

ICU MEDICAL INC/DE
Form 10-K
March 10, 2006

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2005 or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**
For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

33-0022692
(I.R.S. Employer
Identification No.)

951 Calle Amanecer
San Clemente, California
(Address of principal executive offices)

92673
(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark whether if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.
 Yes No

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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act:

Large accelerated filer Accelerated filer Non-accelerated filer

Indicated by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The aggregate market value of the voting stock held by non-affiliates of Registrant as of June 30, 2005, the last business day of Registrant's most recently completed second fiscal quarter, was \$402,155,240*.

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of January 31, 2006 was 14,171,772.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for Registrant's 2006 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 2005, are incorporated by reference into Part III of this Report.

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

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 patients from Catheter Related Bloodstream Infections and healthcare workers from exposure to infectious diseases 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. With the acquisition of Hospira, Inc. s (Hospira) Salt Lake City plant on May 1, 2005 and commencement of production under a twenty-year Manufacturing, Commercialization and Distribution Agreement with Hospira (MCDA), we are now also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems

In 1993, we launched the CLAVE[®], an innovative one-piece, needleless I.V. connection device that accounted for approximately 40% of our revenue in 2005 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. In 2002, we acquired the Punctur-Guard line of blood collection needles. In 2004, we invested in a company developing a new medical device. In 2005, we acquired Hospira s Salt Lake City manufacturing facility (see below). There is no assurance that any of these initiatives will succeed or continue to succeed.

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, known as SetMaker , 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 custom I.V. systems can currently offer.

The principal products that we have introduced in recent years are the CLC2000[®], the MicroCLAVE[®], the 1o2 Valve[®] and the TEGO Connector product, a new connector for use in hemodialysis introduced in 2005. In 2006, we expect to launch a new Y-CLAVE connector with integral check valve, which we are already using in our own production, the Orbit 90 diabetes set, a novel male luer connection device and a line of oncology I.V. therapy products known as the ChemoCLAVE System.

On May 1, 2005, we acquired Hospira s Salt Lake City manufacturing facility, related capital equipment, certain inventories and assumed liabilities for \$31.8 million in cash and \$0.8 million of acquisition costs. We entered into a twenty year MCDA with Hospira, under which we produce for sale, exclusively to Hospira, substantially all the products that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products we are producing, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The majority of the products under the MCDA are critical care products, which include medical devices such as catheters, cardiac monitoring systems and angiography kits. Sales of products manufactured under the MCDA from May to December 2005 were \$46.7 million. 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 also 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 cost to manufacture those

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

same products at the purchase date. We give no assurance as to the amounts of future sales or profits under the MCDA.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

We currently sell substantially all of our products to I.V. product manufacturers and independent distributors. Our largest customer is Hospira, Inc., which accounted for 73% of our revenues in 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 Form 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. We also have our code of ethics posted on our website. The information on our website is not incorporated into this Annual Report.

I.V. Usage and Infection Control

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 needle-safe 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 led to significant federal and state legislation. 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 Y-CLAVE 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 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 Y-CLAVE 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 Y-CLAVE will not replace CLAVE products used in non-piggyback connections. Unlike the original CLAVE site, the Y-CLAVE 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 \$62.5 million or 40% of our revenue in 2005, \$35.4 million or 47% of our revenue in 2004 and \$62.9 million or 59% of our revenue in 2003. CLAVE products and Custom I.V. systems including one or more CLAVES accounted for \$85.9 million, \$53.8 million and \$78.7 million of our revenue in 2005, 2004 and 2003, respectively.

In October 2001, we commenced production of the MicroCLAVE®. It is smaller than the standard CLAVE but is functionally similar. The MicroCLAVE has a feature where upon disconnection of an I.V. administration set or syringe, there is a neutral displacement of fluid. This allows clinicians to utilize known clamping protocols without the risk of device failure. This feature is important as it reduces the burden on nurse education when there are multiple protocols being used in a facility. The MicroCLAVE is being marketed as an extension of the CLAVE product line for use where its smaller size and neutral displacement feature are advantageous.

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 known as SetMaker 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 customer's 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.

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. This agreement is effective to

2014. 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 increases 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 2005, 2004 and 2003, net sales of custom I.V. systems were approximately \$31.8 million, \$26.2 million and \$22.8 million, respectively. The 2005 custom I.V. system growth was spread relatively evenly among Hospira, domestic distributors and international distributors.

Critical Care Products

Critical care products are used to monitor vital signs as well as specific physiologic functions of key organ systems. On May 1, 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into a twenty-year MCDA with Hospira, under which we produce for sale, exclusively to Hospira, substantially all the products that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products we are producing, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The critical care products manufactured at the Salt Lake City facility, which are the majority of the products manufactured there, are invasive hemodynamic monitoring systems that are used to monitor cardiac function and blood flow in critically ill patients. They include all components of the invasive monitoring system except capital equipment such as computers and monitors, which continue to be manufactured elsewhere by Hospira. The products we manufacture, almost all of which are disposable, are the following.

Pressure monitoring devices. Disposable pressure-sensing devices that provide accurate and continuous blood pressure readings and show the immediate effect of fluid management and drug administration. These products are used most commonly on patients with suspected pulmonary disease or cardiovascular dysfunction.

Blood sampling systems. Blood sampling systems that provide the clinician with a convenient, needleless method to obtain a patient's blood sample and to administer I.V. fluids or drugs in conjunction with blood pressure monitoring devices. They are designed to protect the clinician from exposure to bloodborne pathogens and reduce the risk of I.V. line contamination.

Angiography kits. A broad range of devices for use in the cardiac catheterization laboratory to enable physicians to monitor the function of the heart and examine the coronary arteries. They are various types of Left Heart and Right Heart procedural kits which include manifolds, syringes, stopcocks, specialized injection tubing and dye management systems, many of which contain pressure-sensing devices, and waste management systems.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Advanced sensory catheters. Catheters used to measure cardiac output and blood oxygen levels. Depending on specific design, these catheters contain up to five lumens and use fiber-optics to continuously measure mixed venous oxygen saturation, blood pressure and cardiac output. They may also permit administration of fluids and drugs, monitoring patient temperature and pressures and blood sampling.

Pulmonary artery thermodilution catheters. Catheters used for cardiac output determinations, fluid and drug administration, temperature and pressures and blood sampling. Depending on specific design, these catheters contain up to five lumens.

Multi lumen central venous catheters. Catheters used for monitoring central venous pressure, blood sampling, and simultaneous administration of multiple I.V. solutions or drugs at individual flow rates.

We manufacture all critical care products sold by Hospira in the United States and all catheters sold by Hospira outside the United States.

A substantial portion of the invasive monitoring and angiography products are custom products designed to meet the specific needs of the customer. We believe we can significantly expand the market for custom invasive monitoring and angiography products through cost savings using our proprietary low-cost manufacturing techniques.

From May 1 through December 31, 2005, sales of critical care products were \$41.6 million.

Punctur-Guard

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 Sales of Punctur-Guard products for 2005, 2004 and 2003 were \$4.2 million, \$3.9 million and \$7.3 million, respectively.

We are currently concentrating our sales and marketing efforts for the Winged Sets on outpatient provider contracts and the diagnostic laboratory 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 concentrate 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 central venous catheters such as oncology and long-term infusion of medication. CLC2000 accounted for \$5.2 million, \$3.1 million and \$3.9 million our revenue in 2005, 2004 and 2003, respectively.

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 primarily in anesthesia and critical care. 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. Sales of I.V. sets containing 1o2 Valves were approximately \$5.2 million, \$4.4 million and \$3.6 million in 2005, 2004 and 2003, respectively.

Other Products and Revenues

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 needless I.V. connectors.

We manufacture for Hospira a number of other products at the Salt Lake City facility, the principal ones of which are suction products that are used to collect fluids in the operating room and an I.V. line flow controller. We did not buy the capital equipment related to the suction products when we bought the Salt Lake City manufacturing facility, and expect to turn over the equipment and manufacturing to Hospira in the middle of 2006.

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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

We are developing several new products that we intend to introduce in 2006 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. In October 2005, we invested an additional \$1.5 million, increasing our ownership to 68%. 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. There is no assurance as to the timing of or cost of completing a marketable device or whether it will be completed.

In January 2005, we first introduced the TEGO Connector product, a new connector for use in hemodialysis, and expect a full scale launch in 2006. In 2005, we launched a new Y-CLAVE connector with integral check valve, which we are already using in our own production. In 2006, we will launch the Orbit 90 diabetes set, a novel male luer connection device, and a line of oncology I.V. therapy products. There is no assurance as to the levels of sales we will achieve with this new product.

Marketing and Distribution

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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, 2006, we employed 73 product specialists worldwide to support our medical product manufacturing customers and our 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.

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. The MicroCLAVE, 1o2 Valve, CLC2000, Punctur-Guard, Lopez Valve and Rhino products are purchased and 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 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.

Under the MCDA with Hospira, we manufacture produce for sale, exclusively to Hospira, substantially all the products that Hospira had manufactured at that facility. The majority of the products under the MCDA are critical care products. Hospira retains commercial responsibility for the products we are producing, including sales, marketing, distribution, customer contracts, customer service and billing. We manufacture all critical care products sold by Hospira in the United States and all catheters sold by Hospira outside the United States.

Sales to Hospira accounted for approximately 73%, 53% and 67% of revenue in 2005, 2004 and 2003, respectively. Sales to Hospira under the MCDA accounted for approximately 30% of 2005 revenue. The loss of Hospira as a customer could have a significant adverse effect on our business and operating results.

Independent Domestic Distributors

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

As of January 31, 2006, we had approximately 35 independent distributors in the United States and Canada who employ approximately 600 salespeople in the aggregate and which accounted for approximately 16% of our revenues in 2005. 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 2% of revenue in 2005. 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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

We distribute products principally in Europe, Asia Pacific, Southeast Asia, Latin America, South Africa and the Middle East. Foreign sales (excluding Canada) accounted for approximately \$13.0 million, \$9.0 million and \$5.8 million of our revenues in each of the years 2005, 2004, and 2003, respectively. The International Division currently has approximately 37 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 four business development managers serving Europe and four serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add several more business development managers in 2006. 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.

