

ICU MEDICAL INC/DE
Form 10-K
March 01, 2007

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006 or

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

For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

951 Calle Amanecer

San Clemente, California

(Address of principal executive offices)

33-0022692

(I.R.S. Employer
Identification No.)

92673

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:
Common Stock, \$0.10 par value

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

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

Indicate by check mark 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 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

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, 2006, the last business day of Registrant's most recently completed second fiscal quarter, was \$549,812,483*.

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of February 23, 2007 was 14,637,307.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for Registrant's 2007 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 2006, are incorporated by reference into Part III of this Report.

* Without acknowledging that any person other than Dr. George A. Lopez is an affiliate, 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 vascular 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 we incorporate our proprietary products into many of those custom I.V. systems. With the acquisition of Hospira, Inc.'s (Hospira) Salt Lake City plant in May 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 34% of our revenue in 2006 exclusive of CLAVEs incorporated into custom I.V. systems. We believe that the CLAVE offers superior infection control benefits for the patient and for 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 reducing our dependence on our current proprietary products by introducing new products and systems and acquiring product lines. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. Under one of our Hospira Agreements, we manufacture all new custom I.V. systems for sale by Hospira and jointly promote the products under the name SetSource®. A majority-owned subsidiary is developing a new medical device for screening heart disease; 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 Hospira's invasive monitoring, angiography products and certain other products they had manufactured at that facility. Custom I.V. and critical care products accounted for approximately \$56.4 million or 28% of total revenue in 2006, including sales under the Hospira SetSource program of approximately \$15.8 million and custom critical care products that we manufactured for Hospira under the MCDA of approximately \$16.9 million. Sales of critical care products, excluding custom products and products we no longer manufacture, were \$49.6 million in 2006. 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.

The principal products that we have introduced in recent years are the TEGO Connector, a new Y-CLAVE connector with integral check valve, the Orbit 90 diabetes set and a line of custom I.V. therapy products for use in oncology. In 2007, we expect to launch the Spiros Closed Male Connector, Genie Closed Vial Access Device, both of which are initially for use in oncology, and DyePod Contrast Management System and other expansion products to the oncology and angiography product lines.

We currently sell substantially all of our products to I.V. product manufacturers and independent distributors. Hospira, our largest customer, accounted for 77% of our revenues in 2006.

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

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

Commission. We also have our code of ethics posted on our website. The information on our website is not incorporated into this Annual Report.

3

I.V. Products

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 rubber 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.

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 was a significant expansion of the previous OSHA mandate that universal precautions be observed to minimize exposure to blood and other body fluids. In 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.

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 \$68.4 million or 34% of our revenue in 2006. CLAVE products and Custom I.V. systems including one or more CLAVEs accounted for \$97.9 million of our revenue in 2006.

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 permits us to design a custom I.V. set to a hospital's or clinician's exact specifications, commence production in Mexico or Italy 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. 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. The current term of the agreement extends 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 2006, net sales of custom I.V. systems were approximately \$39.4 million. Over half of the custom I.V. set growth was in international sales. Domestic distributors accounted for approximately 25% of the growth and the balance was from Hospira SetSource.

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 \$5.4 million of our revenue in 2006.

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 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 \$5.8 million in 2006.

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 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 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 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 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.

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.

Custom Critical Care A substantial portion of the invasive monitoring and angiography products are custom products designed to meet the specific needs of the customer. Most of the critical care products can be sold in custom systems containing specific components to meet the specific needs of the customer, and in some cases, custom made or acquired components. 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, although there is no assurance that we will succeed in this.

Sales of critical care products were \$66.6 million in 2006. This includes custom critical care products but excludes \$9.4 million of products which we no longer manufacture.

Other Products and Revenues

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

When we bought the Salt Lake City manufacturing facility from Hospira, we agreed to continue production of certain products temporarily pending transfer of production of those products to Hospira. We have now discontinued and transferred to Hospira production of products that accounted for \$9.4 million of our revenues in 2006.

We purchased the Punctur-Guard blood collection needle products in 2002. In late 2006, we decided to discontinue production of the product and terminated production in early 2007. Sales of Punctur-Guard products were \$4.9 million in 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

We are developing several new products that we intend to introduce in 2007 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 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%. In February 2007, we increased our ownership to 94%. 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 investment. There is no assurance that a functional device will be developed or as to the timing of or cost of completing a marketable device.

In 2005, we introduced and in 2006, we launched, the TEGO Connector product, a new connector for use as an infection control device for use with dialysis catheters. Also, in 2005, we launched a new Y-CLAVE connector with integral check valve, which we are using in our own production and expect to sell to Hospira in 2007. In 2006, we introduced the Orbit 90 diabetes set, and in 2007 expect to introduce Spiros, a novel male luer connection device, and a line of I.V. therapy products used primarily for the delivery of hazardous medications such as chemotherapy which, if released can have harmful effects to the healthcare worker and environment. Sales of these new products which have been introduced have been minimal to date due to lack of production tooling and some lack of production capacity. We expect to have adequate

tooling and capacity in 2007.

7

There is no assurance as to the levels of sales we will achieve with the new products or whether production will have adequate capacity for a successful launch of these products.

Marketing and Distribution

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

As of January 31, 2007, we employed 82 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, 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, other than those custom sets that Hospira was manufacturing before we entered into the agreement. 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 the Salt Lake City facility that we purchased from Hospira in 2005. The majority of the products under the MCDA are critical care products. Hospira retains commercial responsibility for the products we produce, including sales, marketing, distribution, pricing, 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.

Worldwide sales to Hospira accounted for approximately 77%, 74% and 53% revenue in 2006, 2005 and 2004, respectively. Sales to Hospira under the MCDA accounted for approximately 38% of 2006 revenue and 30% of 2005 revenue. The loss of Hospira as a customer would have a significant adverse effect on our business and operating results.

Independent Domestic Distributors

As of January 31, 2007, we had approximately 37 independent distributors in the United States and Canada who employ approximately 660 salespeople in the aggregate and which accounted for approximately 14% of our revenues in 2006. 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 2006. 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

International distribution is concentrated principally in Europe, Asia Pacific, Southeast Asia, Latin America, South Africa and the Middle East. Foreign sales (excluding Canada) accounted for approximately \$20.6 million, \$13.0 million and \$9.0 million of our revenues in each of the years ended December 31, 2006, 2005 and 2004, respectively. As of January 31, 2007, we had approximately 38 international 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 personnel serving Europe and four serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add more business development managers in 2007. 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.

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

Manufacturing

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

We own a fully integrated medical device manufacturing facility in Salt Lake City, Utah with approximately 450,000 square feet. This building includes approximately 82,500 square feet of class 100,000 clean room space, approximately 36,000 square feet of other manufacturing space, approximately 104,000 square feet of warehouse space and approximately 155,000 square feet of office space. We acquired the Salt Lake City manufacturing facility from Hospira in 2005. We completed significant improvements to that facility in 2006 and in the summer of 2006 we moved all production in San Clemente, consisting of molding and automated assembly of CLAVE and certain other products, to Salt Lake City. This facility is currently equipped with 61 injection molding machines and ancillary equipment and 40 automated or semi-automated assembly machines. These sophisticated, highly automated assembly systems are designed to minimize human intervention and assemble the CLAVE, Y-CLAVE, MicroCLAVE, CLAVE vial access spike, CLC2000, 1o2 Valve, RF150, B. Braun Protected Needle products and our critical care products, including catheters, angiography kits and cardiac monitoring systems. The assembly systems are custom designed and manufactured for us. 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.

