	102,564	79,736	57,718
Total assets	164,768	164,288	157,032	117,342	92,860
Stockholders' equity	156,348	156,003	145,387	106,677	83,380

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous ("I.V.") therapy applications. Our devices are designed to protect healthcare workers and their patients from exposure to infectious diseases such as Hepatitis B and C and Human Immunodeficiency Virus ("HIV") through accidental needlesticks. We are also a leader in the production of custom I.V. systems and low cost generic I.V. systems and we incorporate our proprietary products on many of those custom I.V. systems.

Results for the Year 2004

The Company reported net income of $5.0 million in 2004, a decrease of $17.3 million from 2003. The decline in net income in 2004 is principally because Hospira, Inc. decreased the level of purchases because it is making a substantial reduction in its inventories of our products. Our sales to Hospira declined $31.5 million from 2003, and $31.3 million of that decline was in CLAVE products. Because of the reduced sales to Hospira, we curtailed our production of CLAVE products; but, since much of our manufacturing costs are fixed, the reduced production resulted in unabsorbed overhead of approximately $5.2 million. Information provided by Hospira indicates that Hospira's unit sales of CLAVE products to its customers have continued to increase throughout 2004. We believe that once Hospira reduces its inventory to the desired level, which they informed us had been accomplished by the end of December 2004, our sales of CLAVE products to Hospira will increase from levels in 2004 and will more closely match its sales to its customers than they have in the past. Because our inventory of CLAVE products was higher than normal at December 31, 2004; we expect reduced production levels and unabsorbed overhead to continue into early 2005.

Sales of our Punctur-Guard products declined from $7.3 million in 2003 to $3.9 million in 2004. We have experienced lower unit volumes and have reduced prices to achieve wider distribution.

In September 2004, we invested approximately $2.5 million in a company developing a new medical device. Approximately $1.2 million of the Company's investment was allocated to in-process research and development, and that amount, which is non-recurring, was charged to research and development expense in the Company's consolidated financial statements in September 2004.

Our operating expenses (including research and development) increased approximately $5.0 million in 2004 as compared to 2003. This was principally because of the $1.2 million expense of in-process research and development mentioned above, costs related to Sarbanes-Oxley compliance, non-recurring patent amortization and increased information technology costs.

The following table is a reconciliation of income from operations from the year ended 2003 to income from operations from the year ended 2004.

(In millions of dollars):	
2003 income from operations	$ 34.1
Sales reduction from $102.7 to $72.7, approximate effect on gross profit	(18.4)
Unabsorbed overhead $5.2 in excess of $0.4 in 2003	(4.8)
Increased operating expenses, including in-process R&D	(5.0)
2004 income from operations	$ 5.9

Risk Factors

In evaluating a transaction in our common stock, investors should consider carefully, among other things, the following risk factors, as well as the other information contained in this Annual Report and our other reports and registration statements filed with the Securities and Exchange Commission.

Because we are increasingly dependent on Hospira for a substantial portion of our sales, any change in our arrangements with Hospira or decline in our sales to it could result in a significant reduction in our sales and profits.

We have steadily increased our sales to Hospira in recent years, except for 2004 when sales to Hospira declined as Hospira reduced its inventories of our products. As a result, we depend on one customer, Hospira, for a high percentage of our sales, and the percentage of our sales attributable to Hospira will increase as we begin manufacturing additional products for Hospira as described below. Although we have increased our sales to independent domestic distributors during recent years, most of the increase resulted from our dealers' acquisition of market shares from a manufacturer with whom we terminated our CLAVE distribution agreement and the addition of the Punctur-Guard line in late 2002. The percentage increase in distributor sales in 2004 is attributable to the decline in sales to Hospira. The table below shows our sales to various types of customers for 2004, 2003 and 2002:

	Years Ended December 31,

	2004		2003		2002	
Hospira	$ 39.8	53%	$ 71.3	69%	$ 50.0	57%
Other manufacturers	1.5	5%	1.5	2%	10.1	16%
Independent distributors	22.4	30%	24.1	23%	17.0	19%
International	9.0	12%	5.8	6%	7.1	8%

In 2004, Hospira substantially reduced its purchases of CLAVE products because it was reducing its inventories of our products. This caused a significant reduction in our sales and led to a net loss in our third and fourth quarters of 2004. We have taken steps to monitor and control the amount of inventory of Hospira CLAVE products manufactured in order to mitigate the need for future inventory reductions similar to that in 2004, but there is no assurance that these steps will be successful, or that Hospira will not attempt to reduce its inventory of CLAVE products even further in the future.

Hospira had disclosed that CLAVE products accounted for approximately 12% of its 2003 consolidated sales. In the past several years, our prices to Hospira have declined by only a small amount. Any significant decrease in our prices to Hospira, unless accompanied by an offsetting increase in purchasing volume, could have an adverse effect on our sales and profits.

Our sales to Hospira will increase substantially as a result of a twenty-year Manufacturing, Commercialization and Development Agreement ("MCDA") that we entered into with Hospira on February 25, 2005. Under the MCDA and related agreements, we will acquire Hospira's Salt Lake City, Utah manufacturing facility, related capital equipment and certain inventories (that do not include ICU Medical products) for approximately $35 million in cash, and produce for sale to Hospira on an exclusive basis substantially all the products manufactured at that plant. Hospira will retain commercial responsibility for the products we will be producing, including sales, marketing, distribution, customer contracts, customer service and billing. The majority of the products we will be producing under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. We have also committed to fund certain research and development to improve critical care products and develop new products for sale to Hospira,

and have committed to provide certain sales specialist support. Our prices and our gross margins on the products we sell to Hospira under the MCDA will be based on cost savings that we are able to achieve in producing those products over Hospira's current cost to manufacture those same products. We expect to move the production to our current facilities or other lower-cost locations over the next several years. We estimate that sales under this agreement will exceed $50 million in 2005, with only small profits, with increasing sales and profits in future years. However, this sales estimate is subject to a variety of factors and there can be no assurance that the prospective results will be indicative of future performance or that actual results will not vary materially from this estimate.

Under the terms of our agreements with Hospira, including the MCDA, we are dependent on the marketing and sales efforts of Hospira for a large percentage of our sales, and Hospira determines the prices at which the products that we sell to Hospira will be sold to its customers. Hospira has conditional exclusive rights to sell CLAVE and our other products as well as custom I.V. systems under the SetSource program in many of its major accounts. Hospira's rights to sell products we produce under the MCDA are exclusive. If Hospira is unable to maintain its position in the marketplace, or if Hospira should experience significant price deterioration, our sales and operations could be adversely affected.

In contrast to our dependence on Hospira, our principal competitors in the market for protective I.V. connection systems are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, we believe that there is a trend among individual hospitals and home healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit our ability to gain market share through our independent dealer network, resulting in continued concentration of sales among and dependence on Hospira.

Hospira, a major supplier of I.V. products, was formerly the Hospital Products Division of Abbott Laboratories. On April 30, 2004, Abbott spun off Hospira to its stockholders as an independent company. Since then, Hospira has been a separate entity, independent of Abbott. The principal Hospira agreement, for products other than the MCDA, is a strategic supply and distribution arrangements to market our products in connection with Hospira's I.V. products. The agreement extends through 2014. Our ability to maintain and increase our market penetration may depend on the success of our arrangements with Hospira and Hospira's arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. If our strategic supply and distribution arrangement proves unsuccessful, our sales would be materially adversely affected. Our business could be materially adversely affected if Hospira terminates its arrangement with us, negotiates lower prices, sells more competing products, whether manufactured by themselves or others, or otherwise alters the nature of its relationship with us. Although we believe that Hospira views us as a source of innovative and profitable products, there is no assurance that our relationship with Hospira will continue in its current form.

If we are unable to manage effectively our internal growth or growth through acquisitions of companies, assets or products, our financial performance may be adversely affected.

We intend to continue to expand our marketing and distribution capability internally, by expanding our sales and marketing staff and resources and may expand it externally, by acquisitions both in the United States and foreign markets. We may also consider expanding our product offerings through further acquisitions of companies or product lines. We intend to build additional production facilities or contract for manufacturing in markets outside the United States to reduce labor costs and eliminate transportation and other costs of shipping finished products from the United States and Mexico to customers outside North America. The expansion of our manufacturing, marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on our management resources and

financial controls. Decentralization of assembly and manufacturing could place further burdens on management to manage those operations, and maintain efficiencies and quality control.

The performance of the MCDA under which we will produce critical care products for Hospira, the acquisition of related manufacturing assets, the addition of more than 750 production personnel, the relocation of manufacturing operations, the implementation of new manufacturing and assembly processes and techniques and the establishment of financial controls will impose a significant burden on our management, human resources, operating and financial and accounting functions. We will need to expand our capabilities in each of these areas and devote significant time and effort to integrating the production under the MCDA with our existing operations, all of which will divert management's attention from our current operations. In addition we may require

additional expertise, capability and capacity that can best be obtained through other acquisitions.

The increasing burdens on our management resources and financial controls resulting from internal growth of acquisitions could adversely affect our operating results. In addition, acquisitions may involve a number of special risks in addition to the difficulty of integrating cultures and operations and the diversion of management's attention, including adverse short-term effects on our reported operating results, dependence on retention, hiring and training of key personnel, risks associated with unanticipated problems or legal liabilities and amortization of acquired intangible assets, some or all of which could materially and adversely affect our operations and financial performance.

If we are unable to reduce substantially the cost of manufacturing products that we will sell to Hospira under the MCDA, we may not be able to produce and sell such products profitably, and our profit margins may decline.

The prices at which we will sell products to Hospira and the gross margins that we will realize under the MCDA will depend on the cost savings that we are able to achieve in producing those products over Hospira's cost to manufacture the same products. Achieving substantial cost reductions will require moving manufacturing operations to lower-cost locations and the development and implementation of innovative manufacturing and assembly processes and techniques.. There is no assurance that these efforts will be successful. If we are unable to achieve the cost savings that we expect, we may not be able to sell products manufactured under the MCDA profitably, and our profit margins may decline.

Because we are dependent on the CLAVE for the majority of our sales, any decline in CLAVE sales could result in a significant reduction in our sales and profits.

During 2004, CLAVE products accounted for approximately 47% of our net sales and 71% of our net sales including customer I.V. systems. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. We cannot give any assurance that sales of CLAVE products will continue to increase indefinitely to Hospira or other customers or that we can sustain current profit margins on CLAVE products indefinitely. Management believes that the success of the CLAVE has motivated, and will continue to motivate, others to develop one piece needleless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline as we lose market share, and/or we could encounter sustained price and profit margin erosion.

If our efforts to increase substantially our custom I.V. system business is not successful or we cannot increase sales of other products and develop new, commercially successful products, our sales may not continue to grow.

Our continued success may be dependent both on the success of our strategic initiative to increase substantially our custom I.V. set business and develop significant market share on a profitable basis and on new product development. Our sales of custom I.V. systems reached $26.2 million in 2004, but this was

only a 15% increase over 2003 sales, whereas 2003 sales increased 50% over 2002. The success of our custom I.V. system sales program will require a larger increase in annual sales in the future than was achieved in 2004. The ability of the custom I.V. system and low-cost I.V. system products to acquire significant market share on a profitable basis depends on whether we are able to continue to develop systems capabilities, improve manufacturing efficiencies, lower inventory carrying costs, reduce labor costs and expand distribution. The accomplishment of each of these objectives will require significant innovation, and we might not succeed in these endeavors. Although we are seeking to continue to develop a variety of new products, there is no assurance that any new products will be commercially successful or that we will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers, with financial and distribution resources substantially greater than ours, have developed and are marketing products intended to fulfill the functions of our products.

Continuing reductions in the prices of our I.V. connector products could have an adverse effect on profit margins and profits.

The Hospira agreement establishes the prices that Hospira will pay for our products, which are lower than our average selling prices in our other sales channels. In response to competitive pressure, we had steadily reduced selling prices of the CLAVE to protect and expand its market although overall pricing has been stable recently. Reductions in selling prices could adversely affect gross margins and profits if we cannot achieve corresponding reductions in unit manufacturing costs or increased volume.

International sales pose additional risks related to competition with larger international companies and established local companies, our possibly higher cost structure, our ability to open foreign manufacturing facilities that can operate profitably, higher credit risks and exchange rate risk.

We have undertaken a program to increase significantly our international sales, and have distribution arrangements in all the principal countries in Western Europe, the Pacific Rim and Latin America, and in South Africa. We plan to sell in most other areas of the world. Currently, we export from the United States and Mexico most of the product sold internationally. Our principal competitors are a number of much larger companies as well as smaller companies already established in the countries into which we sell our products. Our cost structure is often higher than that of our competitors because of the relatively high cost of transporting product to the local market as well as low cost local labor in some markets. For these reasons, among others, we expect to open manufacturing facilities in foreign locations. There is no certainty that we will be able to open local manufacturing facilities or that those facilities will operate on a profitable basis.

Our international sales are subject to higher credit risks than sales in the United States. Many of our distributors are small and may not be well capitalized. Payment terms are relatively long. Our prices to our international distributors are set in U.S. dollars, but their resale prices are set in their local currency. A decline in the value of the local currency in relation to the U.S. dollar may adversely affect their ability to profitably sell in their market the products they buy from us, and may adversely affect their ability to make payment to us for the product they purchase. Legal recourse for non-payment of indebtedness may be uncertain. These factors all contribute to a potential for credit losses.