We manufacture all catheters sold by Hospira outside the United States under the MCDA. We currently deliver those products to Hospira in the United States, for export by Hospira, or ship directly to a Hospira facility outside the U.S. Hospira retains commercial responsibility for those products.

Manufacturing

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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. This facility is currently 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, Y-CLAVE, MicroCLAVE, CLAVE vial access spike, CLC2000, 1o2 Valve, RF150 and 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. The assembly processes for both the BCN and the Winged Set use custom made automated assembly systems.

In May 2005, we purchased a manufacturing facility with approximately 450,000 square feet and related capital equipment in Salt Lake City from Hospira. The building includes approximately 62,000 square feet of class 100,000 clean room space, approximately 36,000 square feet of other manufacturing space, approximately 119,000 square feet of warehouse space and approximately 158,000 square feet of office space. The facility is equipped with 33 molding machines and ancillary equipment and 20 automated or semi-automated assembly machines. We currently manufacture critical care products, including medical devices such as catheters, angiography kits and cardiac monitoring systems.

Excluding products currently assembled in our Salt Lake City facility under the MCDA, 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.

We are moving all molding and automated assembly from our San Clemente and Connecticut facilities to our Salt Lake City facility and expect these moves to be completed by the end of 2006. We are making significant capital improvements to the Salt Lake City facility to accommodate these moves. In addition, we are expanding our production facility in Mexico by 45,000 square feet to accommodate the transfer to Mexico of most of the manual assembly currently done in our Salt Lake City facility, as well as increases in our other product lines. We have already moved some processes to Mexico, and expect these moves to be completed by early 2007.

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.

The products we manufacture in California and Mexico are sterilized in processes which use electron beam (e-beam) radiation. The products we produce in Salt Lake City are currently sterilized in processes using gamma radiation or ethylene oxide gas (EO). The products we assemble in Italy are sterilized using gamma radiation. We prefer to use wherever possible e-beam sterilization because it is quicker and less expensive than gamma radiation or EO. 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. All other sterilization is done by independent contractors.

Government Regulation

Government regulation is a significant factor in the development, marketing and manufacturing of our products. The Food and Drug Administration (FDA) regulates medical product manufacturers and their products under a number of statutes including the Food, Drug and Cosmetic (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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 and European Council Directive 93/42/EEC (ISO) regulations governing medical device manufacturing practices. The FDA, State, Foreign Agencies and ISO require manufacturers to register and subject manufacturers to periodic FDA, State, Foreign Agencies and ISO inspections of their manufacturing facilities. We are a FDA and ISO 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 and ISO'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 QSR and ISO standards would cause the products produced to be considered in violation of the applicable law and subject to enforcement action. The FDA and ISO monitor compliance with these requirements by requiring manufacturers to register with the FDA and ISO, and by subjecting them to periodic FDA inspections of manufacturing facilities. If a FDA or ISO 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 ISO regulations. 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, ISO or agencies in other jurisdictions. In addition, changes in FDA, ISO 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 13485. Those quality standards are similar to the QSR regulations.

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 regulation of EN ISO 13485 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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

The market for I.V. products and critical care 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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Medical, Inc. (B. Braun), Alaris Medical Systems (Alaris) 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 market for critical care devices is highly competitive. Competition is based on pricing, customer service and product features. Until recently, Hospira was losing market share to its competitors. It is now expanding sales and marketing efforts, improving customer service and order fulfillment rates and pursuing new products and new product features. There is no assurance that these efforts will be successful.

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, Alaris, Hospira and B. Braun are leading distributors of I.V. therapy systems, Edwards Life Sciences has a significant share of the critical care catheter market, invasive monitoring disposables market and arterial blood sampling system market, Boston Scientific and Merit Medical are competitive in the angiography kit market, 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 achieve greater market penetration or maintain our existing market position, we have established strategic relationships 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 equivalent to or greater than those that we have, and by other companies that 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. 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 products 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 products.

Patents

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

We have United States and certain foreign patents on the CLAVE, TEGO, CLC2000, Punctur-Guard technology, Click Lock, and Piggy Lock I.V. connectors and have United States patents on the Lopez Valve. We have applications pending for additional United States and foreign patents on the 1o2 Valve, TEGO, Y-CLAVE with integral check valve, Orbit 90, CLC2000, CLAVE and Punctur-Guard. 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.

Hospira owns any patents on critical care and other products manufactured under the MCDA and has granted us a license to use those patents to produce products under the MCDA. Any new patents will be owned by us, Hospira or jointly by us and Hospira under terms specified in the MCDA.

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, 2005 we had finance loans receivable of approximately \$3.6 million that are fully secured by real and personal property. We plan to hold the loans to maturity or payoff and have discontinued new lending activities. Weighted average maturity (principal and interest) at December 31, 2005 was 1.5 years and the weighted average interest rate was 5.1%. There were no unfunded commitments at December 31, 2005.

Employees

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

At January 31, 2006 we had 1,373 full-time employees, consisting of 149 engaged in sales, marketing and administration, and 1,224 in manufacturing, molding, product development and quality control, including 573 in Mexico and 491 in Salt Lake City, Utah. We contract with independent temporary agencies to provide some production personnel who are not our employees. At January 31, 2006, the number of temporary production personnel was 100.

Item 1A. Risk Factors.

In evaluating an investment 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 causing a 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 Hospira for a high percentage of our sales. Sales to Hospira increased by approximately \$75.2 million in 2005. Approximately \$46.7 million of the increase was attributable to the purchase of Hospira's Salt Lake City plant and commencement of production under a twenty-year MCDA as of May 1, 2005. The balance of the increase was attributable to the resumption of more normal levels of CLAVE sales to Hospira in 2005 after a sharp decline in 2004 described below. The table below shows our total revenue to various types of customers for 2005, 2004 and 2003 (dollars in millions):

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

	Years Ended December 31,								
	2005		2004		2003				
Hospira (U.S.)	\$	115.0	73%	\$	39.8	53%	\$	71.3	67%
Other manufacturers		2.2	1%		1.5	2%		1.5	1%
Domestic distributors		24.4	16%		22.4	30%		24.1	23%
International distributors		13.0	8%		9.0	12%		5.8	5%
Other revenue		2.9	2%		2.8	3%		4.6	4%

Our principal agreements with Hospira are the MCDA, a strategic supply and distribution agreement for most of our other medical devices in the domestic and international markets and an agreement to sell Hospira custom I.V. systems; the latter two agreements extend through 2014.

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 the third and fourth quarters of 2004. If the steps we have taken to monitor and control the amount of Hospira's inventory of CLAVE products to avoid future inventory reductions are not successful we could experience sharp declines in sales of CLAVE products to Hospira in the future.

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.

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, and exclusive rights to sell products we produce under the MCDA. 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.

Our ability to maintain and increase our market penetration depends on the success of our arrangement with Hospira and Hospira's arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. 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.

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 alternate site 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 to and dependence on Hospira.

If we are unable to reduce substantially the cost of manufacturing products that we will sell to Hospira under the MCDA, our financial performance may be adversely affected.

The prices at which we sell products to Hospira and the gross margins that we realize under the MCDA depend on the cost savings that we expect to achieve in producing those products over Hospira's cost to manufacture the same products at the purchase date. Achieving substantial cost reductions requires 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, our profits on products manufactured under the MCDA will be adversely affected.

The relocation of our manufacturing and assembly operations imposes a significant burden on our resources, will require specialized expertise, will result in interruption of production and will require relocation and training of personnel, any of which could have an adverse effect on our operations and financial results.

We intend to relocate substantial portions of our manufacturing facilities by early 2007. We plan to move all manufacturing in San Clemente, consisting of molding and automated assembly, to our Salt Lake City facility. We also plan to move remaining manufacturing operations in Connecticut to the Salt Lake City facility. We plan to move most of the manual assembly operations currently performed in Salt Lake City to our Ensenada, Mexico facility, although we may move some of them to another low-cost location and expect that some highly skilled processes may stay in Salt Lake City. Before the move to our Ensenada, Mexico facility we will need to build additional production and warehouse space in that facility.

Our performance under the MCDA, the relocation of our California and Connecticut manufacturing operations, the expansion of our Mexico facility, the implementation of new manufacturing and assembly processes and techniques and the establishment of financial controls impose a significant burden on our management, human resources, operating and financial and accounting functions. We 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 divert management's attention from our other operations. In addition, we may require additional expertise, capability and capacity that can best be obtained through other acquisitions.

The molding and assembly machines are large and require special handling to move them. Installation in a new location can be very difficult and require specialized engineering expertise. This will tax our existing resources. At the same time, we will be attempting to relocate personnel who are important to our manufacturing processes, and failure to accomplish this could substantially hamper the installation and operation of the equipment in Salt Lake City. While we expect to build extra inventory before moving equipment, and move the equipment in phases and maintain production at both locations for a period of time, failure to successfully complete the move and installation of the equipment and critical personnel could cause production interruptions and production quality issues which could adversely affect our sales and income.

Certain of the manual assembly operations require expertise that will require significant and ongoing training of the personnel at the location performing the assembly. The products currently made using manual assembly in Salt Lake City are different than the products that we currently make in Mexico. The transfer of production will require a significant transfer of knowledge from Salt Lake City to the new manufacturing location, and if this is not completed successfully, we could experience production interruptions and production quality issues which could adversely affect our sales and income.

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.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

The increasing burdens on our management resources and financial controls resulting from internal growth and 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.

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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

For 2005, CLAVE products accounted for approximately 40% of our revenue and 55% of our revenue including custom I.V. systems incorporating a CLAVE. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. Most of our CLAVE sales are in the United States, where we expect our growth in sales to moderate in the future as further penetration of markets available to our existing customers in the United States becomes increasingly difficult. Future significant sales increases for CLAVE products may depend on increases in sales of custom I.V. systems expansion in the international markets, which we are aggressively pursuing, or acquisition of new customers in the United States. We cannot give any assurance that sales of CLAVE products will increase indefinitely 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 products 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 product business and develop significant market share on a profitable basis and on new product development. Our total sales of custom products including custom I.V. products and custom critical care products reached \$42.6 in 2005, an increase of 63% over 2004; however, only 22% of this increase was in custom I.V. products. Our sales of custom I.V. products 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 product sales program will require a larger increase in sales in the future than was achieved in 2005 and 2004 and there is no assurance that such an increase will be achieved. 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 same functions as our products.