Most of our manual assembly is done at our facility in Ensenada, Baja California, Mexico. This facility includes approximately 105,000 square feet of production and warehousing space and an electron beam sterilizer. We are currently adding an additional 136,000 square feet of warehouse and clean room space to this facility which should be completed in the spring of 2007. Principal products assembled manually are I.V. therapy systems and custom angiography systems and kits, the Lopez Valve, and CLAVE ancillary products and accessories and critical care products. We have been transferring manual assembly from the Salt Lake City manufacturing facility we acquired from Hospira to the Mexico facility. We expect the expansion in Mexico to be adequate for growth of our business and the completion of the transfer of manual production from Salt Lake City to Mexico.

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 have no contracts with our suppliers beyond the terms of purchase orders issued.

The majority of the non critical care products we manufacture are sterilized in processes which use electron beam (e-beam) radiation. Most critical care products and other certain products are currently sterilized in processes using gamma radiation or ethylene oxide gas (EO). The products we assemble in Italy are sterilized using gamma radiation. In February

2004, we commenced operation of our own sterilization facility at our plant in Mexico that is used to sterilize most of the product assembled in Mexico. All other sterilization is done by independent contractors.

Following the move of San Clemente production to Salt Lake City in the summary of 2006, we sold the building in San Clemente which housed most of the molding and automated assembly in September 2006. We currently have two buildings in San Clemente with a total of approximately 67,000 square feet, used for corporate offices, warehouse and research and development.

In 2006, we purchased a 21,000 square foot building near the facility we bought in northern Italy in 2003. We assemble I.V. therapy systems at that plant, and it also serves as our European distribution center.

We also have a 37,500 square foot facility in Vernon, Connecticut, where we manufactured the Punctur-Guard products. It also houses MedScanSonics, Inc., our 94% owned subsidiary. We are currently considering future utilization of the building, and it may be sold.

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 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 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

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 improved production processes and higher volume production.

Our present and future products compete with needleless I.V. connection systems like those marketed by Baxter Healthcare Corporation, B. Braun Medical, Inc. (B. Braun), Cardinal Healthcare (Cardinal), Becton Dickinson (BD) 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. Under the MCDA we have established specific resources to support the sales and marketing efforts of these products and are pursuing new products and new product features to increase the sales of these product lines. There is no assurance that these efforts will be successful.

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, Cardinal, 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, while Boston Scientific and Merit Medical are competitive in the angiography kit 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 product requirements in these areas. 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

We have United States and certain foreign patents on the CLAVE, CLC2000, Punctur-Guard technology, Click Lock technology, Custom Set Design and Manufacturing Methods 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, Spiros Closed Male Connector, Genie Closed Vial Access Device and DyePod Contrast Management System and Custom Set Design and Manufacturing Methods. The expiration dates of our patents range from 2007 to 2023. 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, 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.

Employees

At January 31, 2007 we had 1,819 full-time employees, consisting of 164 engaged in sales, marketing and administration, and 1,655 in manufacturing, molding, product development and quality control, including 1,166 in Mexico. We contract with independent temporary agencies to provide some production personnel who are not our employees. At January 31, 2007, the number of temporary production personnel was 96.

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 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. As a result, we depend on Hospira for a high percentage of our sales. U.S. sales to Hospira increased by approximately \$33.4 million in the year ended December 31, 2006 compared to the year ended December 31, 2005. Approximately \$29.1 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 table below shows our total revenue attributable to various types of customers for 2006 and 2005 (dollars in millions):

	Years Ended December 31,					
	2006			2005		
Hospira (U.S.)	\$ 148.4	74	%	\$ 115.0	73	%
Other manufacturers	2.1	1	%	2.2	1	%
Domestic distributors	27.7	14	%	24.4	16	%
International customers	20.6	10	%	13.0	8	%
Other revenue	2.8	1	%	2.9	2	%

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 to Hospira; 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 fluctuations in sales of CLAVE products to Hospira in the future.

Except for price reductions for critical care products based on cost savings that we share with Hospira under the terms of the MCDA, our prices to Hospira have declined by only a small amount in the past several years. 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 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 date we purchased the Salt Lake City facility from Hospira. 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. While we have succeeded in reducing costs to date, there is no assurance of the longer term success of these efforts. If we are unable to achieve the cost savings that we expect, our profits on products manufactured under the MCDA will be adversely affected.

Expansion of our manufacturing facilities may result in inefficiencies which could have an adverse effect on our operations and financial results.

In the fourth quarter of 2006, we experienced significant production inefficiencies following a large increase in production volume in Mexico and the transfer of San Clemente production to Salt Lake City. We are currently expanding our Mexico facility and anticipate further increases in volume at that facility. This increase may require further expansion of the workforce. Turnover among new employees is unusually high in Mexico, and the additional time spent in classroom training and on the job training could create production inefficiencies in Mexico in the future. The addition of new products will require additional molding in Salt Lake City, manual assembly work in Mexico and eventually additional automated assembly work in Salt Lake City. The effect of any inefficiencies can be particularly expensive in Salt Lake City because of the high fixed costs in this highly automated facility. Expansions of our production capacity will require significant management attention to avoid inefficiencies of the type experienced in 2006.

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

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

The 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.

For the year ended December 31, 2006, CLAVE products accounted for approximately 34% of our revenue and 49% 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 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.

We believe that the success of the CLAVE has motivated, and will continue to motivate, others to develop one piece needless 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 \$56.4 million in the year ended December 31, 2006, an increase of 32% over the same period in 2005; 55% of this increase was in custom I.V. products. Sales of custom I.V. products increased by 24% in 2006 as compared with the same period in 2005, 23% in 2005 over 2004, and 15% in 2004 over 2003. 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 or sustained. 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 denominated in U.S. dollars, but their resale prices are set in their local currency. A decline in the value of the local currency in relation to the U.S. dollar may adversely affect their ability to profitably sell in their market the products they buy from us, and may adversely affect their ability to make payment to us for the products they purchase. Legal recourse for non-payment of indebtedness may be uncertain. These factors all contribute to a potential for credit losses.

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

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 Euro-denominated sales increase in relation to our total sales, 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 may 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.

If demand for our 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.

We have been and will be ordering production molds for our new products such as the Tego, Orbit 90, Spiros closed male luer and Genie vial access device. We have ordered an automated assembly machine for the Y-CLAVE connector with integrated check valve, and expect to order semi-automated or fully automated assembly machines for the other new products in 2007. If we do not achieve significant sales of these new products, it might be necessary for us to account for impairment in value of the production tooling because it costs 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 significant design, manufacturing and assembly problems with respect to products historically manufactured in San Clemente and Connecticut. We are continuing our assessment of design, manufacturing and assembly operations for critical care products made 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 nine 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 2006, production costs in Mexico were approximately \$39.6 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 December 31, 2006, we employed 1,076 people in our plant in Ensenada, Mexico and we expect to increase in the number of employees in Mexico in the second half of 2007. 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 result in an increase in labor rates. 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 the cost of petroleum-based and natural gas-based products or loss of supply 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 markets are being affected by political uncertainty in the Middle East, and there is no assurance that there will not be an interruption in crude oil supplies. Any such interruption could have an adverse effect on our ability to produce our products. Also, crude oil and natural gas prices in 2006 reached record highs, and continue to be substantially above historical levels. 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 we believe most 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.