In 2003, we acquired a small manufacturer of I.V. systems in northern Italy, and have since transferred our European distribution to this subsidiary. This subsidiary is not yet operating profitably and there is no assurance that it will achieve profitability in the future.

Continuing pressures to reduce healthcare costs may adversely affect our prices. If we cannot reduce manufacturing costs of existing and new products, our sales may not continue to grow and our profitability may decline.

Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid and other payers to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for us to sell our

products at current prices. In the event that the market will not accept current prices for our products, our sales and profits could be adversely affected. We believe that our ability to increase our market share and operate profitably in the long term may depend in part on our ability to reduce manufacturing costs on a per unit basis through high volume production using highly automated molding and assembly systems. If we are unable to reduce unit manufacturing costs, we may be unable to increase our market share for CLAVE products or lose market share to alternative products, including competitors' products. Similarly, if we cannot reduce unit manufacturing costs of new products as production volumes increase, we may not be able to sell new products profitably or gain any meaningful market share. Any of these results would adversely affect our future results of operations.

Increases in costs of electricity or interruptions in electrical service could have an adverse effect on our operations.

We use a significant amount of electricity in our molding and automated assembly operations in San Clemente, California. Rates are approximately double what they were five years ago, and there is no certainty that they will not increase further in the future. In addition, public concerns are again being raised about possible interruptions in service because of a lack of availability of electricity. Any significant increase in electrical costs or a significant interruption in service could have an adverse effect on our operations.

Increases in the cost of oil-based products could have an adverse effect on our profitability.

Most of the material used in our products is resins, plastics and other material that depend upon oil as their raw material. Oil prices in early 2005 are at or near record highs. Our suppliers have passed some of these increases on to us, and if oil prices are sustained or increase further, our suppliers may pass further price increases on to us. Our ability to recover those higher costs may depend upon our ability to raise prices to our customers. In the past, we have rarely ever raised prices and it is uncertain that we would be able to raise them to recover higher prices from our suppliers. Our inability to raise prices in those circumstances could have an adverse effect on our profitability.

Our products could become obsolete if other companies are successful in developing technologies and products that are superior to ours.

Many companies are developing products and technologies to address the need for safe and cost effective I.V. connection systems. It is possible that others may develop superior I.V. connection system technologies or alternative approaches that prove superior to our products. Our products could become obsolete as a result of such developments, which could materially and adversely affect our operating results.

If we are unable to compete successfully on the basis of product innovation, quality, convenience, price and rapid delivery with larger companies that have substantially greater resources and larger distribution networks, we may be unable to maintain market share, in which case our sales may not grow and our profitability may be adversely affected.

The market for I.V. products is intensely competitive. We believe that our ability to compete depends upon continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection and price. The ability of our custom I.V. and low-cost system products to compete will depend on our ability to distinguish our products from the competition based on product pricing, quality and rapid delivery. We encounter significant competition in our markets both from large established medical device manufacturers and from smaller companies. Many of these firms have introduced competitive products with protective features not provided by the conventional products and methods they are intended to replace. Most of our current and prospective competitors have economic and other resources substantially greater than ours and are well established as suppliers to the healthcare industry. Several large, established competitors offer broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply all of their I.V. product requirements. There is no assurance that our competitors will not substantially increase resources devoted to

the development, manufacture and marketing of products competitive with our products. The successful implementation of such a strategy by one or more of our competitors could materially and adversely affect us.

If we were to experience problems with our highly complex manufacturing and automated assembly processes, as we have at times in the past, or if we cannot obtain additional custom tooling and equipment on a timely enough basis to meet demand for our products, we might be unable to increase our sales or might lose customers, in which case our sales could decline.

We manufacture substantially all of our product components, except for standard components which are available as commodity items, and assemble them into finished products. Automated assembly of components into finished products involves complex procedures requiring highly sophisticated assembly equipment which is custom designed, engineered and manufactured for us. As a result of the critical performance criteria for our products, we have at times experienced problems with the design criteria for or the molding or assembly of our products. While we believe that we have resolved all design, manufacturing and assembly problems with respect to current products, there is no assurance that operations will not be adversely affected by unanticipated problems with current products or if such problems are experienced with future products.

We have expanded our manufacturing capacity substantially in recent years, and we expect continuing expansion will be necessary. Molds and automated assembly machines generally have a long lead-time with vendors, often six months or longer. Inability to secure such tooling in a timely manner, or unexpected increases in production demands, could cause us to be unable to meet customer orders. Such inability could cause customers to seek alternatives to our products.

We may not be able to significantly expand our sales of custom and low-cost, generic I.V. systems if we are unable to lower manufacturing costs, price our products below our competitors' prices and shorten delivery times significantly.

Our custom I.V. system products do not have any inherent competitive advantage over other competitors' products. We believe that the success of our I.V. systems operations will depend on our ability to lower per unit manufacturing costs and price our products below our competitors' prices and on our ability to shorten significantly the time from customer order to delivery of finished product, or both. To reduce costs, we have moved labor intensive assembly operations to our facility in Mexico. To shorten delivery times, we have developed proprietary systems for order processing, materials handling, tracking, labeling and invoicing and innovative procedures to expedite assembly and distribution operations. Many of these systems and procedures require continuing enhancement and development. There is a possibility that our systems and procedures may not continue to be adequate and meet their objectives.

If demand for our CLAVE products were to decline significantly, we might not be able to recover the cost of our expensive automated molding and assembly

equipment and tooling, which could have an adverse effect on our results of operations.

Our production tooling is relatively expensive, with each "module," which consists of an automated assembly machine and the molds and molding machines which mold the components, costing several million dollars or more. Most of the modules are for the CLAVE and the integrated Y CLAVE. If the demand for either of these products changes significantly, as might happen with the loss of a customer or a change in product mix, it might be necessary for us to account for the impairment in value of the production tooling because its cost may not be recovered through production of saleable product.

Because we depend to a significant extent on our founder for new product concepts, the loss of his services could have a material adverse effect on our business.

We depend for new product concepts primarily on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer. Dr. Lopez has conceived of substantially all of our

current and proposed new products and the systems and procedures to be used in the custom I.V. products and their manufacturing. We believe that the loss of his services could have a material adverse effect on our business.

Because we have substantial cash balances and liquid investments in interest sensitive securities, continued low interest rates would have an adverse effect on our investment income and on our net income.

We have accumulated a substantial balance of cash and liquid investments principally through profitable operations and the exercise of stock options. These balances amounted to $87.3 million at December 31, 2004, almost all of which was invested in interest sensitive securities. Such securities consist principally of corporate preferred stocks and federal tax-exempt state and municipal government debt securities. Dividend and interest rates are reset at auction mostly at seven to forty-nine day intervals, with a small portion resetting at longer intervals up to one year.

Short-term interest rates have been the lowest in generations for the past four years, and not withstanding recent increases, are still low by historic standards. In 2000, our investment income was $2.1 million on average on cash and liquid investments of approximately $43.4 million. In 2004, the comparable numbers were approximately $1.6 million and $87.2 million, respectively; investment income was approximately $2.6 million lower than it would have been at the rates in 2000. Continued low interest rates would continue to have an adverse effect on our investment income.

Our business could be materially and adversely affected if we fail to defend and enforce our patents, if our products are found to infringe patents owned by others or if the cost of patent litigation becomes excessive.

We have patents on certain products, software and business methods, and pending patent applications on other intellectual property and inventions. There is no assurance, however, that patents pending will issue or that the patent protection from patents which have issued or may issue in the future will be broad enough to prevent competitors from introducing similar devices, that such patents, if challenged, will be upheld by the courts or that we will be able to prove infringement and damages in litigation.

We are substantially dependent upon the patents on our proprietary products such as the CLAVE to prevent others from manufacturing and selling products similar to ours. We have instituted litigation against B. Braun Medical Inc. and Alaris Medical Systems, Inc., a part of Cardinal Health, Inc., for violating our patents and we are seeking injunctive relief and monetary damages. We believe those violations had and continue to have an adverse effect on our sales. Failure to prevail in those litigations or litigation we may bring against others violating our patents in the future would adversely affect our sales.

We have faced patent infringement claims related to the CLAVE and the CLC 2000. We believe the claims had no merit, and all have been settled or dismissed. We may also face claims in the future. Any adverse determination on these claims related to the CLAVE or other products, if any, could have a material adverse effect on our business.

We from time to time become aware of newly issued patents on medical devices which we review to evaluate any infringement risk. We are aware of a number of patents for I.V. connection systems that have been issued to others. While we believe these patents will not affect our ability to market our products, there is no assurance that these or other issued or pending patents might not interfere with our right or ability to manufacture and sell our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Patent infringement litigation, which may be necessary to enforce patents issued to us or to defend ourselves against claimed infringement of the rights of others, can be expensive and may involve a substantial commitment of our resources which may divert resources from other uses. Adverse determinations in litigation or settlements could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, could prevent us from manufacturing and selling our products

or could fail to prevent competitors from manufacturing products similar to ours. Any of these results could materially and adversely affect our business.

Our ability to market our products in the United States and other countries may be adversely affected if our products or our manufacturing processes fail to qualify under applicable standards of the FDA and regulatory agencies in other countries.

Government regulation is a significant factor in the development, marketing and manufacturing of our products. Our products are subject to clearance by the United States Food and Drug Administration ("FDA") under a number of statutes including the Food, Drug and Cosmetics Act ("FDC Act"). Each of our current products has qualified, and we anticipate that any new products we are likely to market will qualify, for clearance under the FDA's expedited pre-market notification procedure pursuant to Section 510(k) of the FDC Act. There is no assurance, however, that new products developed by us or any manufacturers that we might acquire will qualify for expedited clearance rather than a more time consuming pre-market approval procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. In addition, we must manufacture our products in compliance with the FDA's Quality System Regulations.

The FDA has broad discretion in enforcing the FDC Act, and noncompliance with the Act could result in a variety of regulatory actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal penalties. If the

FDA determines that we have seriously violated applicable regulations, it could seek to enjoin us from marketing our products or we could be otherwise adversely affected by delays or required changes in new products. In addition, changes in FDA, or other federal or state, health, environmental or safety regulations or in their application could adversely affect our business.

To market our products in the European Community ("EC"), we 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, we must comply with the quality management standards of EN ISO 9001(1994)/EN 46001 (1996). Those quality standards are similar to the FDA's Quality System 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 regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the "CE" Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. We cannot assure that we will continue to meet the requirements for distribution of our products in Europe.

Distribution of our products in other countries may be subject to regulation in those countries, and there is no assurance that we will obtain necessary approvals in countries in which we wants to introduce our products.

Product liability claims could be costly to defend and could expose us to loss.

The use of our products exposes us to an inherent risk of product liability. Patients, healthcare workers or healthcare providers who claim that our products have resulted in injury could initiate product liability litigation seeking large damage awards against us. Costs of the defense of such litigation, even if successful, could be substantial. We maintain insurance against product liability and defense costs in the amount of $10,000,000 per occurrence. There is no assurance that we will successfully defend claims, if any, arising with respect to products or that the insurance we carry will be sufficient. A successful claim against us in excess of insurance coverage could materially and adversely affect us. Furthermore, there is no assurance that product liability insurance will continue to be available to us on acceptable terms.

Our Stockholder Rights Plan, provisions in our charter documents and Delaware law could prevent or delay a change in control, which could reduce the market price of our common stock.

On July 15, 1997, our Board of Directors adopted a Stockholder Rights Plan (the "Plan") and, pursuant to the Plan, declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on July 28, 1997. The Plan was amended in 2002. Under its current provisions, each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior participating Preferred Stock, no par value, at a Purchase Price of $115 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board a great deal of flexibility in dealing with any attempted takeover of and will cause persons interested in acquiring us to deal directly with the Board, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire us.

Investors should refer to the description of the Plan in our Current Report to the Securities and Exchange Commission on Form 8-K dated July 15, 1997 filed July 23, 1997, as updated by our Current Report dated January 30, 1999 filed February 9, 1999, and the terms of the Rights set forth in an Amended and Restated Rights Agreement, dated as of May 10, 2002 between ICU Medical, Inc. and Mellon Investor Services, L.L.C., as Rights Agent, which are filed as an exhibit to the May 14, 2002 Form 8-A/A.

Our Certificate of Incorporation and Bylaws include provisions that may discourage or prevent certain types of transactions involving an actual or potential change of control, including transactions in which the stockholders might otherwise receive a premium for their shares over then current market prices. In addition, the Board of Directors has the authority to issue shares of Preferred Stock and fix the rights and preferences thereof, which could have the effect of delaying or preventing a change of control otherwise desired by the stockholders. In addition, certain provisions of Delaware law may discourage, delay or prevent someone from acquiring or merging with us.

The price of our common stock has been and may continue to be highly volatile due to many factors.

The market for small-market capitalization companies can be highly volatile, and we have experienced significant volatility in the price of our common stock in the past. In 2004, our trading range was from a high of $41.31 per share to a low of $19.98 per share. We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts' expectations and actual quarterly and annual results, new product introductions by us or our competitors, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders and substantial product orders could contribute to the volatility of the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles and changing interest rates may also adversely affect the market price of our common stock.

Most of our common stock is held by, or included in accounts managed by, institutional investors or managers. Several of those institutions own or manage a significant percentage of our outstanding shares, with the ten largest interests accounting for 79% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate the position in our common stock, it could cause a decrease in the price of the common stock and such decrease could be significant.