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 our products sold internationally. Our principal competitors in international markets 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 our competitors' lower local labor costs 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, outside of Europe, for product shipped to the customers from the United States or Mexico 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,

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

and may adversely affect their ability to make payment to us for the products 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. Sales and most other transactions by this subsidiary are denominated in Euros. As the subsidiary increases in size, a decline in the value of the Euro in relation to the U.S. dollar could have an adverse effect on our reported operating results. There is no assurance as to the growth of this subsidiary or its future operating results.

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.

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 pricing. The 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. 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.

We may not be able to significantly expand our sales of custom I.V. systems, or critical care products, if we are unable to lower manufacturing costs, price our products competitively and shorten delivery times significantly.

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 competitively 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.

We plan to introduce many of the systems and procedures that we have used in our I.V. systems operations into the production of critical care products. If we are unable to do this successfully, we may not be successful in increasing sales of critical care products.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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. 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.

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. We believe that we have resolved all design, manufacturing and assembly problems with respect to products manufactured in San Clemente and Connecticut. We are continuing our assessment of design, manufacturing and assembly operations at the Salt Lake City facility and that assessment has resulted in changes and will result in future changes, some of which may be significant. There is no assurance that operations will not be adversely affected by unanticipated problems with current or 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 are increasingly dependent on manufacturing in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations

We continue to expand our production in Mexico. In 2005, production costs in Mexico were approximately \$19.0 million. Most of the material we use in manufacturing is imported into Mexico, and substantially all the production in Mexico is exported. We depend on our ability to move goods across the border quickly. Any disruption in the free flow of goods across the border could have an adverse effect on our business.

As of January 31, 2006, we employed 573 people in our plant in Ensenada, Mexico, and expect this to increase in the future. Business activity in the Ensenada area is expanding significantly, providing increasing employment opportunities. This could have an adverse effect on our ability to hire or retain necessary personnel and increase amounts we must pay them. We continue to take steps to compete for labor through attractive employment conditions and benefits, but there is no assurance that these steps will continue to be successful or that we will not face increasing labor costs in the future.

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 substantially higher than what they were six 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. We believe that the move of our San Clemente production to Salt Lake City will substantially mitigate this risk, but we do not expect that move to be completed until approximately the fall of 2006.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Increases in the cost of petroleum-based and natural gas-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 or natural gas as their raw material. Crude oil and natural gas supplies continue to be negatively impacted by the recent hurricanes in the Gulf Coast. Related production and supply problems have had a small impact our ability to get uninterrupted supplies of raw materials, which has caused some minor delay in deliveries of certain products under the MCDA. There is no assurance that these supply problems will not persist or get worse. Also, crude oil and natural gas prices in 2005 are at record highs. Our suppliers have passed some of their cost increases on to us, and if such prices are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs have increased because of the effect of higher crude oil prices, and at least some of these costs have been passed 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 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.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer for new product concepts and manufacturing innovation. Dr. Lopez has conceived 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 \$86.7 million at December 31, 2005, of which over 93% 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 decades for the past four years and, notwithstanding 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. For 2005, the comparable numbers were approximately \$2.2 million and \$82.5 million, respectively; investment income was approximately \$1.8 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 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. In April 2005, we settled litigation against B. Braun. We have ongoing litigation against Alaris, a part of Cardinal, 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 this litigation or litigation we may bring against others violating our patents in the future could 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.

From time to time we 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 FDA under a number of statutes including the 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)/ISO 13485 (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 may be 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 want 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.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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. From the beginning of 2005 through January 2006, our trading price ranged from a high of \$43.09 per share to a low of \$23.01 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 in 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 54% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate its position in our common stock, it could cause a decrease in the price of the common stock that 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 15, 2006 was 2,067,228 shares, or approximately 15% 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.

We have outstanding stock options which may dilute the ownership of existing shareholders

At December 31, 2005, we had outstanding stock options to purchase 4.0 million shares, of which 3.9 million had an exercise price below the market price of our stock. Exercise of those options would dilute the ownership interest of existing shareholders.

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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 of financial reporting and our independent registered public accounting firm to audit and report on the design and effectiveness of our internal controls of financial reporting has been extremely expensive. Further, there is no certainty that we will continue to receive unqualified reports on our internal controls of financial reporting from our independent registered public accounting firm and what actions might be taken by securities regulators or investors if we are unable to obtain an unqualified report.

Item 1B. Unresolved Staff Comments.

None.

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 450,000 square foot building in Salt Lake City, Utah, 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.

We have not been required to pay any penalty to the IRS for failing to make disclosures required with respect to certain transactions that have been identified by the IRS as abusive or that have a significant tax avoidance purpose.

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 infringes one of our patents 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. This case is currently set for trial in October 2006. The outcome of this matter cannot be determined at this time.

In an action filed September 10, 2004 entitled ICU Medical, Inc. v. Fulwider Patton Lee & Utecht, LLP, a law firm (Fulwider), in the Superior Court of California for the County of Orange we allege that Fulwider during the course of its representation of us engaged in various matters for our direct competitors including Alaris and others which directly conflicted with our interests, and committed other acts of negligence and breaches of the attorney-client relationship. On November 16, 2005, the Court enjoined Fulwider from advising or representing Alaris in connection with the matter of ICU Medical, Inc. v. Alaris Medical Systems, Inc. On December 2, 2005, with leave of the Court, we filed an amended complaint naming Cardinal Health 303, Inc. (formerly Alaris Medical Systems, Inc.) as an additional defendant. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. At the current time, the Court has not set a trial date. 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.	58	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	33	Vice President of Marketing
Richard A. Costello	42	Vice President of Sales
Francis J. O'Brien	63	Chief Financial Officer, Secretary and Treasurer
Steven C. Riggs	47	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, Related Stockholder Matters, and Issuer Purchases of Equity Securities.

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:

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

2005	High	Low
First Quarter	\$ 36.33	\$ 23.21
Second Quarter	36.36	30.37
Third Quarter	34.43	27.81
Fourth Quarter	40.00	27.09

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, 2005 we had 123 stockholders of record and we believe we have approximately 10,000 beneficial owners of our Common Stock.

We have a 2003 Stock Option Plan under which we may grant options to purchase our Common Stock to our employees. We also have a 2001 Directors' Stock Option Plan under which we have suspended further grants. We 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. 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, 2005, is as follows:

Number of shares to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a))
(a)	(b)	(c)
4,042,050	\$ 19.29	2,429,018

Item 6. Selected Financial Data.

ICU MEDICAL, INC.SELECTED FINANCIAL DATA

Year ended December 31,
(in thousands, except per share data)

	2005	2004	2003	2002	2001
INCOME DATA:					
Revenue					
Net Sales	\$ 154,621	\$ 72,704	\$ 102,726	\$ 84,218	\$ 69,055
Other	2,911	2,846	4,628	3,589	
Total Revenue	157,532	75,550	107,354	87,807	69,055
Cost of Sales	88,128	39,853	48,444	36,464	28,932
Gross profit	69,404	35,697	58,910	51,343	40,123
Selling, general and administrative expenses	36,992	26,409	23,029	19,871	16,816
Research and development expenses	4,817	3,376	1,757	1,472	1,188
Total operating expenses	41,809	29,785	24,786	21,343	18,004
Income from operations	27,595	5,912	34,124	30,000	22,119
Other income	2,721	1,579	1,123	1,432	1,988
Income before income taxes and minority interest	30,316	7,491	35,247	31,432	24,107
Provision for income taxes	10,459	2,600	12,950	11,750	8,720
Minority interest	(417)	(109)			
Net income	\$ 20,274	\$ 5,000	\$ 22,297	\$ 19,682	\$ 15,387
Net income per common share					
Basic	\$ 1.47	\$ 0.37	\$ 1.62	\$ 1.43	\$ 1.20
Diluted	\$ 1.35	\$ 0.33	\$ 1.48	\$ 1.28	\$ 1.06
Weighted average number of shares					
Basic	13,811	13,691	13,753	13,793	12,841
Diluted	15,040	14,960	15,050	15,352	14,454
Cash dividends per share	\$	\$	\$	\$	\$
CASH FLOW DATA:					
Cash flows from operations, excluding tax benefits from exercise of stock options	\$ 23,034	\$ 23,300	\$ 21,987	\$ 17,905	\$ 20,565
Total cash flows from operations	\$ 27,342	\$ 25,283	\$ 22,829	\$ 28,097	\$ 24,329
BALANCE SHEET DATA:					
Cash and liquid investments	\$ 86,742	\$ 87,341	\$ 73,137	\$ 88,465	\$ 73,027
Working capital	123,875	109,590	102,932	102,564	79,736
Total assets	204,537	164,768	164,288	157,032	117,342
Stockholders' equity	189,198	156,348	156,003	145,387	106,677

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 I.V. therapy applications. Our devices are designed to protect patients from Catheter Related Bloodstream Infections and healthcare workers from exposure to infectious diseases 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 in many of those custom I.V. systems. With the acquisition of Hospira's Salt Lake City plant and commencement of production under a twenty-year Manufacturing, Commercialization and Distribution Agreement with Hospira (MCDA), we are now also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

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 7A. 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 and collectibility

is reasonably assured. Under the terms of all our purchase orders, ownership transfers on shipment. 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. We record warranty returns as an expense and amounts have been insignificant. With certain exceptions, customers 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. We rely on prior payment trends, financial status and other factors to estimate the cash which ultimately will be received. Such amounts cannot be known with certainty at the financial statement date. We regularly review individual past due balances for collectibility. 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 (first in, first out) 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. 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 (SFAS 123(R)), which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. SFAS 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 adopted SFAS 123(R) on January 1, 2006. SFAS 123(R) permits public companies to adopt its requirements using one of two methods. We adopted 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 SFAS 123(R) for all share-based payments granted after the effective date and, based on the requirements of SFAS 123, for all awards granted to employees prior to the effective date that remain unvested on the effective date. We expect to substantially curtail grants of stock options in the future and do not expect to record any significant expenses under SFAS 123(R) for options currently outstanding. However, the amount of expense recorded under SFAS 123(R) will depend upon the number of options granted in the future and their valuation.