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.

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. We have had litigation against Alaris, a part of Cardinal, for alleged infringement of our patents. We believe the alleged infringement had and continues to have an adverse effect on our sales. Failure to prevail in litigation we bring against for violating our patents could adversely affect our sales.

In the past, we have faced patent infringement claims related to the CLAVE and the CLC-2000. We believe these claims had no merit, and all have been settled or dismissed. In July 2006, a patent infringement claim related to the CLC-2000 and TEGO was filed against us. We believe we are not infringing and that there is not any significant financial exposure. We intend to vigorously defend ourselves in this action. 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 Food and Drug Administration (FDA) under a number of statutes including the Food Drug and Cosmetics (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 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 maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. There is no assurance 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.

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

Investors should refer to the description of the Plan in our Current Report to the Securities and Exchange Commission on Form 8-K dated July 15, 1997 filed July 23, 1997, as updated by our Current Report dated January 30, 1999 filed February 9, 1999, and the terms of the Rights set forth in an Amended and Restated Rights Agreement, dated as of May 10, 2002 between ICU Medical, Inc. and Mellon Investor Services, L.L.C., as Rights Agent, which are filed as an exhibit to the May 14, 2002 Form 8-A/A. The Plan expires on August 7, 2007, and the Board of Directors has not yet made a decision on the adoption of a new plan or what its provisions may be.

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 January 2006 through January 2007, our trading price ranged from a high of \$48.51 per share to a low of \$33.48 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 January 15, 2007 was 1,754,705 shares, or approximately 12% 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, 2006, we had outstanding stock options to purchase 3.5 million shares, 99% of which 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.

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 over financial reporting and our independent registered public accounting firm to audit and report on the design and effectiveness of our internal controls over financial reporting has been extremely expensive. Further, there is no certainty that we will continue to receive unqualified reports on our internal controls over 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 a 39,000 square foot building and a 28,000 square foot building in San Clemente, California, a 450,000 square foot building in Salt Lake City, Utah, a 37,500 square foot building in Vernon, Connecticut, a 105,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico and a 17,000 square foot and a 21,000 square foot building in Roncanova, Italy.

20

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. in the United States District Court for the Central District of California, we alleged that Alaris infringes ICU's patent in the manufacture and sale of the SmartSite and SmartSite Plus Needle-Free Valves and Systems. On August 2, 2004 the Court denied our request for a preliminary injunction. On December 27, 2004, our complaint was amended to allege that Alaris infringes three additional patents. On July 17, 2006, the Court issued an order interpreting certain claims in certain of our patents in a manner that, if upheld, could significantly impair our ability to enforce those patents against others, including Alaris. The Court also issued a partial summary judgment in favor of Alaris based on one of those interpretations. On January 22, 2007, the Court issued an order granting Alaris summary judgment motion of invalidity as to the remaining claims asserted against Alaris and on February 22, 2007, the Court entered judgment dismissing those claims. We intend to appeal the Court's judgment. The Court's order has not affected all claims under the patents in the suit and we have other patents expected to issue that would potentially be enforceable against Alaris and other competitors, although there can be no certainty that those patents will issue or that we would succeed in enforcing them. 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 (Fulwider), in the Superior Court of California for the County of Orange, we alleged that during the course of its representation of us and continuing thereafter, Fulwider engaged in various matters for our direct competitors, including Alaris and others, and committed other acts of negligence and breaches of the attorney-client relationship. 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. On March 27, 2006, the Court sustained Alaris' demurrers to an amended complaint without leave to amend, effectively removing Alaris as a defendant. As of January 2, 2007, the Company and Fulwider agreed to settle the action against Fulwider for a payment to the Company of \$8 million. We received the payment in January 2007. We are seeking appellate review of the Court's ruling sustaining Alaris' demurrers. The outcome of the proceeding cannot be determined at this time.

In an action filed July 6, 2006 entitled Medegen MMS, Inc. v. ICU Medical, Inc. pending in the United States District Court for the Central District of California, Medegen alleges that ICU Medical infringes one of its patents by the offering for sale and selling the CLC 2000 and Tego, and Medegen seeks monetary damages and injunctive relief. We believe we are not infringing and that there is not any significant financial exposure, other than the cost of litigation. We intend to vigorously defend ourselves in this action.

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.	59	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	34	Vice President of Marketing
Richard A. Costello	43	Vice President of Sales
Scott E. Lamb	44	Controller
Francis J. O'Brien	64	Chief Financial Officer, Secretary and Treasurer
Steven C. Riggs	48	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. Lamb became Controller in April 2003. Prior to joining ICU, he held various finance positions. The last two were at GE Medical Systems Information Technologies and Vitalcom, Inc.

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:

2006	High	Low
First Quarter	\$ 43.09	\$ 33.72
Second Quarter	43.90	33.48
Third Quarter	46.81	39.79
Fourth Quarter	48.51	39.88
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 or to purchase our shares. Any future determination as to payment of dividends or purchase of our shares will depend upon our financial condition, results of operations and such other factors as the Board of Directors deems relevant.

As of December 31, 2006 we had 424 stockholders of record and we believe we have approximately 10,100 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 3 to the Consolidated Financial Statements. Certain information about the plans at December 31, 2006, 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)
3,453,707	\$20.41	2,365,904

Issuer Repurchase of Equity Securities

The following is a summary of our stock repurchasing activity during the third and fourth quarters of 2006:

Period	Shares purchased	Average price paid per share	Shares purchased as part of a publicly announced program	Approximate dollar value that may yet be purchased under the program
07/1/2006 - 07/31/2006		\$		\$ 14,000,000
08/1/2006 - 08/31/2006	72,650	41.14	72,650	11,000,000
09/1/2006 - 09/30/2006	22,405	44.55	22,405	10,000,000
Third quarter 2006 total	95,055	\$ 41.94	95,055	
10/1/2006 - 10/31/2006	21,850	\$ 45.77	21,850	\$ 9,000,000
11/1/2006 - 11/30/2006	23,633	42.31	23,633	8,000,000
12/1/2006 - 12/31/2006	24,785	40.32	24,785	7,000,000
Fourth quarter 2006 total	70,268	\$ 42.68	70,268	

We have a stock repurchase program, originally announced in July 2006. In August 2006, our Board of Directors authorized a \$14.0 million program. This program was terminated in January 2007 after purchasing shares with a cost of approximately \$8.0 million. Also in January 2007, we announced an expanded program to purchase up to at least \$20 million of our shares. However, additional share repurchases may be made as we deem appropriate based upon prevailing market and business conditions.

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

COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2002 TO DECEMBER 31, 2006 AMOUNT ICU MEDICAL, INC., THE NASDAQ, NASDAQ MEDICAL DEVICES INDEX AND PEER GROUP

The following graph shows the total stockholder return on our common stock based on the market price of the Common Stock from January 1, 2002 to December 31, 2006 and the total returns of the Nasdaq Stock Market Tier Index and Common Stocks of a peer group selected by us for the same period.

	12/31/01	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06
ICU Medical, Inc.	\$ 100.00	\$ 125.72	\$ 115.57	\$ 92.15	\$ 132.15	\$ 137.11
Nasdaq	\$ 100.00	\$ 69.13	\$ 103.36	\$ 112.49	\$ 114.88	\$ 126.22
Nasdaq Medical Devices Index	\$ 100.00	\$ 80.89	\$ 119.67	\$ 140.20	\$ 153.93	\$ 162.34

Assumes \$100 invested on December 31, 2001 in ICU Medical Inc.'s Common Stock, the Nasdaq Stock Market National Market Tier Index and the Nasdaq Medical Devices Index.