For the past several years there has been a significant "short" position in our common stock, consisting of borrowed shares sold, or shares sold for future delivery which may not have been borrowed. We do not know whether any of these short positions are covered by "long" positions owned by the short seller. The short position, as reported by the Nasdaq stock market on February 14, 2005 was 3,901,751 shares, or approximately 29% of our outstanding shares. Any attempt by the short sellers to liquidate their position over a short period of time could cause very significant volatility in the price of our common stock.

Continued compliance with recent securities legislation could be uncertain and could substantially increase our administrative expenses.

The Sarbanes-Oxley Act of 2002 imposed significant new requirements on public companies. We have complied with most of these without undue effort or expense. However, compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requiring management to document and report on the effectiveness of internal controls and our independent registered public accounting firm to audit and report on the design and effectiveness of our internal controls has been

extremely expensive. Although we expect to reduce the expense in 2005, it is uncertain that we will be able to do so, particularly if we expand our businesses to new locations or acquire significant assets or operations from external sources. Further, there is no certainty that we will continue to receive unqualified reports on our internal controls from our independent registered public accounting firm and what actions might be taken by securities regulators if we are unable to obtain an unqualified report.

Critical Accounting Policies

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements. In preparing our financial statements, we make estimates and assumptions that affect the expected amounts of assets and liabilities and disclosure of contingent assets and liabilities. We apply our accounting policies on a consistent basis. As circumstances change, they are considered in our estimates and judgments, and future changes in circumstances could result in changes in amounts at which assets and liabilities are recorded.

Investment securities are all marketable and considered "available for sale". See Item 3. Quantitative and Qualitative Disclosures about Market Risk. Under our current investment policies, the securities in which we invest have no significant difference between cost and fair value. If our investment policies were to change, and there were differences between cost and fair value, that difference, net of tax effect, would be reflected as a separate component of stockholders' equity.

We record sales and related costs when ownership of the product transfers to the customer. Under the terms of most purchase orders, ownership transfers on shipment, but in some cases it transfers on delivery. If there are significant doubts at the time of shipment as to the collectibility of the receivable, we defer recognition of the sale in revenue until the receivable is collected. Most of our customers are medical product manufacturers or distributors, although some are end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. Warranty returns have been insignificant. Customers, with certain exceptions, do not retain any right of return and there is no price protection with respect to unsold products; returns from customers with return rights have not been significant. We accrue rebates as a reduction in revenue based on contractual commitments and historical experience. Adjustments of estimates of warranty claims, rebates or returns, which have not been, and are not expected to be material, affect current operating results when they are determined.

Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on specific past due accounts for which we consider collection to be doubtful. Loss exposure is principally with international distributors for whom normal payment terms are long in comparison to those of our other customers and, to a lesser extent, domestic distributors. Many of these distributors are relatively small and we are vulnerable to adverse developments in their businesses that can hinder our collection of amounts due. If actual collection losses exceed expectations, we could be required to accrue additional bad debt expense, which could have an adverse effect on our operating results in the period in which the accrual occurs.

Inventories are stated at the lower of cost or market. We need to carry many components to accommodate our rapid product delivery, and if we misestimate demand or if customer requirements change, we may have components in inventory that we may not be able to use. Most finished products are made only after we receive orders except for certain standard (non-custom) products which we will carry in inventory in

expectation of future orders. For finished products in inventory, we need to estimate what may not be saleable. We regularly review inventory for slow moving items and write off all items we do not expect to use in manufacturing, or finished products we do not expect to sell. If actual usage of components or sales of finished goods inventory is less than our estimates, we could be required to write off additional inventory, which could have an adverse effect on our operating results in the period in which the write-off occurs.

Property and equipment is carried at cost and depreciated on the straight-line method over the estimated useful lives. The estimates of useful lives are significant judgments in accounting for property and equipment, particularly for molds and automated assembly machines that are custom made for us. We may retire them on an accelerated basis if we replace them with larger or more technologically advanced tooling. The remaining useful lives of all property and equipment are reviewed regularly and lives are adjusted or assets written off based on current estimates of future use. As part of that review, property and equipment is reviewed for other indicators of impairment, but to date we have not encountered circumstances indicating the carrying amount of a significant asset, or group of assets, may not be recoverable. An unexpected shortening of useful lives of property and equipment that significantly increases depreciation provisions, or other circumstances causing us to record an impairment loss on such assets, could have an adverse effect on our operating results in the period in which the related charges are recorded.

New Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. The statement 123(R) requires expense for all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We expect to adopt Statement 123(R) on July 1, 2005. Statement 123(R) permits public companies to adopt its requirements using one of two methods. We plan on adopting the modified prospective method, under which compensation cost is recognized beginning with the effective date. The modified prospective method recognizes compensation cost based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and based on the requirements of Statement 123 for all awards granted to employees prior to the effective date that remain unvested on the effective date.

In November 2004, the FASB issued FASB Statement No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4 (SFAS 151), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads should be allocated to inventory based on normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005, however we adopted this on January 1, 2005. We do not expect the adoption of SFAS 151 to have a material effect on our results of operations.

We have implemented all other new accounting pronouncements that are in effect and that may impact our consolidated financial statements and do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our consolidated financial statements.

Business Overview

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost

manufacturer of custom I.V. systems, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy enables us to capture revenue on the entire I.V. system, and not just a component of the system.

We are also increasing our efforts to acquire new products. We acquired the Punctur-Guard line of

blood collection needles in 2002, invested in a company developing a new medical device in 2004, and are continuing to seek other opportunities. However, there can be no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products.

Custom I.V. systems and new products will be of increasing importance to us in future years. We expect CLAVE products will grow in 2005 in the U.S., but at a slower percentage growth rate than prior to 2004 because of our large market penetration. We also potentially face substantial increases in competition if we are unsuccessful in enforcing our intellectual property rights. Growth for all of our products outside the U.S. could be substantial, although to date it has been modest. Therefore, we will be directing increasing product development, acquisition, sales and marketing efforts to custom I.V. systems and new products in the U.S. and increasing our emphasis on the markets outside the U.S.

Our largest customer has been Hospira, which until April 30, 2004, was the Hospital Products Division of Abbott Laboratories. We believe the spin-off of Hospira from Abbott is a positive development for us and will result in new business opportunities. For clarity, all historical references to Abbott and its Hospital Products Division have been changed to Hospira.

Our relationship with Hospira has been and will continue to be of singular importance to our growth. In 2003, approximately 67% of our revenue was from sales to Hospira. While our sales to Hospira declined to approximately 53% of revenue in 2004, we expect this percentage to increase again in the future both as a result of increased sales of CLAVE products and I.V. sets to Hospira and as a result of the new agreements with Hospira as described below. Hospira has a significant share of the I.V. set market in the U.S., and provides us access to that market. We expect that Hospira will be important to our growth for CLAVE, custom I.V. systems, and our other products in the U.S. and also outside the U.S.

On February 25, 2005, we entered into a twenty-year Manufacturing, Commercialization and Development Agreement ("MCDA") with Hospira. Under the MCDA and related agreements, which we expect to close early in the second quarter of 2005, we will acquire Hospira's Salt Lake City, Utah manufacturing facility, related capital equipment and certain inventories for approximately $35 million in cash, and produce for sale to Hospira on an exclusive basis substantially all the products manufactured at that plant. The majority of the products we will be producing under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. We estimate that sales under this agreement will exceed $50 million in 2005, with only small profits in 2005, with increasing sales and profits in future years. However, this sales estimate is subject to a variety of factors and there can be no assurance that the prospective results will be indicative of future performance or that actual results will not vary materially from this estimate.

We believe that achievement of our growth objectives, both within the U.S., and outside the U.S., will require increased efforts by us in sales and marketing and product development, and we started increasing expenditures in those areas during 2004.

There is no assurance that we will be successful in implementing our growth strategy. The custom I.V. systems market is still small and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see opportunity. Product development or acquisition efforts may not succeed, and even if we do develop or acquire products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Hospira, or a deterioration of Hospira's position in the market, could have an adverse effect on us. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain of those risks which may be outside of our control, and there is no assurance that steps we have taken will succeed.

Overview of Operations

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

Product Line	2004	2003	2002
CLAVE	47%	59%	67%
Custom and Generic I.V. Systems	35%	22%	17%
Punctur-Guard	5%	7%	1%
CLC2000	4%	4%	4%
Other Products	5%	4%	7%
License, royalty and revenue share	4%	4%	4%
Total	100%	100%	100%

Most custom I.V. systems include one or more CLAVEs. Total CLAVE sales including custom I.V. systems with at least one CLAVE were 71% of net revenue in 2004 and 73% of net revenue in 2003.

We sell our products to independent distributors and through agreements with Hospira (the "Hospira Agreements") and certain other medical product manufacturers. Most independent distributors handle the full line of our products. Through 2003, Hospira purchased CLAVE products, principally bulk, non-sterile connectors, and the CLC2000. In addition, we sell custom I.V. systems to Hospira under a program referred to as SetSource. In January 2004, we announced the execution of amendments to our existing agreements with Hospira. The amendments extend the terms of our agreements to 2014 and provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide. We signed another contract amendment with Hospira in January 2004 to distribute our Punctur-Guard line of blood collection needles in the U.S. and the rest of the world. We also sell certain other products to a number of other medical product manufacturers.

We believe that as healthcare providers continue to either consolidate or join major buying organizations, our success in marketing and distributing

CLAVE products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term CLAVE contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer's products could have a material adverse effect on our operating results.

In June 2004, Cardinal Health, Inc. ("Cardinal") acquired Alaris Medical Systems, Inc. "Alaris"). Alaris manufactures a connector that competes with the CLAVE. Cardinal is the largest distributor of healthcare products in the United States, and the companies have announced their intent to increase market share growth beyond what Alaris might be able to achieve on its own. We believe the ownership of Alaris by Cardinal could adversely affect our market share and the prices for our CLAVE products.

We believe the success of the CLAVE has motivated, and will continue to motivate others to develop one-piece, swabbable, needleless connectors that may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. We have patents covering the technology embodied in the CLAVE and intend to enforce those patents as appropriate. If we are not successful in enforcing our patents, competition from such products could adversely affect our market share and prices for our CLAVE products. In response to competitive pressure, we have been reducing prices to protect and expand our market, although overall pricing has been stable recently. The price reductions to date have been more than offset by increased volume after excluding the effect of Hospira's temporary reduction of purchases in 2004. We expect that the average price of our CLAVE products may continue to decline. There is no assurance that our current or future products will be able to successfully compete with products developed by others.

The federal Needlestick Safety and Prevention Act, enacted in November 2000, modified standards promulgated by the Occupational Safety and Health Administration to require employers to use safety I.V. systems where appropriate to reduce risk of injury to employees from needlesticks. We believe this law has had and will continue to have a positive effect on sales of our needleless systems and blood collection needles, although we are unable to quantify the current or anticipated effect of the law on our sales.

We are taking steps to reduce our dependence on our current proprietary products. We are seeking to substantially expand our custom I.V. systems business through increased sales to medical product manufacturers and independent distributors. Under one of our Hospira Agreements, we manufacture all new custom I.V. sets for sale by Hospira and jointly promote the products under the name SetSource. We also contract with group purchasing organizations and independent dealer networks for inclusion of our products among those available to members of those entities. Custom I.V. systems accounted for approximately $26.2 million of net sales in 2004, including net sales under the Hospira SetSource program of approximately $12.1 million. We expect continued increases in sales of custom I. V. systems. Also, in the fourth quarter of 2002 we acquired Bio-Plexus. Inc. ("Bio-Plexus"), whose principal products are blood collection needles, under the Punctur-Guard name, that is designed to eliminate exposure to sharp, contaminated needles. Punctur-Guard product revenues in 2004 were $3.9 million. In 2004, we invested in a company developing a new medical device; sales depend on the success of efforts to develop and market the device, and there can be no certainty that those efforts will succeed. There is no assurance that any of these initiatives will continue to succeed.

We have an ongoing program to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. These include use of automated assembly equipment for new and existing products, use of larger molds and molding machines, centralization of all proprietary molding in San Clemente, expansion of our production facility in Mexico, and the establishment of other production facilities outside the U.S.

We distribute products through three distribution channels. Net product revenues for each distribution channel were as follows:

Channel	2004	2003	2002
Medical product manufacturers	57%	71 %	73%
Independent domestic distributors	31%	23 %	19%
International	12%	6 %	8%
Total	100%	100 %	100%

Quarterly results: The healthcare business in the United States is subject to seasonal fluctuations, and activity tends to diminish somewhat in the summer months of June, July and August, when illness is less frequent than in winter months and patients tend to postpone elective procedures. This typically causes seasonal fluctuations in our business. In addition, we can experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and their inventory levels, and less by seasonality. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

Year-to-Year Comparisons

We present summarized income statement data in Item 6. Selected Financial Data. The following table shows, for the three most recent years, the percentages of each income statement caption in relation to revenues, and the percentage change in each caption in each year. (We currently calculate our gross profit percentage based on net sales, which includes only product sales and excludes non-product revenue such as

license fees. See below for more information on non-product revenue. We present the alternative calculation based on net product revenue to give the reader a better view of product gross margins.