We have implemented all 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 has enabled us to capture revenue on the entire I.V. delivery 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 increased our investment in this company in 2005, acquired Hospira's Salt Lake City, Utah manufacturing facility in May 2005 and entered into an agreement to produce critical care products for Hospira, and are continuing to seek other opportunities. However, there is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

Custom I.V. systems and new products will be of increasing importance to us in future years. We expect continued growth in our CLAVE products 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 in our CLAVE business 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 relatively modest. Therefore, we are directing increasing product development, acquisition, sales and marketing efforts to custom I.V. systems and other products that lend themselves to customization and new

products in the U.S. and international markets, and increasing our emphasis on markets outside the U.S.

Our largest customer has been 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, this percentage increased in 2005 to 73%. We expect this percentage to increase 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 MCDA 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 products, and our other products in the U.S. and also outside the U.S.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

On May 1, 2005, we acquired Hospira's Salt Lake City manufacturing facility, related capital equipment, certain inventories and assumed liabilities for \$31.8 million in cash and \$0.8 million of acquisition costs. We entered into a 20-year MCDA with Hospira, under which we produce for sale, exclusively to Hospira, substantially all the products that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products we are producing, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The majority of the products under the MCDA are invasive monitoring and angiography products, which include medical devices such as catheters, cardiac monitoring systems and angiography kits. Sales of products manufactured under the MCDA from May to December 2005 were \$46.7 million. 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 also 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 cost to manufacture those same products at the purchase date. We record revenue net of any such reductions. We give no assurance as to the amounts of future sales or profits under the MCDA.

A substantial portion of the invasive monitoring and angiography products made in Salt Lake City are custom products designed to meet the specific needs of the customer. We believe we can significantly expand the market for custom invasive monitoring and angiography products through cost savings using our proprietary low-cost manufacturing techniques.

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 in these markets.

There is no assurance that we will be successful in implementing our growth strategy. The custom products 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 those 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.

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

Product Line	2005	2004	2003
CLAVE	40%	47%	59%
Custom Products	27%	35%	22%
Critical Care (excluding custom products)	20%		
Punctur-Guard	3%	5%	7%
CLC2000	3%	4%	4%
Other Products	5%	5%	4%
License, royalty and revenue share	2%	4%	4%
Total	100%	100%	100%

Salt Lake City products, including critical care, critical care custom products and other products account for 30% of total revenue for the year ended December 31, 2005. Custom I.V. systems, excluding critical care custom products, were 20% of total revenues for the year ended December 31, 2005.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Most custom I.V. systems include one or more CLAVEs. Total CLAVE sales including custom I.V. systems with at least one CLAVE were \$86.0 million or 55% of total revenue in 2005, \$53.8 million or 71% of total revenue in 2004 and \$78.7 million or 73% of total revenue in 2003.

We sell our I.V. administration products to independent distributors and through agreements with Hospira and certain other medical product manufacturers. Most independent distributors handle the full line of our I.V. administration products. We

sell our invasive monitoring, angiography and I.V. administration products through three agreements with Hospira (the Hospira Agreements). Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors, and the CLC2000 and since 2004, our Punctur-Guard line of blood collection needles. Under a 2001 agreement, we sell custom I.V. systems to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. Under the MCDA, a 2005 agreement, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. The terms of the MCDA extend to 2025. 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, the success of our products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term 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 acquired 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 inventory reductions 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 products 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 non-critical care products among those available to members of those entities. Custom products accounted for approximately \$42.6 million or 27% of total revenue in 2005, including sales under the Hospira SetSource program of approximately \$14.3 million and custom critical care products that we manufactured for Hospira under the MCDA of approximately \$10.8 million. We expect continued increases in sales of custom products. Punctur-Guard product revenues in 2005 were \$4.2 million. In 2004 and 2005, 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. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into the MCDA to produce their invasive monitoring, angiography products and certain other products they had manufactured at that facility. There is no assurance that any of these initiatives will continue to succeed.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 the use of automated assembly equipment for new and existing products, use of larger molds and molding machines, centralization of all proprietary molding in Salt Lake City, expansion of our production facility in Mexico to take over manual assembly currently done in Salt Lake City, and possibly the establishment of other production facilities outside the U.S.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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

Channel	2005	2004	2003
Medical product manufacturers	76%	57%	71%
Independent domestic distributors	16%	31%	23%
International	8%	12%	6%
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. (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 for the convenience of readers.)

	Percentage of Revenues		
	2005	2004	2003
Revenue			
Net sales	98%	96%	96%
Other	2%	4%	4%
Total revenues	100%	100%	100%
Gross profit			
Percentage of net sales	43%	45%	53%
Percentage of total revenues	44%	47%	55%
Operating expenses			
Selling, general and administrative expenses	24%	35%	21%
Research and development expenses	3%	4%	2%
Total operating expenses	27%	39%	23%
Income			
Income from operations	18%	8%	32%
Other income	2%	2%	1%
Income before income taxes and minority interest	20%	10%	33%
Income taxes	7%	3%	12%
Minority interest	0%	0%	0%
Net income	13%	7%	21%

Comparison of 2005 to 2004

Revenues increased \$82.0 million to \$157.5 million in 2005, compared to \$75.6 million in 2004.

Distribution channels: Net U.S. sales to Hospira in 2005 were \$115.0 million, compared to net sales of \$39.8 million in 2004. Net sales of CLAVE Products to Hospira, excluding custom CLAVE I.V. systems increased to \$49.2 million in 2005 from \$24.5 million in 2004. Beginning in the first quarter of 2004, Hospira began decreasing its level of purchases to make a substantial reduction in its inventory of CLAVE products, and this reduced buying continued through the remainder of 2004.

Although Hospira substantially reduced its purchases, information provided by Hospira indicated that its CLAVE unit sales to its customers had continued to increase. Hospira informed us that it had reduced its inventory to the desired level by the end of December 2004. Hospira's purchases of CLAVE products returned to more normal levels in 2005. Sales to Hospira under the SetSource program approximated \$14.3 million in 2005 compared to \$12.1 million in 2004, an increase of 18%. The SetSource increase is attributed to unit sales increases in the custom set market. Sales to Hospira under the MCDA, which began in May 2005, were \$46.7 million or 30% of total revenue. We expect a significant increase in our sales to Hospira in 2006 from the inclusion of critical care products for a full year, continuing growth in sales of custom I.V. systems and a modest percentage growth in CLAVE and other product sales, although there is no assurance that these expectations will be realized.

Net sales to independent domestic distributors (including Canada) increased approximately \$2.0 million, from \$22.4 million in 2004 to \$24.4 million in 2005. Independent domestic distributors had a 17% or \$2.0 million increase in custom I.V. systems and a 17%, or \$0.8 million, increase in CLAVE product sales. Both increases are principally because of an increase in unit volume. These increases were partially offset by a \$1.0 million decrease in sales of Punctur-Guard products due to a decrease in unit sales. We expect that sales to domestic distributors will increase principally from growth in custom I.V. system business, with modest growth in sales of other products, although there is no assurance that these expectations will be realized.

Net sales to international distributors (excluding Canada) were \$13.0 million in 2005, compared with \$9.0 million in 2004, an increase of 45%. Approximately 56% of the increase was attributable to increased sales in Europe, with the balance in Asia Pacific, Latin America and South Africa. The principal product lines showing increases were CLAVE and custom I.V. systems, both on increased unit volumes. We expect significant increases in sales to international distributors across all areas and all principal product lines, although there is no assurance that these expectations will be realized.

Product and other revenue: Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) increased from \$35.4 million in 2004 to \$62.5 million in 2005, or 76%. This increase was primarily due to the resumption in 2005 of more normal levels of unit shipments of CLAVE products to Hospira, discussed above, which increased \$24.8 million from 2004. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$85.9 million in 2005 compared with \$53.8 million in 2004. This increase was due to increased purchases of CLAVE products in all our distribution channels.

Salt Lake City product sales to Hospira were \$46.7 million from May to December 2005, which includes critical care sales and custom critical care sales of \$41.6 million.

Net sales of custom and generic I.V. systems increased approximately \$5.9 million, or 23%, to \$31.8 million in 2005 over 2004, principally because of increased unit volume. The SetSource program with Hospira accounted for approximately \$2.2 million of the increase, domestic distributors accounted for approximately \$2.0 million of the increase and international distributors accounted for the balance of the increase. Unit volume accounted for the majority of the increase.

Net sales of Punctur-Guard products (excluding royalties) were \$4.2 million in 2005 compared to \$3.9 million in 2004. Increased sales to Hospira were offset by a decline in sales to domestic distributors.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Net sales of CLC2000 in 2005 were \$5.2 million compared to \$3.1 million in 2004. The increase is primarily attributable to increases in international sales and sales to Hospira. All distribution channels had increases in sales.

Other revenue consists of license, royalty and revenue shares income and was approximately \$2.9 million in 2005 and 2004 and \$4.6 million in 2003. 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 2005 and 2004, calculated on net sales and excluding other revenue, was 43% and 45%, respectively. The margin decrease in 2005 is due to the addition of the new Salt Lake City products sold to Hospira under the MCDA, which began in May 2005 and have lower margins than most of our traditional products. The average gross margins under the MCDA were 22% for the eight months since inception on May 1, 2005. Excluding the MCDA product sales and related cost of goods sold, our margins calculated on net sales were 52%. The increase in margins from 2004, excluding products under the MCDA was primarily due to greater absorption of fixed overhead because of increased production and greater sales of higher margin products. We expect gross margins in 2006 to improve to 45% to 46% as we make improvements in the Salt Lake City plant and progress on the relocation of manufacturing, although there can be no assurance that these expectations will be realized.