Item 6. Selected Financial Data.

ICU MEDICAL, INC.SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2006	2005	2004	2003	2002
INCOME DATA:					
Revenue					
Net Sales	\$ 198,788	\$ 154,621	\$ 72,704	\$ 102,726	\$ 84,218
Other	2,825	2,911	2,846	4,628	3,589
Total Revenue	201,613	157,532	75,550	107,354	87,807
Cost of goods sold	120,929	88,128	39,853	48,444	36,464
Gross profit	80,684	69,404	35,697	58,910	51,343
Selling, general and administrative expenses	44,245	36,992	26,409	23,029	19,871
Research and development expenses	7,659	4,817	3,376	1,757	1,472
Gain on sale of building	(2,093)				
Total operating expenses	49,811	41,809	29,785	24,786	21,343
Income from operations	30,873	27,595	5,912	34,124	30,000
Other income	4,462	2,721	1,579	1,123	1,432
Income before income taxes and minority interest	35,335	30,316	7,491	35,247	31,432
Provision for income taxes	(10,240)	(10,459)	(2,600)	(12,950)	(11,750)
Minority interest	565	417	109		
Net income	\$ 25,660	\$ 20,274	\$ 5,000	\$ 22,297	\$ 19,682
Net income per common share					
Basic	\$ 1.78	\$ 1.47	\$ 0.37	\$ 1.62	\$ 1.43
Diluted	\$ 1.64	\$ 1.35	\$ 0.33	\$ 1.48	\$ 1.28
Weighted average number of shares					
Basic	14,412	13,811	13,691	13,753	13,793
Diluted	15,599	15,040	14,960	15,050	15,352
Cash dividends per share	\$	\$	\$	\$	\$
CASH FLOW DATA:					
Cash flows from operations, excluding tax benefits from exercise of stock options	\$ 31,608	\$ 23,034	\$ 23,300	\$ 21,987	\$ 17,905
Total cash flows from operations	\$ 31,608	\$ 27,342	\$ 25,283	\$ 22,829	\$ 28,097
BALANCE SHEET DATA:					
Cash and liquid investments	\$ 116,918	\$ 86,742	\$ 87,341	\$ 73,137	\$ 88,465
Working capital	155,519	123,875	109,590	102,932	102,564
Total assets	244,248	204,537	164,768	164,288	157,032
Stockholders' equity	224,887	189,198	156,348	156,003	145,387

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

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous (I.V.) therapy applications. Our devices are designed to protect 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 we incorporate our proprietary products in many of those custom I.V. systems. With the acquisition of Hospira's Salt Lake City plant in May 2005 and commencement of production under a twenty-year Manufacturing, Commercialization and Development 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 a few 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 agreements 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

As described in Note 2 and Note 3 to the Condensed Consolidated Financial Statements, we implemented Financial Accounting Standards Board (FASB) Statement No. 123 (revised 2004) Share Based Payment as of January 1, 2006. The effect of adoption was not significant to our financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes , an interpretation of FASB Statement No. 109 (FIN 48), which provides criteria for the recognition, measurement, presentation and disclosure of uncertain tax positions. A tax benefit from an uncertain position may be recognized only if it is more likely than not that the position is sustainable based on its technical merits. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006 and we will adopt the new requirements in its fiscal first quarter of 2007. The cumulative effects, if any, of adopting FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. We do not expect that FIN 48 will have a material effect on our consolidated financial condition or results of operations.

Statement of Financial Accounting Standards No. 157, Fair Value Measurements (SFAS 157), defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. We will adopt the provisions of SFAS 157 effective January 1, 2008. We do not expect SFAS 157 to have a material impact on our results of operations, financial position, or cash flows.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective for us on January 1, 2008. The provisions of SFAS 159 are elective, and we have not determined whether and to what extent we may implement its provisions or how if implemented, it might affect our financial statements.

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 made our initial investment in a company developing a new medical device in 2004, acquired Hospira's Salt Lake City, Utah manufacturing facility in May 2005 and entered into the MCDA 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.

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

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In 2006, 2005 and 2004, our revenue from U.S. sales to Hospira was 74%, 73% and 53%, respectively. We expect this percentage will be maintained in the future as a result of sales of CLAVE products, custom I.V. sets, new products and critical care products to Hospira. 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.

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, primarily critical care, 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 were \$75.8 million in 2006 and \$46.7 million from May to December 2005, including products that we no longer manufacture of \$9.4 million and \$5.7 million in 2006 and 2005, respectively. 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 critical care 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 both in Salt Lake City and Mexico.

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	2006	2005	2004
CLAVE	34 %	40 %	47 %
Custom Products	28 %	27 %	35 %
Critical Care (excluding custom products)	25 %	20 %	%
CLC2000	3 %	3 %	4 %
Other Products	9 %	8 %	10 %
License, royalty and revenue share	1 %	2 %	4 %
Total	100 %	100 %	100 %

Critical care, including critical care custom products accounted for 38% and 30% of total revenue for the years ended December 31, 2006 and December 31, 2005, respectively. Custom I.V. systems, excluding critical care custom products, were 20% of total revenues for the years ended December 31, 2006 and 2005.

Most custom I.V. systems include one or more CLAVEs. Total CLAVE sales including custom I.V. systems with at least one CLAVE were \$97.9 million or 49% of total revenue in 2006, \$86.0 million or 55% of total revenue in 2005 and \$53.8 million or 71% of total revenue in 2004.

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. 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.

We are reducing our dependence on our current proprietary products by introducing new products and systems and acquiring product lines. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors. Under one of our Hospira Agreements, we manufacture custom I.V. systems for sale by Hospira and jointly promote the products under the name SetSource. In 2004, we made our initial investment 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. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. Custom I.V. and critical care products accounted for approximately \$56.4 million or 28% of total revenue in 2006, including sales under the Hospira SetSource program of approximately \$15.8 million and custom critical care products that we manufactured for Hospira under the MCDA of approximately \$16.9 million. We expect continued increases in sales of custom products. Sales of critical care products, including custom products and products we no longer manufacture were \$58.9 million in 2006. 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.

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 and use of larger molds and molding machines. In 2006, we centralized our proprietary

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

molding in Salt Lake City and expanded our production facility in Mexico which has taken over the majority of our manual assembly previously done in Salt Lake City. We may establish other production facilities outside the U.S.

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

Channel	2006	2005	2004
Medical product manufacturers	76 %	76 %	57 %
Independent domestic distributors	14 %	16 %	31 %
International customers	10 %	8 %	12 %
Total	100 %	100 %	100 %

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S., but used in I.V. products manufactured by Hospira and exported. Those sales are included in sales to medical product manufacturers. Other sales to Hospira for destinations outside the U.S. are included in sales to international customers.

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.

	Percentage of Revenues					
	2006		2005		2004	
Revenue						
Net sales	99 %		98 %		96 %	
Other	1 %		2 %		4 %	
Total revenues	100 %		100 %		100 %	
Gross profit	40 %		44 %		47 %	
Selling, general and administrative expenses	22 %		23 %		35 %	
Research and development expenses	3 %		3 %		4 %	
Gain on sale of building	1 %		%		%	
Total operating expenses	24 %		26 %		39 %	
Income from operations	16 %		18 %		8 %	
Other income	2 %		2 %		2 %	
Income before income taxes and minority interest	18 %		20 %		10 %	
Income taxes	5 %		7 %		3 %	
Minority interest	0 %		0 %		0 %	
Net income	13 %		13 %		7 %	

Comparison of 2006 to 2005

Revenues increased \$44.1 million to \$201.6 million in 2006, compared to \$157.5 million in 2005.