	Percentage of Revenues			Changes	
	2004	2003	2002	2004 v. 2003	2003 v. 2002
Revenue					
Net Sales	96%	96%	96%	(29)%	22%

Other	4%	4%	4%	(39)%	29%
Total Revenues	100%	100%	100%	(30)%	22%
Gross Profit					
Percentage of Net Sales	45%	53%	57%	(39)%	14%
Percentage of All Revenues	47%	55%	58%	(39)%	15%
Selling, General and Administrative expenses	35%	21%	22%	15%	16%
Research and Development expenses	4%	2%	2%	48%	19%
Total operating expenses	39%	23%	24%	20%	16%
Income from operations	8%	32%	34%	(83)%	14%
Investment income	2%	1%	2%	41%	22%
Income before income taxes and minority interest	10%	33%	36%	(79)%	12%
Income taxes	3%	12%	14%	(80)%	10%
Net income	7%	21%	22%	(78)%	13%

Comparison of 2004 to 2003

In 2004 we had total revenues of $75.6 million, which was $31.8 million, or 30%, lower than the total revenues of $107.4 million reported in 2003. The decrease was primarily attributable to decreases in sales of CLAVE products of $27.4 million, sales of Punctur-Guard of $3.4 million, CLC 2000 and other products of $1.7 million and decreased other revenue of $1.8 million, offset by an increase of $3.4 million in custom I.V. systems.

Distribution channels: Net sales to Hospira were $39.8 million in 2004, compared to $71.3 million in 2003, a decrease of 44%. CLAVE sales to Hospira decreased $31.3 million, or 56% to $24.5 million from $55.7 million principally because Hospira had decreased its level of purchases to make a substantial reduction in its inventory of CLAVE products. Although Hospira was reducing its purchases, information provided by Hospira indicates that its CLAVE unit sales to its customers have continued to increase. Sales to Hospira under the SetSource program were approximately $12.1 million in 2004, compared to $10.4 million in 2003, or a 16% increase. Net sales of the CLC2000 to Hospira decreased by approximately $0.6 million, to $1.3 million in 2004, because Hospira was also reducing inventory levels of CLC2000 products. Although we expect sales to Hospira to grow in the future, there is no assurance as to the amount of any of the future sales increases to Hospira.

Net sales to independent domestic distributors (including Canada) decreased approximately 7% to $22.4 million in 2004 from $24.1 million in 2003. This decrease is primarily attributable to a $2.3 million decrease in Punctur-Guard product sales, partially offset by $0.4 million and $0.6 million of increases in CLAVE and custom I.V. system sales, respectively. The decrease in Punctur-Guard product sales is primarily due to a decrease in unit sales and to pricing concessions on our Punctur-Guard products to achieve a wider distribution. We have been seeking increased sales through new outpatient provider

contracts and new distribution focused on the lab market but the success of these efforts is not assured. The CLAVE and custom I.V. system sales increases were both principally due to an increase in unit volume. As part of our program to increase sales of custom I.V. systems, we have been encouraging customers to purchase custom I.V. systems that include CLAVE connectors, rather than purchasing only the CLAVE connectors. There is no assurance as to the amount of any future sales increases to the independent domestic distributors.

Net sales in our international markets (excluding Canada) were $9.0 million in 2004, compared to $5.8 million in 2003. The increase in 2004 was due primarily to a $4.0 million increase in CLAVE and Custom I.V. sales, partially offset by a $1.0 million decrease in Punctur-Guard product sales. In 2003, we experienced a slowing of distributor orders while they reduced CLAVE inventory levels. Orders in most of our international markets have returned to more normal levels in 2004. This and the expansion of our business accounted for the increase in international sales of CLAVE. The increase of custom I.V. systems was attributable primarily to an increase in unit volume. The decrease in sales of Punctur-Guard products is primarily due to a decrease in unit sales and to pricing concessions on our Punctur-Guard products to achieve a wider distribution. We expect increases in foreign sales in the future in response to increased sales and marketing efforts including additional business development managers. Also, we believe we may see a positive impact beginning 2005 from our recent amendments to the Hospira contracts although any such impact may depend upon how quickly Hospira expands its international distribution. There is no assurance that these expectations will be realized.

Product and other revenue*:* Total net sales of CLAVE products (excluding custom CLAVE I.V. systems) decreased approximately $27.5 million or 44% to $35.4 million in 2004 from $62.9 million in 2003. This decrease was due primarily to a decrease in unit shipments of CLAVE products to Hospira, partially offset by an increase in unit shipments to our domestic and international distributors. Sales of custom I.V. systems including one or more CLAVE connectors and CLAVE products combined declined by $24.9 million from $78.7 million in 2003 to $53.8 million in 2004. The decrease was caused by Hospira's lower purchases of CLAVE products. The aggregate average net selling price of CLAVE products in 2004 changed little from 2003, and while we expect some decrease in 2005, we expect the decreases to be minimal. We expect growth in CLAVE unit and dollar sales volume in 2005 in all of our distribution channels. We believe the market for these products will continue to grow. However, there is no assurance that the expectations will be realized.

In October 2001, we commenced production of the MicroCLAVE. It is smaller than the existing CLAVE but is functionally similar. We market it as an extension of the CLAVE product line for use where its smaller size is advantageous, such as pediatric care. Sales are included in CLAVE product sales.

Net sales of custom and generic I.V. systems, which included custom I.V. sets, both with a CLAVE and without a CLAVE, were $26.2 million in 2004 compared to $22.8 million in 2003, an increase of $3.4 million or 15%. The SetSource program with Hospira accounted for approximately 63% of the increase, with most of the balance in sales to independent domestic and international distributors. The increase is due to our continued growth with this product which is because we are able to give the customer customization instead of standard sets at a competitive price.

We acquired the Punctur-Guard product line and technology with the purchase of Bio-Plexus on October 31, 2002. We now produce the Punctur-Guard line of products and also license the technology to two medical device manufacturers for use in catheters. After our acquisition of Bio-Plexus on October 31, 2002, we made significant improvements to the Punctur-Guard products and manufacturing processes. We did not actively promote sales of those products until completion of those product improvements. We completed improvements on the Winged Set products and re-launched them in mid 2003. We completed initial improvements on the tubular blood collection needle and started selling the improved product in late 2003. We completed additional improvements to this product line in 2004. Sales of Punctur-Guard products (excluding royalties) were $3.9 million in 2004 compared to $7.3 million for 2003. The decline was due to a decrease in unit sales and to pricing concessions to achieve wider distribution. We are currently concentrating our sales and marketing efforts for the Winged Set product on outpatient provider

contracts and the lab market. However, we have been unable to achieve success with the Blood Collection Needle (BCN), and we are not currently focusing any significant sales and marketing efforts on the BCN. There is no assurance as to future sales of Punctur-Guard products. In the fourth quarter of 2004 we accelerated the depreciation and amortization of the net cost of equipment and intangible assets for impairment related to the BCN, resulting in a charge of approximately $0.9 million.

Net sales of the CLC2000 declined to $3.1 million in 2004 from $3.9 million in 2003, a decrease of 20%. The decrease is due to lower purchases by Hospira and a small price decrease. We expect sales of the CLC2000 to increase moderately in 2005 and later years, but there is no assurance as to the amount or timing of future CLC2000 sales.

Other revenue consists of license, royalty and revenue share income, and is presented separately in our financial statements since the fourth quarter if 2002; amounts were not significant prior to this. Other revenue in 2004 was comprised of $1.1 million in royalties received from other companies' use of Punctur-Guard technology, $0.8 million for SafeLine revenue share payments from B. Braun and $0.9 million of license revenue. Other revenue in 2003 was comprised of $1.2 million in Punctur-Guard royalties, $0.8 million of SafeLine revenue share and one-time license fees of $2.6 million. We expect to receive ongoing royalties for the use of Punctur-Guard technology and SafeLine revenue share payments from B. Braun as well as additional payments under another license of approximately $0.2 million per quarter for another three years. We may receive other license fees or royalties in the future for the use of our technology. We give no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Gross margin for 2004, calculated on net sales and excluding other revenue, was 45% compared to 53% in 2003. Our overall standard gross margins are approximately 57% (although they can vary depending on product mix). In 2004, gross margins were adversely affected by approximately eight percentage points because of the curtailment in production of CLAVE products due to reduced shipments to Hospira, which resulted in unabsorbed overhead, approximately three percentage points by Punctur-Guard operations, which currently have a lower gross margin than most of our other products and which were also adversely affected by reduced production levels, and the new facility in Italy which was operating substantially below full capacity. In 2003, gross margins were adversely affected by two temporary factors, the principal one relating to improvements on our automated production in San Clemente during the third quarter, which resulted in a period of unabsorbed overhead. The other related to gross margins on our Punctur-Guard products being lower than most of our other products We expect gross margins to be somewhat depressed in the first quarter of 2005 because production will be curtailed as we reduce inventories. After the first quarter, we expect gross margins to improve, but only to somewhat below our overall standard because of the continuing effect of Punctur-Guard operations. We give no assurance as to the amount or timing of future improvements to our gross margins.

Selling, general and administrative expenses ("SG&A") in 2004, increased $3.4 million to $26.4 million and was approximately 35% of revenue in 2004 as compared with $23.0 million, or 21% of revenue in 2003. The increase was primarily due to increased corporate administrative costs, which was principally comprised of $1.4 million of costs related to Sarbanes-Oxley compliance, $0.7 million of non-recurring patent amortization, and increased information technology costs, partially offset by a reduction in costs from our Connecticut office We expect SG&A costs to be approximately the same in 2005 as they were in 2004 as increases in sales and marketing costs are expected to offset decreases in Sarbanes-Oxley compliance costs and lower amortization costs.

Research and development expenses ("R&D") in 2004 were $3.4 million or 4% of revenue compared to $1.8 million, or 2% of revenue, in 2003. The increase was primarily comprised of $1.2 million of in-process R&D related to the investment in a company developing a new medical device and the costs of $0.3 million incurred by this company from September through December 2004, post acquisition. The device is being designed for use in screening for heart disease. The device is at a very early stage of design, uses new technology, and completion of a marketable device is expected to take at least several years. We have agreed to invest an additional $1.5 million in that company if certain milestones are achieved by

November 30, 2005. Excluding in-process R&D, we estimate that R&D costs will increase in 2005 to support on-going new product development, R&D under the MCDA with Hospira. various product and process improvements and R&D costs in the new investment company. However, R&D costs could differ from these estimates and the R&D may not be completed as expected.

Investment income increased $0.5 million in 2004 as compared with 2003, principally because of an increase in invested funds (including finance loans) and an increase in overall yield.

Minority interest of $0.1 million in 2004 represents the minority interest share of the 2004 $0.3 million net loss of the company developing a new medical device for use in screening for heart disease.

Income taxes: Our effective income tax rate in 2004 was 34.7%, a decrease from 36.7% in 2003. The decrease was principally because tax exempt interest and dividends were a higher proportion or income before income taxes, thereby reducing the overall rate, and state tax credits; those reductions were partially offset by the effect of losses of the company developing the new medical device because those losses are not included in our consolidated tax return. We expect an increase in the effective tax rate in 2005.

Comparison of 2003 to 2002

In 2003 we had total revenues of $107.3 million, which was $19.5 million, or 22%, higher than the total revenues of $87.8 million reported in 2002. The increase was primarily attributable to the increase in sales of custom I.V. systems, which increased $7.7 million, Punctur-Guard, which increased by $6.2 million and CLAVE products, which increased by $4.4 million.

Distribution channels: Net sales to Hospira were $71.3 million in 2003, compared to $50.0 million in 2002, an increase of 43%. CLAVE sales to Hospira increased 38% to $55.7 million from $40.5 million principally because of an increase in unit volume as the CLAVE product penetration of Hospira customer accounts increased. Sales of custom I.V. systems to Hospira under the SetSource program approximated $10.4 million for the year, up from $5.7 million in 2002 principally because of an increase in the number of units sold. Net sales of the CLC2000 to Hospira increased to approximately $1.9 million from $1.6 million in 2002. Net sales of Rhino decreased 14% to $1.7 million for 2003.

In connection with the November 2002 settlement of our contract litigation against B. Braun, we terminated the manufacture and supply agreement under which we sold CLAVE products to B. Braun effective December 31, 2002. We sold virtually no CLAVE products to B. Braun in 2003 as compared with $8.2 million in 2002.

Net sales to independent domestic distributors (including Canada) increased approximately 42% to $24.1 million in 2003 from $17.0 million in 2002. The increase was due principally to the inclusion of $6.3 million of Punctur-Guard product sales which included 12 months of revenue compared to $1.1 million in 2002, which included revenue only for the last two months of the year following our acquisition of Bio-Plexus on October 31, 2002. Also contributing to this increase was a 19% increase in custom I.V. systems, and a 9% increase in CLAVE product sales, both principally due to an increase in unit volume.

Net sales to international distributors (excluding Canada) were $5.1 million in 2003, as compared with $7.1 million in 2002. The decrease in 2003 was due primarily to a decrease in CLAVE product sales as distributors slowed their orders to reduce their inventory levels. This decrease was partially offset by an increase in custom I.V. system product sales and Punctur-Guard product sales.

Product and other revenue: Total net sales of CLAVE products (excluding custom CLAVE I.V. systems) increased approximately 8% to $62.9 million in 2003 from $58.5 million in 2002. Total net sales of CLAVE products including custom I.V. systems with CLAVE increased from $67.0 million in 2002 to $78.7 million in 2003, or 16%. This increase was due primarily to an increase in unit shipments of CLAVE products to Hospira and our domestic distributors, offset by a decrease in unit shipments to our international

distributors and the absence of shipments to B. Braun. The aggregate average net selling price of CLAVE products in 2003 changed little from 2002.