Selling, general and administrative expenses (SG&A) increased by \$10.6 million to \$37.0 million, and were 24% of revenues in 2005, as compared with 35% in 2004. The increase in costs was partially due to a \$3.8 million increase in expenses associated with patent lawsuits against two companies and a lawsuit against a law firm. One of the patent lawsuits was settled in April 2005. The expenses of those lawsuits aggregated \$6.1 million in 2005. Compensation and benefit increases accounted for approximately \$4.9 million, principally from increased bonuses, the addition of our Salt Lake City facility, the addition of new sales personnel and increased compensation. Costs for new product introductions and increased travel costs accounted for approximately \$1.4 million of the increase. We expect SG&A in 2006 to be somewhat higher than in 2005, and be approximately 21% to 23% of revenue, principally because of compensation and travel costs for sales personnel. There can be no assurance that these expectations will be realized.

Research and development expenses (R&D) were \$4.8 million in 2005 compared to \$3.4 million in 2004. The 2005 total includes a \$0.4 million charge for in-process R&D (IPR&D) compared to IPR&D of \$1.2 million in 2004. Both of these IPR&D charges were related to our investment in a company developing a new medical device being designed for use in screening for heart disease. \$1.0 million of costs were incurred by this company in 2005, compared to \$0.3 million in 2004. The remaining increase in R&D is primarily from new R&D activity associated with our new products and new R&D activity in our Salt Lake City facility.

Other income increased \$1.1 million to \$2.7 million in 2005 compared to 2004. The increase was primarily due to an increase in overall yield on invested funds and receipt of a \$0.5 million payment under a settlement agreement.

Minority interest was \$0.4 million in 2005 compared to \$0.1 million in 2004 and represents the minority interest share of the net loss of the company developing a new medical device for use in screening heart disease.

Income taxes were accrued at an effective tax rate of 34.5% in 2005 compared to 34.7% in 2004. The 2005 rate differed from the statutory corporate rate of 35% because of tax credits that are higher than expected on a recurring basis, tax exempt interest and dividends, partially offset by state taxes and losses of a company not included in our consolidated tax return. The 2005 rate was slightly lower than the 2004 rate; see below for discussion of the 2004 effective tax rate. We expect our effective tax rate to increase to approximately 37.5% in 2006 because of lower tax credits and larger losses of a company not included in our consolidated tax return.

Comparison of 2004 to 2003

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

In 2004, we had revenues of \$75.6 million, compared to \$107.3 million in 2003.

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. 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.

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. The CLAVE and custom I.V. system sales increases were both principally due to an increase in unit volume.

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 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.

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.

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 continued growth with this product which is because we are able to give the customer customization instead of standard sets at a competitive price.

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.

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.

Other revenue in 2004 was \$2.8 million compared to \$4.6 million in 2003. Other revenue in 2003 included a one-time license fees of \$2.6 million.

Gross margin for 2004, calculated on net sales and excluding other revenue, was 45% compared to 53% in 2003. 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 have a lower gross margin than most 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.

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

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.

Other 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.

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 of 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.

Liquidity and Capital Resources

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

During 2005, our cash and liquid investments were virtually unchanged. Operating activities generated \$27.3 million cash. We received another \$7.7 million from our stock plans, and \$2.6 million from finance loan repayments. This was offset by the \$32.6 million spent on purchasing the Salt Lake City facility and \$5.5 million in purchases of property and equipment.

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 the impact of integrating new locations from

acquisitions, changes in net income, accounts receivable, inventories, the timing of tax payments and tax benefits from exercise of stock options.

Accounts receivable increased from \$8.9 million at December 31, 2004 to \$23.6 million at December 31, 2005, an increase of \$14.7 million. Approximately 72% of the increase was due to new receivables with Hospira under the MCDA. The remaining increase is principally because revenue (excluding sales to Hospira under the MCDA) in fourth quarter of 2005 was 73% more than revenue in the fourth quarter of 2004, offset by cash collections because shipments were spread relatively evenly over each month of the fourth quarter of 2005.

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. The Salt Lake City plant requires more raw material and work-in-process inventories in relation to sales because of the relatively large number of different products produced and relatively long production cycles. Our inventory balance increased by \$7.0 million from December 31, 2004 because of an increase of \$9.8 million in raw material and work in process, partially offset by a decrease of \$2.8 million in finished goods. On May 1, 2005, we acquired \$10.2 million of raw material and work in process inventory as part of the purchase of the Salt Lake City facility from Hospira. At December 31, 2005, we had \$8.1 million of raw material and work in process inventory in our Salt Lake facility, which accounted for most of the \$9.8 million increase. On December 31, 2004, our finished goods inventory was \$4.2 million because we had increased inventory in anticipation of higher sales levels in the latter part of 2004 which did not materialize. That extra inventory has all been sold, but we have had a modest increase as we build a buffer stock of inventory in preparation for our move of production from San Clemente to Salt Lake City, resulting in a net decrease in finished goods inventory of \$2.8 million. We expect to increase inventories further through the first half of 2006 to provide additional buffer stocks before moving production.

The increase in prepaid expenses and other assets includes a \$1.0 million non-trade receivable associated with certain December stock option exercises being remitted to us from the broker; the payment was received in January 2006. Also included in prepaid expenses and other assets is a \$0.7 million non-trade receivable due from Hospira for costs associated with the MCDA. Accrued expenses increased from \$4.8 million at December 31, 2004 to \$8.8 million at December 31, 2005. Approximately \$1.6 million of this increase was comprised of compensation and benefit accruals associated with our employees at our new manufacturing facility in Salt Lake City. The remaining increase is primarily comprised of increased compensation and benefit accruals and accrued exit costs associated with the relocation of our San Clemente manufacturing facility to our Salt Lake City manufacturing facility.

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 2005 were \$4.3 million on the exercise of options to acquire 541,063 shares as compared to \$2.0 million in 2004 on the exercise of options to acquire 232,711 shares. On January 1, 2006, when we adopt provisions of SFAS 123(R), on accounting for share based payments, these tax benefits will be reflected in financing activities to the extent they are tax benefits in excess of the tax effect of stock option based compensation recognized for financial reporting.

We expect our sales will continue to grow in 2006 compared to 2005. As sales increase, working capital is expected to increase to fund the increase in operations.

Investing Activities: During the 2005, we used cash of \$33.6 million in investing activities. This was comprised of cash paid for acquired assets of \$32.6 million, purchases of property and equipment of \$5.5 million, offset by the net proceeds from sales of liquid investments of \$1.8 million and proceeds from finance loan payments of \$2.6 million.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

We are moving all molding and automated assembly to our Salt Lake City facility from our San Clemente and Connecticut facilities, which will require improvements to our Salt Lake City facility. In addition, we are expanding our production facility in Mexico by 45,000 square feet to take over most of the manual assembly currently done in our Salt Lake City facility. The above moves began in July 2005 and we expect them to be completed by early 2007.

We estimate that capital expenditures in 2006, including the building improvements in our Salt Lake City and Mexico facilities, will be approximately \$12.5 million. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

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, 2005, \$3.6 million in loans were outstanding. Scheduled maturities are: 2006 \$1.2 million; 2007 \$1.1 million and 2008 \$1.3 million. Weighted average maturity (principal and interest) at December 31, 2005 was 1.5 years and the weighted average interest rate was 5.1%. There were no unfunded commitments at December 31, 2005.

Financing Activities: Cash provided by stock options and the employee stock purchase plan, excluding tax benefits, was \$7.7 million in 2005 to purchase 561,329 shares compared to \$3.2 million to purchase 253,592 shares in 2004.

In 2004, we acquired our own common stock for \$10.1 million. We did not acquire shares of our common stock in 2005; however, we may purchase our shares in the future. Future purchases of our common stock, if any, will depend on market conditions and other factors.

We have a substantial 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, and 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 cash and liquid investments along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months.

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 contractual obligations of approximately the following amounts. These amounts exclude purchase orders for goods and services for current delivery. The majority of our purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a commitment liability on the blanket purchase orders. Since we do not have the ability to separate out blanket purchase orders from non-blanket purchase orders for goods and services for current delivery, these amounts are excluded from the table below. The commitments under the MCDA include commitments to fund certain research and development to improve critical care products and develop new products for sale to Hopsira and to provide sales specialists focused on critical care. There are no obligations past 2009. (in thousands)

	2006	2007	2008	2009
MCDA	\$ 6,717	\$ 5,500	\$ 5,500	\$ 5,500
Property and equipment	2,448			
Total	\$ 9,165	\$ 5,500	\$ 5,500	\$ 5,500

Forward Looking Statements

Forward Looking Statements

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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, SG&A, and R&D expense, income, losses, cash flow, new product completion and introductions, changes in working capital items such as receivables and inventory, selling prices, and income taxes;

factors affecting operating results, such as shipments to specific customers, reduced dependence on current proprietary products, expansion in international markets, selling prices, future increases or decreases in sales of certain products and in certain markets and distribution channels, impact of safety legislation, increases in systems capabilities, introduction and sales of new products, manufacturing efficiencies and cost savings, unit manufacturing costs, oil prices, acquisition and use of production equipment and expansion of facilities and assembly capacity, relocation of manufacturing facilities and personnel, expansion of markets and the need for additional facilities, and personnel, 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 contract amendments with Hospira, effect of the acquisition of Hospira's Salt Lake City manufacturing facility and the manufacture of products for Hospira under the MCDA, cost savings and use of our systems and procedures under the MCDA, and the outcome of our strategic initiatives;

regulatory approvals and compliance; 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; factors impacting our stock price; future stock option grants; working capital requirements; foreign currency denominated financial instruments; capital expenditures; acquisitions of other businesses or product lines; indemnification liabilities; contractual liabilities; and common stock repurchases.

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 Item 1A of this Annual Report to the Securities and Exchange Commission. Also, 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 at seven to 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; they

are readily saleable at par at auction dates, and can normally be sold at par between auction dates. As of December 31, 2005, we had no declines in the market values 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, 2005 we had outstanding commercial loans of approximately \$3.6 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. Maturities are three years or less and the weighted average maturity (principal and interest payments) is 1.5 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 to our financial statements. Sales from the U.S. and Mexico 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, except for Italy, where our net Euro position at December 31, 2005 was approximately 2.2 million. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to 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 has 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.

[THE REMAINDER OF THIS PAGE LEFT INTENTIONALLY BLANK]

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

ICU Medical, Inc.