Distribution channels: Net U.S. sales to Hospira in 2006 were \$148.4 million, compared to net sales of \$115.0 million in 2005, an increase of \$33.4 million or 29%. Net sales of CLAVE products to Hospira, excluding custom CLAVE I.V. systems, increased to \$52.7 million in 2006 from \$49.2 million in 2005, an increase of 7% on increased unit volume. Sales to Hospira under the SetSource program approximated \$15.8 million in 2006 compared to \$14.3 million in 2005, an increase of 11%. 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 \$75.8 million or 38% of total revenue in 2006 and were \$46.7 million or 30% of total revenue in 2005. This includes sales of \$9.4 million and \$5.7 million in 2006 and 2005, respectively, for a product we discontinued manufacturing of under the MCDA in October 2006. We expect an increase in our sales to Hospira in 2007 from continued growth in critical care, and 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) were \$27.7 million, an increase of approximately \$3.3 million or 13%, from \$24.4 million in 2005. Independent domestic distributors had a 14% or \$1.9 million increase in custom I.V. systems and a 15%, or \$0.8 million, increase in CLAVE product sales. Both increases are principally because of an increase in unit volume. 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, including new products, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were \$20.6 million in 2006, compared with \$13.0 million in 2005, an increase of 58%. Approximately 87% of the increase was attributable to increased sales in Europe, 9% of the increase was attributable to increased sales in South Africa. The principal product lines showing increases were custom I.V. systems and CLAVE, both on increased unit volumes. We expect significant increases in sales to international customers 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 \$62.5 million in 2005 to \$68.4 million in 2006, an increase of \$5.9 million or 10%. This increase was primarily due to increased sales to Hospira of \$3.5 million from 2005 and increased international sales of \$1.9 million. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$97.9 million in 2006 compared with \$85.9 million in 2005. This increase was due to increased purchases of CLAVE and custom CLAVE products in all our distribution channels.

Sales to Hospira of critical care products, excluding custom critical care products and products we no longer manufacture, were \$49.5 million in 2006 and \$30.2 million from May to December 2005.

Net sales of custom products, including custom critical care products, were \$56.4 million in 2006 compared to \$42.6 million in 2005. The \$13.8 million and 32% increase over 2005 was principally from increased unit volume sales. The higher revenue was from increases in custom critical care product sales under the MCDA of \$6.1 million which was due to higher sales and to the inclusion of only the last eight months of 2005 under the MCDA, international sales of \$4.3 million, the SetSource program with Hospira of \$1.5 million and domestic distributors of \$1.9 million.

Net sales of CLC2000 in 2006 were \$5.4 million compared to \$5.2 million in 2005. The increase was from modest increases in domestic and international distributors, offset by lower purchases by Hospira.

Sales of other products were \$19.1 million and \$14.1 in 2006 and 2005, respectively. The 2006 and 2005 sales include \$9.4 million and \$5.7 million of sales of a product we no longer manufacturer under the MCDA. Other product sales also include net sales of Punctur-Guard products (excluding royalties) of \$4.9 million in 2006 and \$4.2 million in 2005, which is being phased out of production in the first quarter of 2007.

Other revenue consists of license, royalty and revenue share income and was approximately \$2.8 million in 2006 and \$2.9 million in 2005. 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 2006 and 2005 was 40% and 44%, respectively. Production and gross margins were relatively stable in the first two quarters of 2006 and reflected further costs savings at our Salt Lake City and Mexico plants. In the third quarter, the margin was negatively impacted by approximately \$3.0 million of non-recurring costs including

unabsorbed overhead as the San Clemente plant was shut down and production commenced in Salt Lake City, costs of moving machinery, and severance costs in San Clemente. While all costs directly related to the move from San Clemente to Salt Lake City were complete by the

32

end of the third quarter, we incurred temporary production inefficiencies in the fourth quarter. Those inefficiencies and lower production scheduling through the holiday seasons in the fourth quarter negatively impacted our gross margin by approximately \$2.8 million.

In addition, in the first three quarters of 2006 we added significant production volume in Mexico, both through new business and transfer of production from Salt Lake City. To meet this volume we increased headcount from approximately 450 people to approximately 1,100 people. This was more than needed based on production volumes, but was necessary in the short term to maintain quality and meet delivery schedules. Bringing on new employees created inefficiencies because turnover among new employees is high and time is spent on training. In addition, we started instituting changes in our production processes in the fourth quarter which will ultimately increase our efficiencies, but in the short term will decrease efficiency as production personnel and supervisors adapt to the new processes. The combined effect of these factors in Mexico negatively impacted our gross margin by approximately \$2.1 million.

Other negative impacts were \$0.7 million of charges related to the termination of Punctur-Guard products and approximately \$0.5 million of excess freight costs because of delays in receiving materials and in shipping product to customers.

While all of the negative impacts on our gross margin are non-recurring expenses or are temporary, approximately \$3.0 million of the costs will continue into the first quarter of 2007 and a smaller portion into the second quarter of 2007. We estimate that all of the inefficiencies will be resolved by the end of the second quarter of 2007, if not sooner, and that our gross margins for the year will approximate 43% to 44%. However, we give no assurance as to gross margins in 2007 or when all adverse effects of inefficiencies will be eliminated.

Selling, general and administrative expenses (SG&A) increased by \$7.3 million to \$44.2 million, and were 22% of revenues in 2006, compared with 23% in 2005. The increase in costs was partially due to \$4.1 million of increased compensation and benefit expenses, including the addition of new sales personnel, increased bonuses and increased pay rates. Travel expense increases accounted for \$1.1 million of the increase. Computer related costs, which includes software expenses, maintenance costs and hosting costs, increased by \$1.0 million as we continued to upgrade our systems and network. Amortization of intangibles accounted for \$0.5 million of the increase. We expect SG&A in 2007 to be 21% to 23% of revenue. An expected increase in costs for sales personnel is expected to be more than offset by a significant decrease in expenses associated with patent lawsuits and a lawsuit against a law firm which has been settled. Expense of those lawsuits aggregated to \$6.4 million in 2006. There is no assurance that these expectations will be realized.

Research and development expenses (R&D) were \$7.7 million and three percent of revenue in 2006 compared to \$4.8 million and three percent of revenue in 2005. This increase was primarily from R&D activity associated with a \$2.9 million increase in R&D on critical care products. We expect R&D in 2007 to be four to five percent of revenue, although there is no assurance that these expectations will be realized.

Gain on sale of building of \$2.1 million was from the sale of one of our buildings in San Clemente. The building was used for manufacturing prior to moving the manufacturing to our Salt Lake City facility.

Other income increased \$1.7 million to \$4.5 million in 2006 compared to 2005. Other income in 2006 includes \$3.7 million of interest income and \$0.8 million of payment under a settlement agreement. Other income in 2005 includes \$2.2 million of interest income and \$0.5 million of payment under a settlement agreement. The increase in interest income was primarily due to increased investment earnings due to higher yield rates and higher invested balances.