Net sales of custom and generic I.V. systems, which included custom I.V. sets, both with a CLAVE and without a CLAVE, were $22.8 million in 2003 compared to $15.2 million in 2002, an increase of $7.0 million, or 50%. Sales to Hospira accounted for approximately 69% of the increase, with most of the balance in sales to independent domestic and international distributors.

We acquired the Punctur-Guard product line and technology with the purchase of Bio-Plexus on October 31, 2002. Sales of Punctur-Guard products (excluding royalties) were $7.3 million in 2003 compared to $1.1 million for the last two months of 2002.

Net sales of the CLC2000 grew slightly from $3.7 million in 2002 to $3.9 million in 2003, an increase of 4%. Sales to Hospira and domestic distributors accounted for all the growth offset by a decrease in sales to foreign distributors.

Other revenue consisted principally of ongoing royalties received for other companies' use of Punctur-Guard technology of $1.2 million, SafeLine revenue share payments from B. Braun of approximately $0.8 million and one-time license fees of $2.6 million. Other revenue in 2002 consisted principally of payment for a fully paid up license to use certain of our patents of $3.2 million received in December 2002.

Gross margin for 2003, calculated on net sales and excluding other revenue, was 53% as compared to 57% in 2002. We believe this difference is principally due to two temporary factors, one relating to improvements in our automated production in San Clemente during the third quarter which resulted in a period of unabsorbed overhead. The other relates principally to gross margins in our Punctur-Guard products being lower than most of our other products. In the fourth quarter of 2003 gross margin had improved to 55%.

Selling, general and administrative expenses ("SG&A") in 2003, excluding research and development expenses, increased 16% to $23.0 million and was approximately 21% of revenue in 2003 as compared with $19.9 million, or 23% of revenue in 2002. A portion of the increase was because of the inclusion of Bio-Plexus and a small increase in sales and marketing costs related to increased sales. Administrative costs were higher because of personnel additions and increased information technology expenses, but those higher costs were offset by decreased litigation expenses.

Research and development expenses ("R&D") in 2003 increased 19% to $1.8 million and was 1.6% of revenue in 2003 as compared to 1.7% in 2002. Spending was principally on new product development, product improvements to Punctur-Guard, and software development to support manufacturing and distribution of custom and generic I.V. systems.

Investment income decreased in 2003 as compared with 2002, principally because of a decrease in the investment portfolio and declines in interest rates slightly offset by higher interest rates through our finance loans receivable.

Income taxes: Our effective income tax rate in 2003 was 36.7%, a decrease from 37.4% in 2002 principally because of savings in state income taxes

Liquidity and Capital Resources

During 2004, our working capital increased by $6.7 million to $109.6 million from $102.9 million. The increase was primarily due to cash generated from operations, cash received from employee equity plans and a reduction in finance loans which was partially offset by the purchases of treasury stock and investment in property and equipment. Our cash and cash equivalents and investment securities position increased in 2004 by

$14.2 million to $87.3 million from $73.1 million at December 31, 2003. This is principally because the aggregate of cash provided by operating activities (including tax benefits from exercise of stock options) of $25.3 million, cash provided by the company's employee equity plans of $3.2 million and net receipts of $2.7 million under finance loans exceeded the purchases of treasury stock of $10.1 million and property and equipment of $7.1 million.

Operating Activities*:* Our cash provided by operating activities tends to increase over time because of our positive operating results. However, it is subject to fluctuations, principally from changes in net income, accounts receivable, inventories, current liabilities and tax benefits from the exercise of stock options.

Normally the substantial majority of our accounts receivable are current or no more than thirty days past due. In recent years, the majority of each quarter's sales have been in that last half of the quarter with the result that the amount of accounts receivable reported as of the end of each quarter tends to be higher than the amounts at other times during a quarter.

Accounts receivable decreased from $24.9 million in 2003 to $8.9 million in 2004, or 64%; the decrease was principally because revenue in the fourth quarter of 2004 was 49% less than revenue in the fourth quarter of 2003.

We generally try to maintain a minimal amount of inventory of finished goods and work in process, but will maintain larger amounts of components (classified as raw material) acquired from third parties to avoid production delays if deliveries by our suppliers are late. However, in order to avoid production inefficiencies caused by fluctuating production levels, we have begun to level out our production volumes and build finished goods of our standard (non-

custom) products to meet anticipated future orders.

Inventories increased $5.0 million from $3.4 million at December 31, 2003 to $8.4 million at December 31, 2004. principally because of our decision in early 2004 to increase our production volumes beyond current orders and increase our finished goods inventories in anticipation of higher sales in the latter part of 2004. Those higher sales did not materialize. Our finished good inventory increased in 2004, but we expect to reduce our finished good inventories substantially by the end of the first quarter of 2005.

In 2004, our prepaid taxes increased by $4.9 million to $6.6 million. This increase was due to an overestimate of 2004 taxable earnings in the first half of 2004, resulting in a overpayment carried as a prepaid tax. We intend to seek a refund of part of the overpayment and apply the balance to estimated 2005 liabilities.

The tax benefits from the exercise of stock options, which we believe are more properly related to the sale of our stock which is a financing activity, fluctuates based principally on when employees choose to exercise their vested stock options. Tax benefits from the exercise of stock options in 2004 were $2.0 million on the exercise of options to acquire 232,711 shares as compared to $0.8 million in 2003 on the exercise of options to acquire 167,996 shares and $10.2 million in 2002 on the exercise of options to acquire 962,193 shares. Once we adopt revisions to SFAS 123(R) on accounting for share based payments, these tax benefits will be reflected in financing activities.

We expect that sales of our products will grow in 2005. If sales continue to increase, working capital is expected to increase to fund the increase in operations. As a result of these and other factors, we expect the use of working capital to fund our operations to continue to increase.

Investing Activities*:* In the year ended December 31, 2004, we used cash of $14.8 million in investing activities. This was comprised primarily of purchases of property and equipment of $7.1 million and the net purchases of liquid investments of $10.4 million utilizing cash generated by operations in excess of other investing needs, partially offset by the net cash receipt of $2.7 million in finance loans.

Capital expenditures in 2004 of $7.1 million were principally to maintain capacity and for building efficiency improvements.

Upon completing an evaluation of the design and capacity of our manufacturing facilities, we estimate that our current facilities will be adequate through 2005, but that production after 2005 may require additional clean room facilities for molding and automated assembly. We expect to decide in the future how to meet the need for any additional facilities and the location of additional clean room facilities for molding and automated assembly.

We currently estimate that capital expenditures for 2005 will be approximately $7.0 million and will be paid from cash we generate from operations. We expect the $7.0 million will be spent on molds, molding equipment and automated assembly equipment, computers and software to maintain current capacity including targeted growth for 2005. Amounts of spending are estimates and actual spending may substantially differ from those amounts. These amounts exclude any spending under the MCDA.

ICU Finance, Inc. is a wholly owned consolidated subsidiary that we established in 2002 as a licensed commercial lender to provide financing to companies involved in distribution of healthcare products and provision of healthcare services. Loans were made only to credit-worthy healthcare entities and are fully secured by real and personal property. At December 31, 2004, it had $6.2 million in loans outstanding. Scheduled maturities are: 2005 $2.6 million; 2006 $1.2 million; 2007 $1.1 million and 2008 $1.3 million. Weighted average maturity (principal and interest) at December 31, 2004 was 1.4 years and the weighted average interest rate was 5.5%. In October 2003, we discontinued new lending activities. As of December 31, 2004, we have no unfunded lending commitments on existing credit facilities.

Financing Activities: In 2004, we purchased 365,844 shares of our common stock for $10.1 million, as compared with 589,292 shares purchased for $15.3 million in 2003. We may purchase additional shares in the future. However, future purchases, if any, will depend on market conditions and other factors.

Cash provided by stock options and the employee stock purchase plan, was $3.2 million in 2004 as compared with $2.6 million in 2003; options were exercised on 232,711 shares in 2004 as compared with 167,996 shares in 2003.

We have a large cash and liquid investment position generated from profitable operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures, repurchase our common stock and potentially to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation, as further described in Item 7A, Quantitative and Qualitative Disclosures about Market Risk. Our liquid investments have very little credit risk or market risk.

We believe that our existing working capital, supplemented by income from operations, will be sufficient to fund our capital expenditures and increased working capital requirements for the foreseeable future.

Off Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. We have never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, we do not have any "off balance sheet arrangements".

Contractual Obligations

We have the following contractual obligations of approximately the following amounts. These amounts exclude purchase orders for goods and services for current delivery; we do not have any long-term purchase commitments for such items. These amounts also exclude any future obligations under the MCDA.

	Total	Payments due: less than 1 year from December 31, 2004
Property and equipment	$1.0 million	$1.0 million

Forward Looking Statements

Various portions of this Report, including this Management's Discussion and Analysis, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are "forward looking statements," and we identify them by using words such as "believe," "expect," "estimate," "plan," "will," "continue," "could," may," and by similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, among other things, statements about:

- future operating results and various elements of operating results, including: future expenditures on sales and marketing and product development; future sales and unit volumes of products; future license, royalty and revenue share income; production costs; gross margins; manufacturing costs and factors impacting them such as electrical service and oil prices; SG&A and individual elements of SG&A expenses such as personnel costs, information technology costs and costs of compliance with the Sarbanes-Oxley Act of 2002, and R&D expense; income; losses; cash flow; new product development and introduction, selling prices and income taxes;

- factors affecting operating results, such as shipments to specific customers, expansion in international markets, selling prices, the market shift to needleless technology, future increases or decreases in sales of certain products and in certain markets and distribution channels, ability to locate alternative distribution, ability to compete with other products, impact of safety legislation, increases in systems capabilities, introduction and sales of new products, overhead absorption, manufacturing efficiencies, unit manufacturing costs, acquisition and use of production equipment and expansion of facilities and assembly capacity, expansion of markets and the need for additional facilities, effect of acquisitions, business seasonality and fluctuations in quarterly results, customer ordering patterns and warranty claims, rebates and returns;

- new or extended contracts with manufacturers and buying organizations, and dependence on a small number of customers, effect of Abbott's spin-off of its Hospital Products Division, effect of contract amendments with Hospira including the MCDA and related agreements, ability to replace distributors, and the outcome of our strategic initiatives;

- regulatory approval; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, the impact of Cardinal's acquisition of Alaris, consolidation of the healthcare provider market and downward pressure on selling prices; and working capital requirements, changes in accounts receivable and inventories, current liabilities, foreign currency denominated financial instruments, capital expenditures, acquisitions of other businesses or product lines, indemnification liabilities, contractual liabilities, common stock repurchases payment of dividends and issuance of stock options.

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

Second, one should read the forward looking statements in conjunction with the Risk Factors in this Annual Report to the Securities and Exchange Commission.

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

- general economic and business conditions;

- the effect of price and safety considerations on the healthcare industry;

- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;

- unanticipated market shifts and trends;

- the impact of legislation affecting government reimbursement of healthcare costs;

- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;

- unanticipated production problems; and

- the availability of patent protection and the cost of enforcing and of defending patent claims.

We disclaim any obligation to update the statements or to announce publicly the result of any revision to any of the statements contained herein to reflect future events or developments.

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

We have a portfolio of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities. The securities are all "investment grade" and we believe that we have virtually no exposure to credit risk. Dividend and interest rates reset at auction for most of the securities from between seven and forty-nine day intervals, with some longer but none beyond twelve months, so we have very little market risk, that is, risk that the fair value of the security will change because of changes in market interest rates. The securities are readily saleable at par at auction dates, and can normally be sold at par between auction dates. As of December 31, 2004, we had no declines in the market value of these securities.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities and corporate preferred stocks in the portfolio and market conditions specific to the securities in which we invest.

At December 31, 2004 we had outstanding commercial loans of approximately $6.2 million. Loans were made only to credit worthy parties and are fully secured by real and personal property. We plan to hold the loans until maturity or payoff. As of December 31, 2004, maturities were four years or less and the weighted average maturity (principal and interest payments) was 1.4 years. Because of the relatively small amount of the commercial loans, market risk is not significant to our financial statements.

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable and accounts payable, is not significant. Sales from the U.S. to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the Euro, British

Pound, and Mexican Peso. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable in the same foreign currency. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will increase. We currently do not hedge our foreign currency exposures.

Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes have not been material. We are not dependent upon any single source for any of our principal raw materials or products for resale, and all such materials and products are readily available.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

ICU Medical, Inc.
San Clemente, CA

We have audited the accompanying consolidated balance sheets of ICU Medical, Inc. and subsidiaries (the "Company") as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in Item 15(a)2. These consolidated financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and the financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from 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, such consolidated financial statements present fairly, in all material respects, the financial position of ICU Medical, Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2005 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

DELOITTE & TOUCHE LLP

Costa Mesa, CA
March 11, 2005

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(All dollar amounts in thousands, except share data)

ASSETS

	December 31,	
	2004	**2003**

CURRENT ASSETS:		
Cash and cash equivalents	$ 5,616	$ 1,787
Liquid investments	81,725	71,350
Cash and liquid investments	87,341	73,137
Accounts receivable, net of allowance for doubtful accounts of $912 in 2004 and $742 in 2003	8,922	24,943
Finance loans receivable - current portion	2,634	4,142
Inventories	8,429	3,398
Prepaid income taxes	6,576	1,662
Prepaid expenses and other current assets	1,986	1,927
Deferred income taxes - current portion	1,156	2,008
Total current assets	117,044	111,217
PROPERTY AND EQUIPMENT, at cost:		
Land, building and building improvements	22,021	16,887
Machinery and equipment	31,860	26,429
Furniture and fixtures	6,698	6,572
Molds	9,345	11,480
Construction in process	3,778	10,247
	73,702	71,615
Less—Accumulated depreciation	(32,768)	(30,574)
	40,934	41,041
FINANCE LOANS RECEIVABLE - non current portion	3,613	4,765
DEFERRED INCOME TAXES - non current portion	-	2,680
INTANGIBLE ASSETS, net	2,780	4,166
OTHER ASSETS	397	419
	$164,768	$164,288

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

LIABILITIES AND STOCKHOLDERS' EQUITY

(All dollar amounts in thousands, except share data)

	December 31,	
	2004	2003
CURRENT LIABILITIES:		
Accounts payable	$ 2,693	$ 3,051
Accrued liabilities	4,761	5,234
Total current liabilities	7,454	8,285
COMMITMENTS AND CONTINGENCIES	-	-
MINORITY INTEREST	966	-
STOCKHOLDERS' EQUITY:		
Convertible preferred stock, $1.00 par value Authorized—500,000 shares; Issued and outstanding—none	-	-
Common stock, $0.10 par value-Authorized—80,000,000 shares; Issued — 14,158,612 shares in 2004 and 2003	1,416	1,416
Additional paid-in capital	61,751	63,535
Treasury stock, at cost — 583,643 and 471,390 shares in 2004 and 2003, respectively	(15,290)	(12,116)
Retained earnings	107,991	102,991
Accumulated other comprehensive income	480	177
Total stockholders' equity	156,348	156,003
	$164,768	$164,288

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME

(All amounts in thousands, except per share data)

	For the years ended December 31,		
	2004	2003	2002

REVENUES:			
Net sales	$ 72,704	$ 102,726	$ 84,218
Other	2,846	4,628	3,589
TOTAL REVENUE	75,550	$ 107,354	$ 87,807
COST OF GOODS SOLD	39,853	48,444	36,464
Gross profit	35,697	58,910	51,343
OPERATING EXPENSES:			
Selling, general and administrative	26,409	23,029	19,871
Research and development	3,376	1,757	1,472
Total operating expenses	29,785	24,786	21,343
Income from operations	5,912	34,124	30,000
OTHER INCOME	1,579	1,123	1,432
Income before income taxes and minority interest	7,491	35,247	31,432
PROVISION FOR INCOME TAXES	(109)	-	-
MINORITY INTEREST	2,600	12,950	11,750
NET INCOME	$ 5,000	$ 22,297	$ 19,682
NET INCOME PER COMMON SHARE			
Basic	$ 0.37	$ 1.62	$ 1.43
Diluted	$ 0.33	$ 1.48	$ 1.28
Weighted average number of shares			
Basic	13,691,139	13,752,732	13,792,760
Diluted	14,960,378	15,050,437	15,352,419

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME

(All dollar amounts in thousands, except share data)

	Common Stock							
	Number of Shares Outstanding	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income	Total	Comprehensive Income
BALANCE, December 31, 2001	13,126,055	$ 887	$ 45,765	$ (987)	$ 61,012	$ -	$106,677	
Exercise of stock options and related income tax benefits, and other	962,193	79	18,023	987	-	-	19,089	
Stock split	(1,222)	443	(504)	-	-	-	(61)	
Net income	-	-	-	-	19,682	-	19,682	19,682
BALANCE, December 31, 2002	14,087,026	1,409	63,284	-	80,694	-	145,387	19,682
							-	
Purchase of treasury stock	(589,292)	-	-	(15,324)	-	-	(15,324)	
							-	
Exercise of stock options and related income tax benefits	166,994	6	14	2,885	-	-	2,905	
Proceeds from employee stock purchase plan	22,493	1	237	323	-	-	561	
							-	
Comprehensive income							-	
Net income	-	-	-	-	22,297	-	22,297	22,297
							-	
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment	-	-	-	-	-	177	177	177
BALANCE, December 31, 2003	13,687,221	1,416	63,535	(12,116)	102,991	177	156,003	22,474
							-	
Purchase of treasury stock	(365,844)	-	-	(10,133)	-	-	(10,133)	
		-					-	

Exercise of stock options and related income tax benefits	232,711	-	(1,753)	6,388	-	-	4,635	
Proceeds from employee stock purchase plan	20,881	-	(31)	571	-	-	540	
							-	
Comprehensive income							-	
Net income	-	-	-	-	5,000	-	5,000	5,000
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment	-	-	-	-	-	303	303	303
BALANCE, December 31, 2004	13,574,969	$ 1,416	$ 61,751	$(15,290)	$107,991	$ 480	$156,348	$ 27,777

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(All dollar amounts in thousands)

	For the years ended December 31,		
	2004	2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 5,000	$ 22,297	$ 19,682
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	8,598	7,361	5,288
Provision for doubtful accounts	298	170	77
Minority interest	(109)	-	-
Write-off of in-process research and development	1,154	-	-
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired in business combination			
Accounts receivable	15,723	(8,480)	(3,265)
Inventories	(5,031)	3,462	(2,869)
Prepaid expenses and other assets	(41)	13	(831)
Accounts payable	(358)	(774)	2,283
Accrued liabilities	(552)	(1,548)	(3,176)
Prepaid and deferred income taxes	(1,382)	(514)	716
	23,300	21,987	17,905
Tax benefits from exercise of stock options	1,983	842	10,192
Net cash provided by operating activities	25,283	22,829	28,097
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(7,101)	(10,668)	(11,894)
Cash paid for acquisitions, net of cash acquired	-	(5,882)	(9,484)
Advances under finance loans	(1,010)	(8,907)	-
Proceeds from finance loan repayments	3,670		
Purchases of investments	(23,625)		
Proceeds from sale of investments	13,250	12,950	(15,174)
Net cash (used in) investing activities	(14,816)	(12,507)	(36,552)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options and other	2,689	2,063	8,719
Proceeds from employee stock purchase plan	503	561	-
Purchase of treasury stock	(10,133)	(15,324)	-
Net cash provided by (used in) financing activities	(6,941)	(12,700)	8,719
Effect of exchange rate changes on cash	303	-	-
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,829	(2,378)	264
CASH AND CASH EQUIVALENTS, beginning of year	1,787	4,165	3,901
CASH AND CASH EQUIVALENTS, end of year	$ 5,616	$ 1,787	$ 4,165
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for income taxes	$ 1,814	$ 14,065	$ 1,145

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

(All dollar amounts in tables in thousands, except share and per share data)

1. Summary of Significant Accounting Policies

a. Introduction

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

ICU Medical, Inc. (the "Company" - a Delaware corporation) operates principally in one business segment engaged in the development, manufacturing and marketing of disposable medical devices designed to protect healthcare workers and patients from the spread of infectious diseases. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States and a small portion internationally. All subsidiaries are wholly or majority owned and are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

b. Cash and Cash Equivalents

Cash and cash equivalents are liquid investments with an original maturity of three months or less.

c. 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 consist of the following at December 31:

	2004	2003
Raw materials	$ 3,745	$ 2,699
Work in process	507	340
Finished goods	4,177	359
	$ 8,429	$ 3,398

d. 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	15 - 30 years
Building improvements	15 years
Machinery and equipment	2 - 10 years
Furniture, fixtures and molds	2 - 5 years

The Company follows the policy of capitalizing expenditures that materially increase the life of the related assets; maintenance and repairs are expensed 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 at the time of disposal. Depreciation expense was $7.2 million, $6.6 million and $5.1 million in the years ended December 31, 2004, 2003 and 2002, respectively.

e. Intangible Assets

Intangible assets, which are carried as cost less accumulated amortization were as follows:

		December 31, 2004		
	Amortization Life in Years	Cost	Accumulated Amortization	Net
Patents and licenses	10	$ 2,306	$ 1,255	$ 1,051
Royalty agreements	6	1,399	410	989
Non compete agreement	5	818	200	618
Other	5 to 10	176	54	122
Total		$ 4,699	$ 1,919	$ 2,780

		December 31, 2003		
	Amortization Life in Years	Cost	Accumulated Amortization	Net
Patents and licenses	10	$ 2,923	$ 1,020	$ 1,903
Royalty agreements	6	1,630	308	1,322
Non compete agreement	5	818	36	782

Other	5 to 10	206	47	159
Total		$ 5,577	$ 1,411	$ 4,166

In 2004, we recorded a $0.4 million reduction in intangible asset costs due to adjustments to the costs accrued, net of tax effect, in connection with an acquisition made in 2002. Also in 2004, we wrote off the cost and accumulated amortization of the patents related to the Blood Collection Needle (BCN) for impairment totaling $0.9 million. Amortization expense in 2004, 2003 and 2002 was $1.4 million and $0.7 million and $0.2 million, respectively. The 2004 amortization expense includes $0.7 million of expense for the BCN patent impairment. Intangible assets are carried at cost, less accumulated amortization. Estimated annual amortization for each of the next five years is approximately $0.6 million.

f. Impairment or Disposal of Long-Lived Assets

The Company accounts for any impairment or disposal of long-lived assets in accordance with SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets." This SFAS requires a periodic review of long-lived assets for indicators of impairment.

No impairment charges, other than previously discussed, were recorded in the years ended December 31, 2004, 2003 and 2002.

g. Research and Development

The Company expenses research and development costs as incurred.

h. Net Income (Loss) Per Share

"Basic" earnings per share is computed by dividing net income by the weighted average number of common shares outstanding. "Diluted" earnings per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of average market value), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method.

i. Investment Securities

The Company accounts for investments in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities," as amended. That statement

requires that securities classified as available for sale be carried at their fair values and changes in the securities' fair values be recorded, net of income tax effect, as a separate component of stockholders' equity. Debt securities that the Company would intend to hold to maturity would be carried at amortized cost reduced only for other-than-temporary impairment in values; the Company has no debt securities that it intends to hold to maturity. As of December 31, 2004 and 2003, the Company has no temporary or other-than-temporary impairment on its securities.

j. Income Taxes

The Company accounts for income taxes in accordance with SFAS 109 "Accounting for Income Taxes" using the asset and liability approach. Under this approach, deferred taxes are determined based on the differences between the financial statements and the tax bases using rates as enacted in tax laws. A valuation allowance is established if it is "more likely than not" that all or a portion of the deferred tax assets will not be realized.

k. Revenue Recognition

Most of the Company's product sales are FOB shipping point and ownership of the product transfers to the customer on shipment by the Company. Certain other product sales are FOB destination and ownership of the product transfers to the customer at destination. The Company records sales and related costs when ownership of the product transfers to the customer. Most of the Company's customers are distributors or medical product manufacturers, although there are some sales to end-users. The Company's only post-sale obligations are warranty and certain rebates. Customers, with certain exceptions, do not retain any right of return and there is no price protection with respect to unsold product; returns from customers with return rights have not been historically significant, therefore no accrual is recorded for this.

The Company warrants products against defects and has a policy permitting the return of defective products. The Company provides a reserve for warranty returns and total warranty expense has been insignificant. The Company accrues rebates based on contractual commitments and on historical experience as a reduction in revenue at the time of sale; amounts have not been significant.

Other revenue consists of license, royalty and revenue sharing payments. Payments expected to be received 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, payments are not recorded until reported by the payers.

l. Post-retirement and Post-employment Benefits

The Company does not provide post-retirement or post-employment benefits to employees. The Company maintains a Section 401(k) retirement plan for employees. Company contributions to that plan in 2004, 2003 and 2002 were approximately $0.1 million in each year.

m. Stock Options

The Company accounts for its stock options granted to employees and directors 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," and does not recognize compensation expense because the exercise price of the options equals the fair market value of the underlying shares at the date of grant. Under SFAS No. 123, the Company is required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that Statement. The fair value for options granted in 2004, 2003, and 2002 was estimated as of the date of grant using a Black-Scholes option pricing model. 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.

The following information is provided pursuant to SFAS No. 123, as amended. The pro forma adjustment reflects stock-based compensation cost calculated under the fair value method, net of related tax effects, calculated pursuant to SFAS No. 123.

	2004	2003	2002
Net Income, as reported	$ 5,000	$ 22,297	$ 19,682
Pro forma adjustment	(6,327)	(5,131)	(6,271)
Net Income (Loss), pro forma	($ 1,327)	$ 17,166	$ 13,411
Net Income (Loss) per share			
Basic, as reported	$ 0.37	$ 1.62	$ 1.43
Diluted, as reported	$ 0.33	$ 1.48	$ 1.28
Basic, pro forma	($ 0.10)	$ 1.28	$ 1.00
Diluted, pro forma	($ 0.10)	$ 1.16	$ 0.89

Under revisions to SFAS No. 123 adopted in December 2004, the Company will be required to reflect stock-based compensation cost in its financial statements. The Company will adopt the "modified prospective method" under which it will reflect such costs in its financial statements commencing July 1, 2005 for all options granted on or after that date, as well as the unamortized cost at July 1, 2005, calculated as described above, for options granted prior to that date. In addition, in the consolidated statement of cash flow, the tax benefits from exercise of stock options will be included as a financing activity. Currently, it is reflected in operating activities.