San Clemente, CA

We have audited the consolidated balance sheet of ICU Medical, Inc. and subsidiaries as of December 31, 2005, and the related consolidated statements of income, stockholders' equity and comprehensive income and cash flows for the year then ended. Our audit also included the 2005 financial statement schedule listed at Item 15. These financial statements and the schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ICU Medical, Inc. and subsidiaries as of December 31, 2005, and the results of their operations and their cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles. 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 also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of ICU Medical, Inc.'s and subsidiaries' internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 6, 2006 expressed an unqualified opinion on management's assessment of the effectiveness of ICU Medical, Inc.'s and subsidiaries' internal control over financial reporting and an unqualified opinion on the effectiveness of ICU Medical, Inc. and subsidiaries' internal control over financial reporting.

/s/ McGladrey & Pullen, LLP

Irvine, California
March 6, 2006

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 sheet of ICU Medical, Inc. and subsidiaries (the Company) as of December 31, 2004, and the related consolidated statements of income, stockholders' equity and comprehensive income, and cash flows for each of the two years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in Item 15(a)2 for each of the two years in the period ended December 31, 2004. 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 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 the results of their operations and their cash flows for each of the two 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, for each of the two years in the period ended December 31, 2004, 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.

/s/ Deloitte & Touche LLP

DELOITTE & TOUCHE LLP

Costa Mesa, CA
March 11, 2005

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except share and per share data)

	December 31,	
	2005	2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 6,854	\$ 5,616
Liquid investments	79,888	81,725
Cash and liquid investments	86,742	87,341
Accounts receivable, net of allowance for doubtful accounts of \$593 in 2005 and \$912 in 2004	23,644	8,922
Finance loans receivable - current portion	1,178	2,634
Inventories	15,435	8,429
Prepaid income taxes	3,768	6,576
Prepaid expenses and other current assets	3,522	1,986
Deferred income taxes - current portion	3,473	1,156
Total current assets	137,762	117,044
PROPERTY AND EQUIPMENT, net	52,194	40,934
FINANCE LOANS RECEIVABLE - non current portion	2,422	3,613
INTANGIBLE ASSETS, net	10,963	2,780
DEFERRED INCOME TAXES - non current portion	723	
OTHER ASSETS	473	397
	\$ 204,537	\$ 164,768
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 5,078	\$ 2,693
Accrued liabilities	8,809	4,761
Total current liabilities	13,887	7,454
COMMITMENTS AND CONTINGENCIES		
DEFERRED INCOME TAXES	529	
MINORITY INTEREST	923	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 2005 and 2004, outstanding 14,136,298 and 13,574,969 shares in 2005 and 2004, respectively	1,416	1,416
Additional paid-in capital	60,154	61,751
Treasury stock, at cost 22,314 and 583,643 shares in 2005 and 2004, respectively	(609)	(15,290)
Retained earnings	128,265	107,991
Accumulated other comprehensive income (loss)	(28)	480
Total stockholders equity	189,198	156,348
	\$ 204,537	\$ 164,768

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

ICU MEDICAL, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF INCOME**

(Amounts in thousands, except share and per share data)

	For the years ended December 31,		
	2005	2004	2003
REVENUES:			
Net sales	\$ 154,621	\$ 72,704	\$ 102,726
Other	2,911	2,846	4,628
TOTAL REVENUE	157,532	75,550	\$ 107,354
COST OF GOODS SOLD			
	88,128	39,853	48,444
Gross profit	69,404	35,697	58,910
OPERATING EXPENSES:			
Selling, general and administrative	36,992	26,409	23,029
Research and development	4,817	3,376	1,757
Total operating expenses	41,809	29,785	24,786
Income from operations	27,595	5,912	34,124
OTHER INCOME			
	2,721	1,579	1,123
Income before income taxes and minority interest	30,316	7,491	35,247
PROVISION FOR INCOME TAXES			
	10,459	2,600	12,950
MINORITY INTEREST			
	(417)	(109)	
NET INCOME	\$ 20,274	\$ 5,000	\$ 22,297
NET INCOME PER COMMON SHARE			
Basic	\$ 1.47	\$ 0.37	\$ 1.62
Diluted	\$ 1.35	\$ 0.33	\$ 1.48
Weighted average number of shares			
Basic	13,810,516	13,691,139	13,752,732
Diluted	15,039,890	14,960,378	15,050,437

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**

(Amounts in thousands, except share data)

	Common Stock					Accumulated			
	Number		Additional	Treasury	Retained	Other	Total	Comprehensive	
	of Shares	Amount	Paid-In	Stock	Earnings	Comprehensive		Income	
	Outstanding		Capital			Income			
BALANCE, December 31, 2002	14,087,026	\$ 1,409	\$ 63,284	\$	\$ 80,694	\$	\$ 145,387		
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, net of tax effect of (\$104)						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		(1,729)	6,388			4,659		
Proceeds from employee stock purchase plan	20,881		(55)	571			516		
Comprehensive income									
Net income					5,000		5,000	\$	5,000
Other comprehensive income, net of tax benefit: Foreign currency translation adjustment net of tax effect of (\$143)						303	303		303
BALANCE, December 31, 2004	13,574,969	1,416	61,751	(15,290)	107,991	480	156,348	\$	5,303
Exercise of stock options and related income tax benefits	541,063		(2,421)	14,137			11,716		
Proceeds from employee stock purchase plan	20,266		(63)	544			481		
Research and Development tax credit originating from stock options			887				887		
Comprehensive income									
Net income					20,274		20,274	\$	20,274
Other comprehensive income, net of tax benefit: Foreign currency translation adjustment net of tax effect of \$262						(508)	(508)		(508)
BALANCE, December 31, 2005	14,136,298	\$ 1,416	\$ 60,154	\$ (609)	\$ 128,265	\$ (28)	\$ 189,198	\$	19,766

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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

ICU MEDICAL, INC. AND SUBSIDIARIESCONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	For the years ended December 31,		
	2005	2004	2003
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	\$ 20,274	\$ 5,000	\$ 22,297
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	9,698	8,598	7,361
Provision for doubtful accounts	(181)	298	170
Minority interest	(417)	(109)	
Write-off of in-process research and development	374	1,154	
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired in business combination			
Accounts receivable	(14,656)	15,723	(8,480)
Inventories	3,069	(5,031)	3,462
Prepaid expenses and other assets	(2,247)	(41)	13
Accounts payable	2,210	(358)	(774)
Accrued liabilities	3,263	(552)	(1,548)
Prepaid and deferred income taxes	1,647	(1,382)	(514)
	23,034	23,300	21,987
Tax benefits from exercise of stock options	4,338	1,983	842
Net cash provided by operating activities	27,372	25,283	22,829
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(5,509)	(7,101)	(10,668)
Cash paid for acquisitions, net of cash acquired			(5,882)
Cash paid for acquired assets	(32,606)		
Advances under finance loans		(1,010)	(8,907)
Proceeds from finance loan repayments	2,649	3,670	
Purchases of investments	(60,413)	(23,625)	
Proceeds from sale of investments	62,250	13,250	12,950
Net cash used in investing activities	(33,629)	(14,816)	(12,507)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options and other	7,176	2,689	2,063
Proceeds from employee stock purchase plan	481	503	561
Purchase of treasury stock		(10,133)	(15,324)
Net cash provided by (used in) financing activities	7,657	(6,941)	(12,700)
Effect of exchange rate changes on cash	(162)	303	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,238	3,829	(2,378)
CASH AND CASH EQUIVALENTS, beginning of year	5,616	1,787	4,165
CASH AND CASH EQUIVALENTS, end of year	\$ 6,854	\$ 5,616	\$ 1,787
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for income taxes	\$ 4,465	\$ 1,814	\$ 14,065

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

ICU MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2005, 2004 and 2003

(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. 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:

	2005	2004
Raw material	\$ 9,746	\$ 3,745

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Work in process	4,323	507
Finished goods	1,366	4,177
Total	\$ 15,435	\$ 8,429

d. Property and Equipment

Property and Equipment consist of the following at December 31:

	2005	2004
Machinery and equipment	\$ 38,421	\$ 31,860
Land, building and building improvements	31,588	22,021
Molds	9,123	9,345
Computer equipment and software	6,369	5,020
Furniture and fixtures	2,042	1,678
Construction in progress	3,577	3,778
Total property and equipment, cost	91,120	73,702
Accumulated depreciation	(38,926)	(32,768)
Net property and equipment	\$ 52,194	\$ 40,934

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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
Computer equipment and software	3 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 \$8.0 million, \$7.2 million and \$6.6 million in the years ended December 31, 2005, 2004 and 2003, respectively.

e. Intangible Assets

Intangible assets, amortized on a straight-lined basis, are carried as cost less accumulated amortization were as follows:

	Amortization Life in Years	Cost	December 31, 2005	
			Accumulated Amortization	Net
Patents and licenses	10	\$ 2,843	\$ 1,436	\$ 1,407
MCDA contract	10	8,926	595	8,331
Royalty agreements	6	1,399	668	731
Non compete agreement	5	818	409	409
Other	5 to 10	176	91	85
Total		\$ 14,162	\$ 3,199	\$ 10,963

	Amortization Life in Years	Cost	December 31, 2004	
			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

In 2005, the Company acquired a manufacturing facility from Hospira and entered into a twenty-year Manufacturing, Distribution, Commercialization and Development (MCDA) agreement with them. The Company recorded an intangible asset for the MCDA contract of \$8.9 million (Note 2).

In 2004, the Company 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, the Company 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 2005, 2004 and 2003 was \$1.3 million and

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

\$1.4 million and \$0.7 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 \$1.6 million for 2006, \$1.5 million for 2007, \$1.4 million for 2008, \$1.1 million for 2009 and \$1.0 million for 2010.

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, 2005, 2004 and 2003.

g. Research and Development

The Company expenses research and development costs as incurred.

h. Net Income 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, 2005 and 2004, 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

All of Company's product sales are FOB shipping point and ownership of the product transfers to the customer on shipment by the Company. The Company records sales and related costs when ownership of the product transfers to the customer and collectibility is reasonably assured. 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. With certain exceptions, customers 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. Accounts Receivable

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. This allowance is used to state trade receivables at estimated net realizable value. The Company relies on prior payment trends, financial status and other factors to estimate the cash which ultimately will be received. Such amounts cannot be known with certainty at the financial statement date. The Company regularly reviews individual past due balances for collectibility.

m. 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 the plan in 2005 were approximately \$0.3 million and in 2004 and 2003 were approximately \$0.1 million in each year.

n. Stock Options

The Company accounts for its stock options granted to employees and directors using the intrinsic value method 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 or as to the 2002 Employee Stock Purchase Plan, the Plan is non-compensatory under the provisions of APB Opinion No. 25. 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 2005, 2004, and 2003 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.