Minority interest was \$0.6 million in 2006 compared to \$0.4 million in 2005 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 29.0% in 2006 compared to 34.5% in 2005. The 2006 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, and because of tax benefits of foreign tax losses, partially offset by state taxes and tax losses of a company not included in our consolidated tax return. We expect our effective rate to be approximately 34.5% in 2007.

Comparison of 2005 to 2004

Revenues increased \$81.9 million to \$157.5 million in 2005, compared to \$75.6 million in 2004.

33

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.

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.

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.

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.

Critical care product sales to Hospira, excluding custom critical care products and products we no longer manufacture, were \$30.2 million from May to December 2005.

Net sales of custom products, including custom critical care products were \$42.6 million in 2005 compared to \$25.9 million in 2004. Net sales of custom critical care products were \$10.8 million in 2005. Net sales of custom I.V. system increased approximately \$5.9 million, 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.

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.

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.

Gross margin for 2005 and 2004 was 44% and 47%, respectively. The margin decrease in 2005 was 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 were 53%. 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.

Selling, general and administrative expenses (SG&A) increased by \$10.6 million to \$37.0 million, and were 23% 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.

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.

Liquidity and Capital Resources

During 2006, our cash and liquid investments increased by \$30.2 million.

Operating Activities: Our cash provided by operating activities tends to increase over time because of our positive operating results. However, it is subject to fluctuations, principally from 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.

During 2006, 2005 and 2004, cash provided by operations was \$31.6 million, \$27.4 million and 25.3 million, respectively. The 2006 operating cash was mainly comprised of net income of \$25.7 million, depreciation and amortization of \$11.2 million, offset by changes in our operating assets and liabilities. The 2005 and 2004 operating cash included tax benefit from stock options of \$4.3 million and \$2.0 million, respectively. The similar benefit in 2006 is included in the cash flows from financing activities under FAS 123(R).

Investing Activities: During 2006, we used cash of \$34.5 million in investing activities. This was comprised of purchases of property and equipment of \$19.6 million, net investment purchases of \$23.9 million, partially offset by \$2.9 million in proceeds from finance loan payments and \$6.1 million from proceeds from the sale of one of our buildings in San Clemente.

In June 2006, we purchased the land and building that our plant in Italy operates in for \$2.1 million. Also, we made improvements at our Salt Lake City facility to accommodate moving all molding and automated assembly from our San Clemente factory at a cost of \$3.6 million. In addition, we have also expanded our production facility in Mexico by 45,000 square feet to take over most of the manual assembly from our Salt Lake City facility and growth in our custom I.V. system business. The moves from Salt Lake City to Mexico began in July 2005 and we expect most of them to be completed by Spring 2007. The moves from San Clemente to Salt Lake City began in April 2006 and were completed in September 2006. We will also add another 136,000 square feet to our production facility in Mexico at a total estimated cost of \$9.2 million.

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

Construction of this addition commenced in the fourth quarter of 2006 and is estimated to be completed in the spring of 2007.

In September 2006, we sold one of our buildings in San Clemente. This building was used for the molding and automation manufacturing that was moved to Salt Lake City. The net book value of the land and building was \$4.0 million. After deducting selling fees, we recognized a gain of \$2.1 million on a net sales price of \$6.1 million. The gain is reflected in operating expenses. The proceeds are reflected in investing activities.

35

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

We estimate that capital expenditures in 2007, including the building improvements in our Mexico facility, will be approximately \$20.0 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, 2006, \$0.7 million for one loan was outstanding. Scheduled maturity for this loan is \$0.1 million in 2007 and \$0.6 million in 2008. Weighted average maturity (principal and interest) at December 31, 2006 was 1.5 years and the weighted average interest rate was 9.8%. There were no unfunded commitments at December 31, 2006.

Financing Activities: Cash provided by stock options and the employee stock purchase plan, including tax benefits of \$6.5 million, was \$16.3 million in 2006 to purchase 649,446 shares. Cash provided by stock options and the employee stock purchase plan in 2005, excluding tax benefits of \$4.3 million, was \$7.7 million to purchase 561,329 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options. The amount in 2005, as explained above, is included in Cash Flows from Operating Activities.

In July 2006, we adopted a plan to initially purchase common stock at a cost of up to \$2.0 million and thereafter purchase common stock at a cost of up to \$1.0 million each month for a year. We purchased \$7.0 million of our common stock in 2006, and \$8.0 million in total through January 2007 when this program was terminated. In January 2007, we announced an expanded program to purchase up to at least \$20.0 million of our shares.

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 amounts set forth in the table below. 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 are those 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. 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 meet commitments under all of our contractual obligations. There are no obligations past 2009. (In thousands)

	2007	2008	2009
MCDA	\$ 6,395	\$ 5,500	\$ 5,500
Property and equipment	12,808		
Total	\$ 19,203	\$ 5,500	\$ 5,500

Forward Looking Statements

Various portions of this Report, including this Management's Discussion and Analysis, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are forward looking statements, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, and by similar expressions and 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, litigation expense, SG&A, R&D expense, future costs of expanding our custom I.V. systems business, income, losses, cash flow, 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, increases in systems capabilities, introduction and sales of new products, warranty claims, rebates, product returns, bad debt expense, inventory requirements, manufacturing efficiencies and cost savings, unit manufacturing costs, oil and gas prices, effect of interruption of crude oil supplies; establishment of production facilities outside the U.S., adequacy of production capacity, results of R&D, asset impairment losses, relocation of manufacturing facilities and personnel, expansion of markets and the need for additional facilities and personnel, effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies, business seasonality and fluctuations in quarterly results, customer ordering patterns and the effects of new accounting pronouncements;
- new or extended contracts with manufacturers and buying organizations, dependence on a small number of customers, 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; future purchases of treasury stock; working capital requirements; foreign currency denominated financial instruments; capital expenditures; acquisitions of other businesses or product lines; indemnification liabilities; contractual liabilities.

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 Part I, 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, 2006, 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.

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 and accruals in the same foreign currency, except for Italy, where our net Euro position at December 31, 2006 was approximately 2.7 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 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 sheets of ICU Medical, Inc. and subsidiaries as of December 31, 2006 and 2005, and the related consolidated statements of income, stockholders' equity and comprehensive income and cash flows for the two years then ended. Our audits also included the 2006 and 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ICU Medical, Inc. and subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for the years 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.

As described in Note 1 to the consolidated financial statements, the Company changed its method of accounting for stock-based compensation in 2006.

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, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2007 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
February 28, 2007
39

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

ICU Medical, Inc.