On December 28, 2004, the Company amended provisions of certain stock options outstanding under the 1993 Plan to accelerate their vesting; see Note 5. Acceleration of the vesting of certain options in December 2004 increased the proforma adjustment by approximately $1.4 million, or $0.11 per share. Remaining proforma unamortized expense at December 31, 2004 was approximately $0.2 million, and most of that will amortize by July 1, 2005.

n. Accounting Estimates

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

2. Acquisitions

In September 2004, the Company purchased an interest of approximately 57% in a company developing a new medical device for use in screening for heart disease for approximately $2.5 million in cash. The Company has agreed to invest an additional $1.5 million if certain milestones are achieved by November 30, 2005. The company had no operations prior to the investment. Its only asset is technology related to the device, which will require pre-market submission to the Food and Drug Administration. The company is included in the consolidated financial statements since September 2004, and the interests of the other stockholders, who are the founders, are shown as minority interest. Approximately $1.2 million of the Company's investment was allocated to in-process research and development, based in part on an independent appraisal, and that amount was charged to research and development expens e in the Company's consolidated financial statements in September 2004. The pro forma effects of this acquisition were not significant. This company incurred a net loss $0.3 million from September through December 2004, post acquisition.

In June 2003, the Company acquired the assets of two affiliated manufacturers of intravenous therapy systems located in northern Italy for a cash payment of approximately $4.6 million. Principal assets acquired are assembly facilities and related equipment of $2.4 million and inventories of $1.1 million and an agreement not to compete valued at approximately $0.8 million. The acquired assets and related operating results are included in the Company's consolidated financial statements since June 30, 2003. The effect of this acquisition on the Company's

financial statements is immaterial.

3. Liquid Investments

The Company's liquid investments, all of which are marketable securities and 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, principally 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. They are readily saleable at par at auction dates, and can normally be sold at par between auction dates. All securities are "investment grade' and there have been no gains or losses on their disposal. Balances consist of the following at December 31:

	2004	2003
Corporate preferred stocks	$ 25,900	$ 19,100
Federal tax-exempt debt securities	55,825	52,250
	$ 81,725	$ 71,350

The scheduled maturities of the debt securities are: $2.0 million between 2005-2009, $2.0 million between 2010-2014, $2.9 million between 2015-2019 and $48.9 million after 2019.

Investment income, including, money market funds and finance loans, consisted of the following for each year:

	2004	2003	2002
Corporate dividends	$ 263	$ 280	$ 432
Tax-exempt interest	799	605	874
Other interest	517	238	126
	$ 1,579	$ 1,123	$ 1,432

4. Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2004	2003
Salaries and benefits	$ 1,540	$ 1,778
Professional fees	915	639
Incentive compensation	909	1,555
Other	1,397	1,262
	$ 4,761	$ 5,234

5. Common Stock and Common Stock Options Granted

In June 2003, stockholders approved the 2003 Stock Option Plan (the "2003 Plan") under which 1,500,000 shares of common stock were reserved for issuance to employees. Options may be granted with exercise prices at no less than fair market value at date of grant. Options granted under the 2003 Plan may be "nonstatutory stock options" which expire no more than ten years from date of grant of "incentive stock options" as defined in Section 422 of the Internal Revenue Code of 1986, as amended. Upon exercise of nonstatutory stock 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; the Company is generally not entitled to any tax deduction on an incentive stock option. The 2003 Plan includes conditions whereby options not vested are cancelled if employment is terminated.

Options were previously granted to employees under the 1993 Stock Incentive Plan (the "1993 Plan"). The 1993 Plan had terms similar to those of the 2003 Plan, except that options expired no more than eleven years from

issuance, and the 1993 Plan did not provide for issuance of incentive stock options. Options may no longer be granted under the 1993 Plan since January 2005.

All options have been granted at fair market value at date of grant. All options issued through early 2000 are time-accelerated options which vest upon the earlier of the Company attaining specific operating performance levels or ten years from the date of grant. Most options issued after early 2000 vest in equal amounts on the first, second and third anniversary of their issuance ("time vested").

On December 28, 2004, the Company amended provisions of certain stock options outstanding under the 1993 Plan to vest stock options with an exercise price above the December 28, 2004 closing price for the Company's Common Stock on the Nasdaq Stock Market on the later of December 31, 2004 or six months from the date such stock option was granted. As a result of the amendment, stock options covering 468,947 shares became exercisable on December 31, 2004 and options covering an additional 13,250 will become exercisable during the first six months of 2005. The vesting provisions of stock options that vest based on performance criteria were not amended. There were no other changes to any stock options.

The Company will substantially curtail grants of stock options in the future. It believes that the amended vesting provisions will partially mitigate the resulting reduction in employees' equity-based incentive compensation. The Company has decided to follow the "modified prospective method" in implementing recent amendments by the Financial Accounting Standards Board in Accounting for Stock-Based Compensation. The acceleration will reduce the future amortization of the Company's stock option compensation expense which the Company believes will enhance comparability of the Company's financial statements with those of prior and subsequent years.

In May 2002, stockholders approved the 2001 Directors' Stock Option Plan (the "Directors' Plan"), which had been adopted in November 2001. There are 750,000 shares reserved for issuance under the Directors' Plan. Options to purchase 1,875 shares of Common Stock are granted quarterly to non-employee Directors (of which there are currently six) at fair market value of the Common Stock at the date of grant. The options become exercisable six months after the grant date and expire eleven years after the grant date. Options not vested terminate if directorship is terminated. Options to purchase 101,250 shares of Common Stock were issued upon stockholder approval of the Directors' Plan; they included 11,250 granted subject to stockholder approval in November 2001 for which a compensation charge of $117,000 was recorded for the increase in the fair market value of the Common Stock from the grant date to the date of stockholder approval. An additional 22,500 options were granted later in 2002, 45,000 in 2003 and 45,000 in 2004. All further grants under the Director's Plan have been suspended.

Upon approval of the Directors' Plan by the stockholders, the existing Directors' Stock Award Plan, under which each non-employee Director was awarded 1,500 shares of Common Stock annually, was terminated and the award payable on the date of the 2002 annual meeting was not made.

In 2002, the Company adopted the 2002 Employee Stock Purchase Plan (the "ESPP") under which certain employees may purchase up to $25,000 annually of Common Stock at 85% of its fair market value at the beginning or the end of a six-month offering period, whichever is lower. There are 750,000 shares of Common Stock reserved for issuance under the ESPP, which number is subject to annual increase; the Board of Directors determined that the annual increase due January 1, 2003, 2004 and 2005 would not take place. The ESPP is intended to constitute an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. Employees purchased 20,881 shares of Common Stock under the ESPP Plan in 2004 and purchased approximately 10,500 shares of Common Stock in the offering period ending February 11, 2005.

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

	Shares	Exercise Price Range			Weighted Average
Outstanding at December 31, 2001	4,388,598	$ 5.08	-	$ 29.17	$ 10.95
Granted	707,150	26.51	-	40.62	33.83
Exercised	(962,193)	5.33	-	32.48	9.13
Forfeited	(20,754)	12.17	-	29.89	19.72
Outstanding at December 31, 2002	4,112,801	5.08	-	40.62	13.62
Granted	457,250	24.83	-	37.29	31.25
Exercised	(166,994)	5.33	-	33.07	12.36
Forfeited	(47,127)	14.81	-	39.30	29.82
Outstanding at December 31, 2003	4,355,930	5.08		40.62	16.88
Granted	344,995	22.25	-	39.03	31.55
Exercised	(232,711)	5.54	-	32.48	11.55
Forfeited	(58,131)	12.90	-	39.56	31.57
Outstanding at December 31, 2004	4,410,083	$ 5.08		$ 40.62	$ 18.11
Exercisable at December 31:					
2002	2,869,651	$ 5.08	-	$ 39.25	$ 11.09
2003	3,368,078	5.08	-	40.62	13.06
2004	4,285,831	5.08	-	40.62	18.03
Available for grant at December 31, 2004, reflecting January 2005 expiration of the 1993 Plan:					
2003 Plan	1,400,000				
Director's Plan	536,250				
	1,936,250				

There are 4,410,083 options outstanding at December 31, 2004 of which 4,096,333 were issued under the 1993 Plan, 100,000 under the 2003 Plan and 213,750 were issued under the Directors' Plan. Of the 124,252 unvested options, 52,500 options are time accelerated options issued from 1999 to 2001 and the remaining are time vested options granted in 2003 and 2004 with vesting dates from 2004 to 2007. All options expire eleven years after issuance, except for 100,000 option issued under the 2003 Plan, which expire ten years after issuance. Options outstanding at December 31, 2004 were issued as follows:

Options Outstanding					Options Exercisable	
Range of Exercise Price		Number Outstanding	Weighted Average Remaining Contractual Life (yrs)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 5.08	7.29	452,405	3.51	$ 6.11	452,405	$ 6.11
$ 8.04	8.17	1,136,144	4.01	$ 8.17	1,136,144	$ 8.17
$ 8.50	10.33	513,662	3.56	$ 10.25	513,662	$ 10.25
$ 10.63	18.63	498,697	9.22	$ 14.73	461,198	$ 15.04
$ 18.79	28.31	446,117	7.97	$ 23.43	359,366	$ 23.00
$ 28.50	30.32	465,614	8.56	$ 29.66	465,613	$ 29.66
$ 30.34	33.99	489,667	9.27	$ 32.37	489,666	$ 32.37
$ 34.14	40.62	407,777	8.88	$ 37.07	407,777	$ 37.07
$ 5.08	40.62	4,410,083	6.41	$ 18.11	4,285,831	$ 18.03

Year of Grant	Options Outstanding	Exercise Price Range		Weighted Average
1994	4,375	5.54	5.54	5.54
1996	352,763	10.25	10.25	10.25
1997	448,030	5.08	7.29	6.12
1998	1,142,116	8.04	10.63	8.17
1999	224,670	8.50	14.29	10.69
2000	425,454	9.58	18.79	15.23
2001	436,283	17.00	29.16	23.88
2002	620,785	27.77	40.62	34.09
2003	438,861	24.83	37.08	31.25
2004	316,746	22.59	39.03	31.52

Dilutive stock options account for the difference in the number of shares used to calculate basic and diluted net income per share and were 1,269,239 in 2004, 1,297,705 in 2003 and 1,559,659 in 2002. The average number of options that are anti-dilutive because their average exercise price exceeded the average market price of the Company's common stock approximated 1,117,000, 575,000 and 130,000 in 2004, 2003 and 2002, respectively. At December 31, 2004, 3,017,275 outstanding options had exercise prices less than the market price of the Company's common stock and 1,392,808 had exercise prices greater than the market price of the Company's common stock.

The following information relates to the pro forma earnings information presented pursuant to SFAS No. 123, as amended. It pertains to options under the

Company's 1993 Plan, the 2003 Plan, the Directors' Plan, and the ESPP. The following weighted-average assumptions for 2004, 2003, and 2002 were used: risk-free interest rate of 3.2, 2.7 and 4.1 percent, respectively; expected option life of 4.4, 4.6 and 4.9 years, respectively; expected volatility of 51, 51 and 52 percent, respectively; and, no dividends. The total estimated fair value is amortized to expense over the vesting period. The weighted average number of common shares used in calculating pro forma net income per share is as follows: 2004 basic 13,691,000; diluted 14,960,000, 2003 basic 13,378,000, diluted 14,720,000; and 2002 basic 13,452,000, diluted 15,012,000.

6. Stockholder Rights Plan

In July 1997, the Board of Directors adopted a Stockholder Rights Plan. The Company distributed a Preferred Share Purchase Right (a "Right") for each share of the Company's Common Stock outstanding. The Rights generally will not be exercisable until a person or group has acquired 15% or more of the Company's Common Stock in a transaction that is not approved in advance by the Board of Directors or ten days after the commencement of a tender offer which could result in a person or group owning 15 percent or more of the Common Stock.

On exercise, each Right entitles the holder to buy one share of Common Stock at an exercise price of $115, as amended in April 2002. In the event a third party or group were to acquire 15 percent or more of the Company's outstanding Common Stock without the prior approval of the Board of Directors, each Right will entitle the holder, other than the acquirer, to buy Common Stock with a market value of twice the exercise price, for the Right's then current exercise price. In addition, if the Company were to be acquired in a merger, shareholders with unexercised Rights could purchase common stock of the acquirer with a value of twice the exercise price of the Rights.

The Company's Board of Directors may redeem the Rights for a nominal amount at any time prior to the tenth business day following an event that causes the Rights to become exercisable. The Rights will expire unless previously redeemed or exercised on August 7, 2007.

7. Income Taxes

The provision for income taxes for the years ended December 31, 2004, 2003 and 2002 is as follows:

	2004	2003	2002
Current:			
Federal	$ (524)	$10,762	$ 8,591
State	(418)	1,040	2,443
	(942)	11,802	11,034
Deferred:			
Federal	3,430	838	759
State	112	310	(43)
	3,542	1,148	716
	$2,600	$12,950	$11,750

Current income taxes payable were reduced from the amounts in the above table by $2.6 million, $0.8 million, and $10.2 million in 2004, 2003 and 2002, respectively, equal to the tax benefit that the Company receives upon exercise of stock options by employees and directors. That benefit is allocated to stockholders' equity. The Company has accrued contingencies for potential tax assessments, which is included as a reduction of prepaid income taxes.