	2005		2004		2003
Net income, as reported	\$ 20,274	\$	5,000	\$	22,297
Pro forma adjustment	(924)		(6,327)		(5,131)
Net income (loss), pro forma	\$ 19,350	\$	(1,327)	\$	17,166
Net income (loss) per share					
Basic, as reported	\$ 1.47	\$	0.37	\$	1.62
Diluted, as reported	\$ 1.35	\$	0.33	\$	1.48
Basic, pro forma	\$ 1.41	\$	(0.10)	\$	1.28

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Diluted, pro forma	\$	1.29	\$	(0.10)	\$	1.16
--------------------	----	------	----	--------	----	------

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 adopted the modified prospective method under which it will reflect such costs in its financial statements commencing January 1, 2006 for all options granted on or after that date, as well as the unamortized cost at January 1, 2006, 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 to the extent they are tax benefits in excess of the tax effect of stock option based compensation recognized for financial reporting. Currently, they are 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 6. Acceleration of the vesting of certain options in December 2004 increased the proforma adjustment by approximately \$1.4 million, or \$0.11 per share. As of December 31, 2005, remaining unamortized expense was approximately \$0.1 million.

o. 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. Asset Purchase

On May 1, 2005, the Company acquired a Salt Lake City, Utah manufacturing facility, related capital equipment, certain inventories and assumed liabilities from Hospira, Inc. (Hospira) for approximately \$31.8 million in cash and \$0.8 million in acquisition costs. The Company has a twenty-year Manufacturing, Commercialization and Development Agreement (MCDA) with Hospira under which the Company produces for sale to Hospira on an exclusive basis substantially all the products that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products the Company is producing, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The majority of the products the Company produces 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 to 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. The Company's prices and gross margins on the products it sells to Hospira under the MCDA are based on cost savings that it is able to achieve in producing those products over Hospira's cost to manufacture those same products at the purchase date. The Company records revenue net of any such reductions

The Company is moving all molding and automated assembly to the Salt Lake City location from its San Clemente and Connecticut locations. In addition, the Company is expanding its production facility in Mexico to take over all manual assembly currently done in its Salt Lake City facility. These changes are expected to be completed by early 2007.

Hospira is reimbursing the Company for severance costs and certain other termination costs for workers employed at the Salt Lake City plant at the date of purchase who are involuntarily terminated within two years of the May 1, 2005 date of purchase. The Company will charge to expense as incurred costs of relocating personnel to Salt Lake City, and moving machinery to and installing it in Salt Lake City. Such costs have not been significant to date. The Company expects to pay one-time termination benefits to certain employees in San Clemente and Connecticut who are involuntarily terminated because of the move to Salt Lake City if they continue to render service until terminated and the liability for such benefits is being accrued ratably over the employees' expected service period in accordance with Statement of Financial Accounting Standards (SFAS) No. 146 Accounting for Costs Associated with Exit or Disposal Activities. As of December 31, 2005, the Company has \$0.6 million accrued for these exit costs. The total estimated exit costs associated with these terminations is \$1.2 million. Costs of moving production to Mexico will be capitalized or charged to expense immediately, as appropriate; relocation costs to Mexico are not expected to be material. Total costs of moving, relocation and termination benefits charged to expense in 2005 were approximately \$1.0 million and are included in cost of good sold.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

The Company does not expect to incur a significant loss on the disposition of equipment in San Clemente or Connecticut in connection with the move to Salt Lake City. The management of the Company has not yet determined what to do with building space that will no longer be needed for production, but the management of the Company does not believe that it will incur any loss on that space.

The purchase price of \$31.8 million and acquisition costs of \$0.8 million were allocated to the assets and liabilities assumed based on their estimated fair market values as follows.

Property, plant and equipment	\$	14,547
Inventory		10,195
Intangible asset MCDA		8,926
Liabilities assumed		(1,062)
Total	\$	32,606

3. 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. In October 2005, the Company invested an additional \$1.5 million into this Company, increasing its interest to 68%. The company had no operations prior to the initial 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 \$0.4 million and \$1.2 million of the Company's investment was allocated to in-process research and development (IPR&D) in 2005 and 2004, respectively. The IPR&D was based in part on an independent appraisal, and that amount was charged to research and development expense in the Company's consolidated financial statements. The pro forma effects of this acquisition were not significant. This company incurred a net loss of \$1.0 million in 2005 and \$0.3 million from September through December 2004.

4. 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:

	2005		2004	
Corporate preferred stocks	\$	17,425	\$	25,900
Federal tax-exempt debt securities		60,700		55,825
United States treasury bill		1,763		
	\$	79,888	\$	81,725

The scheduled maturities of the debt securities are: \$2.6 million in 2006, \$7.0 million between 2012-2019, \$11.4 million between 2020-2029 and \$41.5 million after 2029.

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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

	2005		2004		2003	
Corporate dividends	\$	505	\$	263	\$	280
Tax-exempt interest		1,300		799		605
Other interest		392		517		238
	\$	2,197	\$	1,579	\$	1,123

5. Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2005		2004
Salaries and benefits	\$ 3,479	\$	1,540
Professional fees	1,105		915
Incentive compensation	2,548		909
Other	1,677		1,397
	\$ 8,809	\$	4,761

6. 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 or 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. As of January 2005, options may no longer be granted under the 1993 Plan.

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 became 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 33,335 unvested stock options on December 31, 2005. There were no other changes to any stock options.

The Company has substantially curtailed grants of stock options. 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

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 shares of Common Stock granted under the Directors' Plan in 2003, 2004 and 2005 were 45,000, 45,000 and 22,500, respectively. All further grants under the Directors' Plan have been suspended.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

In 2002, the Company adopted the 2002 Employee Stock Purchase Plan (the ESPP) under which U.S. employees other than executive officers of the Company 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, 2005 and 2006 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 20,266 and 20,881 shares of Common Stock under the ESPP Plan in 2005 and 2004, respectively.

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

	Shares	Exercise Price		Weighted Average
		Range		
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	
Granted	171,500	32.92 - 34.79	33.04	
Exercised	(541,063)	5.08 - 37.15	13.64	
Forfeited	(20,562)	13.00 - 40.62	36.55	
Outstanding at December 31, 2005	4,019,958	\$ 5.08 - \$ 39.56	\$ 19.26	
Exercisable at December 31:				
2003	3,368,078	\$ 5.08 - \$ 40.62	\$ 13.06	
2004	4,285,831	5.08 - 40.62	18.03	
2005	3,986,623	5.08 - 39.56	19.21	
Available for grant at December 31, 2005:				
2003 Plan	1,251,000			
Director's Plan	513,750			
	1,764,750			

There are 4,019,958 options outstanding at December 31, 2005 of which 3,534,708 were issued under the 1993 Plan, 249,000 under the 2003 Plan and 236,250 were issued under the Directors' Plan. Of the 33,335 unvested options, 15,000 options are time accelerated options issued in 2001 and the remaining are time vested options granted in 2003 and 2004 with vesting dates in 2006 and 2007. All options expire eleven years after issuance, except for 100,000 options issued under the 2003 Plan in 2004 and 149,000 under the 2003 Plan in 2005, which expire ten years after issuance. Options outstanding at December 31, 2005 were issued as follows:

Range of Exercise Price	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (yrs)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 5.08	7.29	392,008	2.31	\$ 6.00	392,008	\$ 6.00
\$ 8.04	8.17	1,134,644	3.01	\$ 8.17	1,134,644	\$ 8.17
\$ 8.50	10.90	227,405	4.50	\$ 10.43	227,405	\$ 10.43
\$ 11.58	14.63	323,466	5.61	\$ 14.49	323,466	\$ 14.49
\$ 14.81	19.46	193,030	6.05	\$ 18.84	193,030	\$ 18.84
\$ 19.49	29.18	414,491	7.22	\$ 25.89	381,156	\$ 25.97
\$ 29.27	37.08	1,200,664	8.36	\$ 32.59	1,200,664	\$ 32.59
\$ 37.83	39.56	134,250	7.56	\$ 39.03	134,250	\$ 39.03
\$ 5.08	39.56	4,019,958	5.56	\$ 19.26	3,986,623	\$ 19.21

Year of Grant	Options Outstanding	Exercise Price		Weighted Average
		Range		
1996	17,056	\$ 10.25	\$ 10.25	\$ 10.25
1997	392,008	5.08	7.29	6.00
1998	1,136,744	8.04	10.63	8.17
1999	212,079	8.50	14.29	10.62
2000	407,399	9.58	18.63	15.27
2001	404,924	17.00	29.16	24.06
2002	576,025	26.08	39.56	34.23
2003	407,144	24.83	37.08	31.20
2004	295,079	22.59	39.03	31.51
2005	171,500	32.92	34.79	33.04

Dilutive stock options account for the difference in the number of shares used to calculate basic and diluted net income per share and result in incremental shares totaling 1,229,374 in 2005, 1,269,239 in 2004 and 1,297,705 in 2003. The number of options that are anti-dilutive because their exercise price exceeded the average market price of the Company's common stock approximated 791,000, 1,117,000 and 575,000 in 2005, 2004 and 2003, respectively. At December 31, 2005, 3,914,208 outstanding options had exercise prices less than the market price of the Company's common stock and 105,750 had exercise prices greater than the market price of the Company's common stock.

A majority-owned subsidiary of the Company has adopted a stock option plan under which 300,000 shares are reserved for issuance to employees and directors. The terms are similar to the Company's 2003 Plan. The subsidiary options were granted with exercise prices at fair market value at the date of grant and have been issued for approximately 8.5% of the outstanding shares of the subsidiary. As of December 31, 2005, 255,000 stock options are outstanding under this plan and 95,000 are exercisable. There were 165,000 stock options granted in 2005. All outstanding and exercisable stock options have an average exercise price of \$2.00 and a weighted average remaining contractual life of 8.3 years.