San Clemente, CA

We have audited the accompanying consolidated statements of income, stockholders' equity and comprehensive income, and cash flows for the year ended December 31, 2004 of ICU Medical, Inc. and subsidiaries (the Company). Our audit also included the financial statement schedule listed in Item 15(a)2 for the year 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 results of operations and cash flows of ICU Medical, Inc. and subsidiaries for the year 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 the year 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

40

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2006	2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 13,153	\$ 6,854
Liquid investments	103,765	79,888
Cash and liquid investments	116,918	86,742
Accounts receivable, net of allowance for doubtful accounts of \$310 in 2006 and \$593 in 2005	26,533	23,644
Finance loans receivable - current portion	73	1,178
Inventories	16,315	15,435
Prepaid income taxes	4,541	3,768
Prepaid expenses and other current assets	4,182	3,522
Deferred income taxes - current portion	2,876	3,473
Total current assets	171,438	137,762
PROPERTY AND EQUIPMENT, net	59,037	52,194
FINANCE LOANS RECEIVABLE - non current portion	646	2,422
INTANGIBLE ASSETS, net	9,781	10,963
DEFERRED INCOME TAXES - non current portion	2,878	723
OTHER ASSETS	468	473
	\$ 244,248	\$ 204,537
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 8,130	\$ 5,078
Accrued liabilities	7,789	8,809
Total current liabilities	15,919	13,887
COMMITMENTS AND CONTINGENCIES		
DEFERRED INCOME TAXES - non current portion	3,084	529
MINORITY INTEREST	358	923
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 14,746,951 and 14,158,612 shares in 2006 and 2005,		
outstanding 14,620,421 and 14,136,298 shares in 2006 and 2005,		
respectively	1,475	1,416
Additional paid-in capital	74,489	60,154
Treasury stock, at cost 126,530 and 22,314 shares in 2006		
and 2005, respectively	(5,383)	(609)
Retained earnings	153,925	128,265
Accumulated other comprehensive income (loss)	381	(28)
Total stockholders equity	224,887	189,198
	\$ 244,248	\$ 204,537

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,		
	2006	2005	2004
REVENUES:			
Net sales	\$ 198,788	\$ 154,621	\$ 72,704
Other	2,825	2,911	2,846
TOTAL REVENUE	201,613	157,532	75,550
COST OF GOODS SOLD			
	120,929	88,128	39,853
Gross profit	80,684	69,404	35,697
OPERATING EXPENSES:			
Selling, general and administrative	44,245	36,992	26,409
Research and development	7,659	4,817	3,376
Gain on sale of building	(2,093)		
Total operating expenses	49,811	41,809	29,785
Income from operations	30,873	27,595	5,912
OTHER INCOME			
	4,462	2,721	1,579
Income before income taxes and minority interest	35,335	30,316	7,491
PROVISION FOR INCOME TAXES	(10,240)	(10,459)	(2,600)
MINORITY INTEREST	565	417	109
NET INCOME	\$ 25,660	\$ 20,274	\$ 5,000
NET INCOME PER COMMON SHARE			
Basic	\$ 1.78	\$ 1.47	\$ 0.37
Diluted	\$ 1.64	\$ 1.35	\$ 0.33
Weighted average number of shares			
Basic	14,411,699	13,810,516	13,691,139
Diluted	15,599,132	15,039,890	14,960,378

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		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income		Comprehensive Income
	Number of Shares Outstanding	Amount				Total		
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
Purchase of treasury stock	(165,323)			(6,986)			(6,986)	
Exercise of stock options and related income tax benefits	604,240	57	13,528	1,282			14,867	
Proceeds from employee stock purchase plan	45,206	2	320	930			1,252	
Stock compensation			487				487	
Comprehensive income								
Net income					25,660		25,660	\$ 25,660
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of \$(127)						409	409	409
BALANCE, December 31, 2006	14,620,421	\$ 1,475	\$ 74,489	\$ (5,383)	\$ 153,925	\$ 381	\$ 224,887	\$ 26,069

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,		
	2006	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	\$ 25,660	\$ 20,274	\$ 5,000
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	11,231	9,698	8,598
Provision for doubtful accounts	(273)	(181)	298
Stock compensation expense	487		
Minority interest	(565)	(417)	(109)
Write-off of in-process research and development		374	1,154
Gain on sale of building	(2,093)		
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired in business combination			
Accounts receivable	(2,353)	(14,656)	15,723
Inventories	(785)	3,069	(5,031)
Prepaid expenses and other assets	(1,504)	(2,247)	(41)
Accounts payable	3,034	2,210	(358)
Accrued liabilities	(1,141)	3,263	(552)
Prepaid and deferred income taxes	(90)	1,647	(1,382)
Tax benefits from exercise of stock options in 2005 and 2004		4,338	1,983
Net cash provided by operating activities	31,608	27,372	25,283
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(19,612)	(5,509)	(7,101)
Proceeds from sale of building, net of gain	6,062		
Cash paid for acquired assets		(32,606)	
Advances under finance loans			(1,010)
Proceeds from finance loan repayments	2,881	2,649	3,670
Purchases of investments	(43,724)	(60,413)	(23,625)
Proceeds from sale of investments	19,847	62,250	13,250
Net cash used in investing activities	(34,546)	(33,629)	(14,816)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	8,497	7,176	2,689
Proceeds from employee stock purchase plan	1,252	481	503
Tax benefits from exercise of stock options in 2006	6,512		
Purchase of treasury stock	(6,986)		(10,133)
Net cash provided by (used in) financing activities	9,275	7,657	(6,941)
Effect of exchange rate changes on cash	(38)	(162)	303
NET INCREASE IN CASH AND CASH EQUIVALENTS	6,299	1,238	3,829
CASH AND CASH EQUIVALENTS, beginning of year	6,854	5,616	1,787
CASH AND CASH EQUIVALENTS, end of year	\$ 13,153	\$ 6,854	\$ 5,616
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for income taxes	\$ 4,001	\$ 4,465	\$ 1,814

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, 2006, 2005 and 2004

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

Note 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:

	2006	2005
Raw material	\$ 9,996	\$ 9,746
Work in process	3,258	4,323
Finished goods	3,061	1,366
Total	\$ 16,315	\$ 15,435

d. Property and Equipment

Property and Equipment, stated at cost, consist of the following at December 31:

	2006	2005
Machinery and equipment	\$ 38,373	\$ 38,421
Land, building and building improvements	38,336	31,588
Molds	10,959	9,123
Computer equipment and software	7,257	6,369
Furniture and fixtures	2,143	2,042
Construction in progress	5,250	3,577
Total property and equipment, cost	102,318	91,120
Accumulated depreciation	(43,281)	(38,926)
Net property and equipment	\$ 59,037	\$ 52,194

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 - 5 years

The Company follows the policy of capitalizing expenditures that materially increase the life of the related assets; maintenance and repairs are expensed as incurred. The costs and related accumulated depreciation applicable to property and equipment sold or retired are removed from the accounts and any gain or loss is reflected in the statements of income at the time of disposal. Depreciation expense was \$9.4 million, \$8.0 million and \$7.2 million in the years ended December 31, 2006, 2005 and 2004, respectively. In 2006, the Company accelerated the depreciation of fixed assets related to its blood collection needle products purchased in 2002, recording an additional \$0.4 million of depreciation. This amount is included in the depreciation expense noted above.

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	December 31, 2006		Net
		Cost	Accumulated Amortization	
Patents and licenses	10	\$ 3,200	\$ 1,279	\$ 1,921
MCDA contract	10	8,571	1,429	7,142
Royalty agreements	6	1,399	926	473
Non compete agreement	5	818	573	245
Total		\$ 13,988	\$ 4,207	\$ 9,781

	Amortization Life in Years	December 31, 2005		Net
		Cost	Accumulated Amortization	
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

In 2005, the Company acquired a manufacturing facility from Hospira and entered into a twenty-year Manufacturing, Commercialization and Development Agreement (MCDA) with them. The Company recorded an intangible asset for the MCDA contract of \$8.6 million (Note 4).

In 2006, the Company wrote off the cost and accumulated amortization of patents and other intangibles related to the blood collection needle products purchased in 2002 for impairment in connection with the decision to discontinue production of this product. The impairment loss was \$0.2 million in 2006 and \$0.7 million in 2004 and was charged to selling, general and administrative expenses. The impairment loss was determined by comparing non-discounted future cash flows to the book value of these intangibles.