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

	2004		2003		2002	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$2,622	35.0%	$12,336	35.0%	$10,687	34.0%
State income tax, net of federal benefit	266	3.5	994	2.8	1,562	5.0
Tax-exempt interest and dividends	(371)	(4.9)	(284)	(0.8)	(400)	(1.3)
Tax credits	(418)	(5.6)	(96)	(0.3)	(99)	(0.3)
Loss of subsidiary not consolidated for tax purposes	501	6.7	-	-	-	—
Provision	$2,600	34.7%	$12,950	36.7%	$11,750	37.4%

The components of the Company's deferred income tax provision for the years ended December 31, 2004, 2003, and 2002 are as follows:

	2004	2003	2002
Allowance for doubtful accounts	$ 30	$ (33)	$ (31)
Inventory reserves	244	101	(114)
Accruals	(496)	171	167
State income taxes	(605)	(508)	507
Acquired future tax deductions	(269)	359	585
Depreciation	(2,446)	1,058	(398)
	$ 3,542	$1,148	$ 716

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

	2004	2003
Current deferred tax asset (liability):		
Allowance for doubtful accounts	$ 347	$ 317
Inventory reserves	520	276
Accruals	523	1,044
State income taxes	(234)	371
	$ 1,156	$2,008
Non-current deferred tax asset (liability):		
Depreciation	$(2,275)	$ 61
Acquired future tax deductions	2,522	2,723
Foreign currency translation adjustments	(247)	(104)
	-	$2,680

Acquired future tax deductions are the benefits of future tax deductions in the Company's consolidated income tax returns originating in Bio-Plexus Inc., an entity purchased in 2002, before its acquisition by the Company. They consist of: (a) the net benefit of items expensed for financial statement purposes but capitalized and amortized for tax purposes of $1.9 million at acquisition date, less $0.5 million realized since acquisition; most of the balance of $1.4 million will be realized in approximately equal amounts over the next eight years; (b) the benefit of a portion of Bio-Plexus's net operating loss ("NOL") carryforward of $1.8 million, less $0.3 million realized since acquisition, which will be realized in approximately equal amounts over the next eighteen years, (c) reduced by the tax effect of non-amortizable basis differences of $0.4 million.

At October 31, 2002, Bio-Plexus had federal NOL carryforwards of approximately $86.0 million. Under Section 382 of the Internal Revenue Code, certain ownership changes limit utilization of the NOL carryforwards, and the amount recorded is the net federal benefit. Bio-Plexus also has approximately $33.0 million of Connecticut State NOL carryforwards expiring through 2007. Realization of any of these is unlikely, and the Company has not ascribed any value to them.

The accounting for the benefits of the acquired future tax deductions as described above will not have any direct impact on net income in the future. However, if any benefits are realized in excess of those recorded, they will be allocated to reduce non-current intangible assets related to the acquisition (patent and royalty rights, and other) until those amounts are reduced to zero, with any excess then recognized as a reduction in tax expense.

Foreign currency translation adjustments, and related tax effects, are an element of "other comprehensive income" and are not included in net income.

8. Products, Major Customers and Concentrations of Credit Risks

All of the Company's products are disposable medical devices. The Company's principal product is its CLAVE needleless I.V. connection system which accounted for $35.4 million of consolidated net sales in 2004, $62.9 million in 2003 and $58.5 million in 2002. Custom I.V. systems, many of which incorporate the CLAVE connector, accounted for $26.2 million of consolidated net revenues in 2004, $22.2 million in 2003 and $15.2 million in 2002. Each of the Company's other products account for less than 8% of net revenues.

The Company sells products, which are sold on credit terms on an unsecured basis, principally throughout the United States to medical product manufacturers, independent medical supply distributors, and in selected cases to hospitals and homecare providers. The manufacturers and distributors, in turn, sell the Company's products to healthcare providers. For the years ended December 31, 2004, 2003 and 2002, the Company had sales of 10 percent or greater of total revenues to one manufacturer of 53%, 67% and 57%, respectively. For the year ended December 31, 2002, another manufacturer accounted for 11%.

Export sales and sales outside the United States and Canada accounted for 12%, 5% and 8% of consolidated net revenue in 2004, 2003 and 2002, respectively.

Approximately $17.0 million of the Company's long-lived assets, principally property and equipment, are located outside the United States: approximately $13.5 million in Mexico and approximately $3.5 million in Italy.

9. Finance Loans Receivable

Finance loans receivable are commercial loans by ICU Finance, Inc., a wholly-owned consolidated subsidiary. The Company plans to hold the loans to maturity or payoff. They are carried at their outstanding principal amount, and will be reduced for an allowance for credit losses and charge offs if any such reductions are determined to be necessary in the future. Interest is accrued as earned based on the stated interest rate and amounts outstanding. Loan fees and costs have not been material. Scheduled maturities are: 2005 $2.6 million; 2006 $1.2 million; 2007 $1.1 million and 2008 $1.3 million. Weighted average maturity (principal and interest) at December 31, 2004 is 1.4 years and the weighted average interest rate is 5.5%. In October 2003, the Company decided to discontinue new lending activities. There are no unfunded commitments at December 31, 2004.

10. 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, the resolution of the legal proceedings in which the Company is involved will not have a material adverse impact on the Company's financial position or results of operations.

In the normal course of business, we have agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. We have never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, we do not have any "off balance sheet arrangements".

11. **Quarterly Financial Data — Unaudited**

	Quarter Ended			
	March 31	**June 30**	**Sept. 30**	**Dec. 31**
2004				
Total Revenue	$22,233	$21,664	$16,468	$15,185
Gross Profit	12,420	12,064	6,514	4,699
Net Income (Loss)	4,140	3,410	(1,036)	(1,514)
Net Income (Loss) Per Share:				
Basic	$ 0.30	$ 0.25	$ (0.08)	$ (0.11)
Diluted	$ 0.28	$ 0.23	$ (0.08)	$ (0.11)
2003				
Total Revenue	$30,776	$21,283	$25,524	$29,771
Gross Profit	17,732	12,135	12,278	16,765
Net Income	7,070	3,899	4,175	7,153
Net Income Per Share:				
Basic	$ 0.50	$ 0.28	$ 0.31	$ 0.54
Diluted	$ 0.46	$ 0.26	$ 0.28	$ 0.48

12. **New Agreement with Hospira**

On February 25, 2005, the Company entered into a twenty-year Manufacturing, Commercialization and Development Agreement ("MCDA") with Hospira, Inc. ("Hospira"). Under the MCDA and related agreements, which is expected to close early in the second quarter of 2005, the Company will acquire Hospira's Salt Lake City, Utah manufacturing facility, related capital equipment and certain inventories for approximately $35 million in cash, and produce for sale to Hospira on an exclusive basis substantially all the products manufactured at that plant. Hospira will retain commercial responsibility for the products the Company will be producing, including sales, marketing, distribution, customer contracts, customer service and billing. The majority of the products the Company will be producing under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. The Company has also committed fund certain research and development to improve critical care products and develop new products for sale to Hospira, and has also committed to provide certain sales specialist support.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Regulations 13a-14(c) and 15a-14(c) under the Securities Exchange Act of 1934) as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities Exchange Commission. There were no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the date of the principal executive officer's and principal financial officer's evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Management's Annual Report on Internal Controls over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate control over the Company's financial reporting.

Management has used the criteria in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its internal controls over financial reporting.

Management of the Company has concluded that the Company has maintained effective internal control over its financial reporting as of December 31, 2004 based on the criteria in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The Company's internal control over financial reporting is a process designed under the supervision of the Company's principal executive and principal financial officers and effected by the Company's Board of Directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K has issued to the Company an attestation report on Management's Assessment of the Company's Internal Control over Financial Reporting and that report is included on the following page.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
ICU Medical
San Clemente, CA

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Controls over Financial Reporting, that ICU Medical, Inc. and subsidiaries (the "Company") maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and the financial statement schedule as of and for the year ended December 31, 2004 of the Company and our report dated March 11, 2005 expressed an unqualified opinion on those financial statements and the financial statement schedule.

/s/ Deloitte & Touche LLP

DELOITTE & TOUCHE LLP

Costa Mesa, CA
March 11, 2005

Item 9B. Other Information

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, 2004 and such information is incorporated herein by 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 14.

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, Item 13 - Certain Relationships and Related Transactions and Item 14 – Principal Accountant Fees and Services) 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, 2004, and such information is incorporated herein by this reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 10-K

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

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

3. Exhibits

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

Exhibit Number	Description
3.1	Registrant's Certificate of Incorporation, as amended.(1)
3.2	Registrant's Bylaws, as amended.(1)
10.1	Form of Indemnity Agreement with Executive Officers.(1)
10.2	Registrant's Amended and Restated 1993 Incentive Stock Plan.(2)
10.3	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B.Braun, Inc. relating to the Protected Needle product.(3)
10.4	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(4)
10.5	Rights Agreement dated July 15, 1998 between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(5)
10.6	SafeLine Agreement effective October 1, 1999 by and between Registrant and B.Braun Medical, Inc.(6)

Exhibit Number	Description
10.7	Amendment to April 3, 1995 Supply and Distribution Agreement, dated January 1, 1999, between Registrant and Abbott Laboratories.(7)
10.8	Amendment No. 1 to Rights Agreement, dated January 30, 1999, between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(8)
10.9	Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories.(9)
10.10	Amended and Restated Rights Agreement, dated as of May 10, 2002, between Registrant and Mellon Investor services, L.L.C., as Rights Agent. (10)
10.11	Registrant's 2001 Directors' Stock Option Plan.(11)
10.12	Registrant's 2002 Employee Stock Purchase Plan.(11)
10.13	Registrant's 2003 Stock Option Plan.(12)

10.14 Amendment to April 3, 1995 Supply and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories.(13)

10.15 Amendment to February 27, 2001 Co-Promotion and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories.(13)

21.1 Subsidiaries of Registrant.

23.1 Consent of Deloitte & Touche LLP.

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Filed as an exhibit to Registrant's Registration Statement Form S-1 (Registration No. 33-45734) filed on February 14, 1992, and incorporated herein by reference.

(2) Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 4, 1999 and incorporated herein by reference.

(3) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.

(4) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1995, and incorporated herein by reference.

(5) Filed as an exhibit to Registrant's Registration Statement on Form 8-A dated July 23, 1998 and incorporated herein by reference.

(6) Filed as an exhibit to Registrant's Current Report on Form 8-K dated June 18, 1999, and incorporated herein by reference.

(7) Filed as an exhibit to Registrant's Current Report on Form 8-K dated February 23, 1999, and incorporated herein by reference.

(8) Filed as an exhibit to Registrant's Registration Statement on Form 8-A/A dated February 9, 1999 and incorporated herein by reference.

(9) Filed as an exhibit to Registrant's Current Report on Form 8-K dated March 7, 2001 and incorporated herein by reference.

(10) Filed as an Exhibit to Registrant's Registration Statement on Form 8A/A dated May 14, 2002, and incorporated herein by reference.

(11) Filed as an exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 2, 2002 and incorporated herein by reference

(12) Filed as an exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 25, 2003 and incorporated herein by reference.

(13) Filed as an exhibit to Registrant's Current Report on Form 8-K dated January 15, 2004, and incorporated herein by reference.

(b) Reports on Form 8-K.

Items 2.02 and 9.01 – October 2004

SIGNATURES

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

ICU MEDICAL, INC.

By: /s/ George A. Lopez, M.D.
George A. Lopez, M.D.
Chairman of the Board

Dated: March 11, 2005

SIGNATURES

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

Signature	Title	Date
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	March 11, 2005
/s/ Francis J. O'Brien Francis J. O'Brien	Chief Financial Officer (Principal Financial Officer)	March 11, 2005
/s/ Scott E. Lamb Scott E. Lamb	Controller (Principal Accounting Officer)	March 11, 2005
/s/ Jack W. Brown Jack W. Brown	Director	March 11, 2005
/s/ John J. Connors John J. Connors	Director	March 11, 2005
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	March 11, 2005
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	March 11, 2005
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	March 11, 2005
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	March 11, 2005

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(All dollars in thousands)		Additions			
Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts	Write-offs/ Disposals	Balance at End of Period
For the year ended December 31, 2002:					
Allowance for doubtful accounts	$ 581	$ 100	$ 11	$ (27)	$ 665
For the year ended December 31, 2003:					
Allowance for doubtful accounts	$ 665	$ 170	$ -	$ (93)	$ 742
For the year ended December 31, 2004:					
Allowance for doubtful accounts	$ 742	$ 298	$ -	$ (128)	$ 912

EXHIBIT INDEX

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Exhibit 21.1

Subsidiaries of Registrant

Name	State of Incorporation
ICU Medical Sales, Inc.	Delaware
ICU Finance, Inc.	California
Budget Medical Products, Inc.	California
ICU MedEurope Limited	United Kingdom
ICU MedEurope (NZ) Limited	New Zealand
ICU Medical Europe S.r.l.	Italy
BMP de MÉxico, S.A. de C.V.	Mexico
MedScanSonics, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements No. 333-04171 No. 333-58024, No. 333-90642 and No. 333-90464 of ICU Medical, Inc. on Form S-8 of our report, dated March 11, 2005 relating to the consolidated financial statements and financial statement schedule of ICU Medical, Inc. and subsidiaries and management's report on the effectiveness of internal controls over financial reporting, appearing in this Annual Report on Form 10-K of ICU Medical, Inc. for the year ended December 31, 2004.

/s/ Deloitte & Touche LLP
DELOITTE & TOUCHE LLP

Costa Mesa, California
March 11, 2005

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, the Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of ICU Medical, Inc.:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 11, 2005

/s/ George A. Lopez, M.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, the Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of ICU Medical, Inc.:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 11, 2005

/s/ Francis J. O'Brien
Chief Financial Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George A. Lopez, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

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

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francis J. O'Brien, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Francis J. O'Brien
Francis J. O'Brien