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 2005, 2004, and 2003 were used: risk-free interest rate of 4.3, 3.2 and 2.7 percent, respectively; expected option life of 4.0, 4.4 and 4.6 years, respectively; expected volatility of 52, 51 and 51 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: 2005 basic 13,753,000, diluted 15,025,000; 2004 basic 13,691,000, diluted 14,960,000 and 2003 basic 13,378,000, diluted 14,720,000.

7. 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.

8. Income Taxes

The provision (benefit) for income taxes for the years ended December 31, 2005, 2004 and 2003 is as follows:

	2005	2004	2003
Current:			
Federal	\$ 12,206	\$ (524)	\$ 10,762
State	502	(418)	1,040
	12,708	(942)	11,802
Deferred:			
Federal	(1,629)	3,430	838
State	103	112	310
Foreign	(723)		
	(2,249)	3,542	1,148
	\$ 10,459	\$ 2,600	\$ 12,950

Current income taxes payable were reduced from the amounts in the above table by \$4.3 million, \$2.0 million and \$0.8 million in 2005, 2004 and 2003, 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.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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

	2005		2004		2003	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	\$ 10,611	35.0%	\$ 2,622	35.0%	\$ 12,336	35.0%
State income tax, net of federal benefit	933	3.1	266	3.5	994	2.8
Tax-exempt interest and dividends	(530)	(1.7)	(371)	(4.9)	(284)	(0.8)
Tax credits	(1,038)	(3.4)	(418)	(5.6)	(96)	(0.3)
Loss of domestic subsidiary not consolidated for tax purposes	483	1.5	501	6.7		
Provision	\$ 10,459	34.5%	\$ 2,600	34.7%	\$ 12,950	36.7%

The components of the Company's deferred income tax provision for the years ended December 31, 2005, 2004 and 2003, are as follows:

	2005	2004	2003
Allowance for doubtful accounts	\$ 100	\$ (30)	\$ (33)
Inventory reserves	(344)	(244)	101
Accruals	(236)	496	171
State income taxes	(1,575)	605	(508)
Acquired future tax deductions	322	269	359
Depreciation	207	2,446	1,058
Net operation loss carryforward	(723)		
	\$ (2,249)	\$ 3,542	\$ 1,148

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

	2005	2004
Current deferred tax asset:		
Allowance for doubtful accounts	\$ 247	\$ 347
Inventory reserves	864	520
Accruals	1,021	523
State income taxes	1,341	(234)
	\$ 3,473	\$ 1,156
Non-current deferred tax asset:		
Net operating loss carry forwards	\$ 1,571	\$
Valuation allowance	(848)	
	\$ 723	\$
Non-current deferred tax liability:		
Depreciation	\$ (2,674)	\$ (2,275)
Acquired future tax deductions	2,130	2,522
Foreign currency translation adjustments	15	(247)
	\$ (529)	\$

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 \$0.7 million realized since acquisition; most of the balance of \$1.2 million will be realized in approximately equal amounts over the next seven years; (b) the benefit of a portion of Bio-Plexus's net operating loss (NOL)

carryforward of \$1.8 million, less \$0.5 million realized since acquisition, which will be realized in approximately equal amounts over the next seventeen years, (c) reduced by the tax effect of non-amortizable basis differences of \$0.4 million.

Under Section 382 of the Internal Revenue Code, certain ownership changes limit utilization of the NOL carryforwards, and the amount of Bio-Plexus federal NOL carryforwards recorded is the net federal benefit available. Bio-Plexus also has approximately \$18.0 million of Connecticut State NOL carryforwards expiring through 2022. Realization of any significant portion 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.

A domestic subsidiary not consolidated for tax purposes has a NOL of \$1.3 million expiring in 2024 and 2025. The realization of the approximately \$0.5 million benefit of this NOL, is uncertain, so it has been offset by a valuation allowance.

A foreign subsidiary has a NOL carryforward of approximately \$3.2 million expiring in 2007 to 2009, which would have a future benefit of approximately \$1.1 million if it is all realized. The realization of approximately \$0.4 million of this benefit is uncertain and has been offset by a valuation allowance. The Company fully expects to utilize this NOL.

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

9. 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 \$62.5 million of revenues in 2005, \$35.4 million of revenues in 2004 and \$62.9 million of revenues in 2003. Custom I.V. systems, many of which incorporate the CLAVE connector, accounted for \$31.8 million of revenues in 2005, \$26.2 million of revenues in 2004 and \$22.8 million of revenues in 2003. Critical care products, including custom critical care products, accounted for \$42.6 million of revenues in 2005.

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, 2005, 2004 and 2003, the Company had sales of 10 percent or greater of total revenues to one manufacturer of 73%, 53% and 67%, respectively. As of December 31, 2005 and 2004, the Company had Accounts Receivable of 10 percent or more to one manufacture of 68% and 30%, respectively.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

Export sales and sales outside the United States and Canada accounted for 8%, 12% and 5% of consolidated net revenue in 2005, 2004 and 2003, respectively.

As of December 31, 2005, approximately \$18.9 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately \$16.0 million in Mexico and approximately \$2.9 million in Italy.

10. 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: 2006 \$1.2 million; 2007 \$1.1 million and 2008 \$1.3 million. Weighted average maturity (principal and interest) at December 31, 2005 was 1.5 years and the weighted average interest rate was 5.1%. There were no unfunded commitments at December 31, 2005.

11. 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, the company has 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 the Company's products. There is no maximum limit on the indemnification that may be required under these agreements. The Company has never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, the Company does not have any off balance sheet arrangements.

12. Quarterly Financial Data - Unaudited

	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
<u>2005</u>				
Total revenue	\$ 27,085	\$ 40,693	\$ 46,524	\$ 43,230
Gross profit	15,225	16,333	19,276	18,570
Net income	4,417	4,739	5,807	5,311
Net income per share:				
Basic	\$ 0.32	\$ 0.34	\$ 0.42	\$ 0.38
Diluted	\$ 0.30	\$ 0.31	\$ 0.39	\$ 0.35
<u>2004</u>				
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)

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

None.

Item 9A. Controls and Procedures.

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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 Control 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 control 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, 2005 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

To the Board of Directors
ICU Medical, Inc.
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 maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). ICU Medical, Inc.'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 opinion.

A company's internal control over financial reporting is a process designed 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 its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that 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 ICU Medical, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also in our opinion, ICU Medical, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of ICU Medical, Inc. and subsidiaries as of December 31, 2005, and the related consolidated statements of income, stockholders equity and comprehensive income and cash flows of ICU Medical, Inc. and subsidiaries and our report dated March 6, 2006 expressed an unqualified opinion.

/s/ McGladrey &
Pullen, LLP

Irvine, California
March 6, 2006

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, 2005 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 through 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 and Related Stockholder Matters, 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, 2005, and such information is incorporated herein by this reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

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

1. Financial Statements

The financial statements listed below are set forth in Item 8 of this Annual Report.

Reports of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2005 and 2004

Consolidated Statements of Income for the Years Ended December 31, 2005, 2004 and 2003

Consolidated Statements of Stockholders' Equity and Comprehensive Income for the Years Ended December 31, 2005, 2004 and 2003

Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2004 and 2003

Notes to Consolidated Financial Statements

**Form 10-K
Page No.**

2. Financial Statement Schedules

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

Schedule II - Valuation and Qualifying Accounts

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
2.1	Asset Purchase Agreement dated February 25, 2005 between Registrant and Hospira, Inc. (14)
2.2	Letter Agreement dated May 1, 2005 between Registrant and Hospira, Inc. (14)
2.3	Real Estate Purchase Agreement dated February 25, 2005 between Registrant and Hospira, Inc. (14)
2.4	Transition Services Agreement dated May 1, 2005 between Registrant and Hospira, Inc. (15)

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

- 2.5 List of schedules and exhibits to Asset Purchase Agreement, Letter Agreement, Real Estate Purchase Agreement and Transition Services Agreement. (14)
- 2.6 Letter Agreement dated July 13, 2005 between Registrant and Hospira, Inc. re: Asset Purchase Agreement dated February 25, 2005 (15)
- 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)

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

- 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)
- 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)
- 10.16 Manufacturing, Commercialization and Development Agreement between Registrant and Hospira, Inc. effective May 1, 2005 (14)
- 10.17 Employment Agreement between Registrant and George A. Lopez, M.D. effective January 1, 2006
- 10.18 Form of Employment Agreements between Registrant and its Executive Officers effective January 1, 2006
- 10.19 Form of ICU Medical, Inc. 2005 Long Tem Retention Plan (14)
- 10.20 Letter Agreement dated July 8, 2005 between Registrant and Hospira, Inc. re: Manufacturing, Commercialization and Development Agreement effective May 1, 2005 (15)
- 21.1 Subsidiaries of Registrant.
- 23.1 Consent of McGladrey & Pullen LLP.
- 23.2 Consent of Deloitte & Touche LLP
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Edgar Filing: ICU MEDICAL INC/DE - Form 10-K

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.
- (14) Filed as an Exhibit to Registrant s Quarterly Report on Form 10-Q for the Quarter ended March 31, 2005, and incorporated herein by reference
- (15) Filed as an Exhibit to Registrant s Quarterly Report on Form 10-Q for the Quarter ended June 30, 2005, and incorporated herein by reference

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 9, 2006

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 9, 2006
/s/ Francis J. O'Brien Francis J. O'Brien	Chief Financial Officer (Principal Financial Officer)	March 9, 2006
/s/ Scott E. Lamb Scott E. Lamb	Controller (Principal Accounting Officer)	March 9, 2006
/s/ Jack W. Brown Jack W. Brown	Director	March 9, 2006
/s/ John J. Connors John J. Connors	Director	March 9, 2006
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	March 9, 2006
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	March 9, 2006
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	March 9, 2006
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	March 9, 2006

ICU MEDICAL, INC.VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Charged to Costs and Expenses	Additions	Charged to Other Accounts	Write-offs/ Disposals	Balance at End of Period
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
For the year ended December 31, 2005:						
Allowance for doubtful accounts	\$ 912	\$ (181)		\$	\$ (138)	\$ 593