Amortization expenses in 2006, 2005 and 2004 was \$1.8 million, \$1.3 million and \$1.4 million, respectively, including \$0.2 million in 2006 and \$0.7 million in 2004 for impairment related to the blood collection needle products. Estimated annual amortization for each of the next five years is approximately \$1.5 million for 2007, \$1.4 million for 2008, \$1.1 million for 2009, \$1.1 million for 2010 and \$1.1 million for 2011.

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 discussed in notes 1 and 5, were recorded in the years ended December 31, 2006, 2005 and 2004.

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, 2006 and 2005, 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 the 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.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48), which provides criteria for the recognition, measurement, presentation and disclosure of uncertain tax positions. A tax benefit from an uncertain position may be recognized only if it is more likely than not that the position is sustainable based on its technical merits. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006 and the Company will adopt the new requirements in its fiscal first quarter of 2007. The cumulative effects, if any, of adopting FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. We do not expect that FIN 48 will have a material effect on our consolidated financial condition or results of operations.

The Company elected a new accounting policy in 2006 in conjunction with the adoption of FAS 123(R) and as permitted by interpretations of FAS 123(R), related to intra-period tax allocation of tax benefits that the Company receives upon exercise of stock options. The indirect tax benefits of these deductions, such as those recognized for research and development credits and Domestic Production Activities Deductions, are recorded as net reductions of the tax provision. In prior years, these other indirect tax effects were recorded as additional-paid-in-capital. The direct tax benefits of share based compensation will continue to be recorded through additional-paid-in capital.

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 assesses if a reserve for warranty returns is needed. Total warranty expense has been insignificant. The Company accrues rebates based on agreements and on historical experience as a reduction in revenue at the time of sale; adjustments to amounts accrued 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 an assessment of various factors. The Company considers prior payment trends, the age of the accounts receivable balances, 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 retirement or post-employment benefits to employees. The Company maintains a Section 401(k) retirement plan for employees. Company contributions to the plan in 2006, 2005 and 2004 were approximately \$0.3 million, \$0.3 million and \$0.1 million, respectively.

n. Accounting Estimates

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

o. New Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109 (FIN 48), which provides criteria for the recognition, measurement, presentation and disclosure of uncertain tax positions. A tax benefit from an uncertain position may be recognized only if it is more likely than not that the position is sustainable based on its technical merits. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006 and the Company will adopt the new requirements in its fiscal first quarter of 2007. The cumulative effects, if any, of adopting FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. The Company does not expect that FIN 48 will have a material effect on the Company's consolidated financial condition or results of operations.

Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157), defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. The Company will adopt the provisions of SFAS 157 effective January 1, 2008. The Company does not expect SFAS 157 to have a material impact on our results of operations, financial position, or cash flows.

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 108 (SAB 108). Due to diversity in practice among registrants, SAB 108 expresses SEC staff views regarding the process by which misstatements in financial statements are evaluated for purposes of determining whether financial statement restatement is necessary. SAB 108 is effective for fiscal years ending after November 15, 2006. SAB 108 does not have an impact on the Company's reported results from operations or financial position.

In February 2007, the FASB issued SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective for the Company on January 1, 2008. The provisions of SFAS 159 are elective, and the Company has not determined whether and to what extent we may implement its provisions or how if implemented, it might affect the Company's financial statements.

Note 2: New Accounting Policy Share Based Awards

Prior to the January 1, 2006 adoption of the Financial Accounting Standards Board (FASB) Statement No. 123 (revised 2004), "Share-Based Payment" (SFAS 123R), the Company accounted for stock-based compensation granted to employees and directors under Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" (APB No. 25) and related interpretations as permitted by SFAS No. 123 "Accounting for Stock-Based Compensation" (SFAS 123). Accordingly, because the exercise price of the options equaled the fair market value of the underlying shares at the date of grant and because rights to purchase stock under the 2002 Employee Stock Purchase Plan (ESPP) were non-compensatory under the provisions of APB No. 25, no compensation cost was recognized by the Company for stock-based compensation. As required by SFAS No. 123, the Company presented certain proforma information for stock-based compensation in the notes to the consolidated financial statements.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123R, using the modified-prospective transition method. Under this transition method, stock-based compensation cost was recognized in the consolidated financial statements for all share based payments after January 1, 2006. These include stock options, and rights to purchase stock under the ESPP, because the related purchase discounts for the ESPP exceeded the amount allowed under SFAS 123R for non-compensatory treatment. Compensation cost recognized includes the estimated expense for the portion of the vesting period after January 1, 2006 for share based payments prior to, but not vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123. Results for prior periods have not been restated, as provided for under the modified-prospective method. Shares to be issued to satisfy future stock option exercises and stock purchase rights under the ESPP will be issued either from authorized but unissued shares or from treasury shares.

Prior to the adoption of SFAS 123R, the Company presented all tax benefits resulting from the exercise of stock options as operating cash inflows in the consolidated statements of cash flows, in accordance with the provisions of the Emerging Issues Task Force (EITF) Issue No. 00-15, "Classification in the Statement of Cash Flows of the Income Tax Benefit Received by a Company upon Exercise of a Nonqualified Employee Stock Option." In the Company's case, all tax benefits received were tax benefits of tax deductions in excess of stock compensation cost recognized because no stock compensation cost was recognized under APB No. 25. SFAS 123R requires the benefits of tax deductions in excess of the compensation cost recognized for those options to be classified as financing cash inflows rather than operating cash inflows, on a prospective basis. This amount is shown as "tax benefits from exercise of stock options" on the consolidated statement of cash flows. Other than this classification change, the effect of adopting SFAS 123R had no effect on the Company's Condensed Consolidated Statement of Cash Flows.

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

The following information shows the effect on net income and net income per share for the year end December 31, 2005 and 2004 had compensation cost been recognized based upon the estimated fair value on the grant dates of stock options, and ESPP, in accordance with SFAS 123R.

	2005	2004
Net income, as reported	\$ 20,274	\$ 5,000
Deduct: stock-based compensation expense determined under fair value method, net of tax	(1,948)	(6,327)
Net income (loss), pro forma	\$ 18,326	\$ (1,327)
Net income (loss) per share		
Basic, as reported	\$ 1.47	\$ 0.37
Diluted, as reported	\$ 1.35	\$ 0.33
Basic, pro forma		
Basic, pro forma	\$ 1.33	\$ (.10)
Diluted, pro forma	\$ 1.22	\$ (.10)

On December 28, 2004, the Company amended provisions of certain stock options outstanding under the 1993 Plan to accelerate their vesting. Acceleration of the vesting of certain options in December 2004 increased the proforma adjustment by approximately \$1.4 million, or \$0.11 per share.

Note 3: Stock-Based Compensation

At December 31, 2006, the Company has stock option plans for employees and directors, a subsidiary has a stock option plan and the Company has an employee stock purchase plan. Total stock-based compensation cost recognized in the year ended December 31, 2006 was \$0.5 million for stock options and the ESPP. The tax benefit from the stock-compensation cost recognized in 2006 was \$1.5 million, consisting of \$0.1 million benefit from stock compensation expense and \$1.4 million of indirect tax benefit that the Company received upon the exercise of stock options. These tax benefits exclude direct tax benefits from exercise of stock options, which are separately reported in the consolidated statement of cash flows. The indirect benefit upon exercise of stock options relates to research and development tax credits and other tax credits which were recorded in 2006 as permitted by interpretation of SFAS 123R; in prior years, such benefits were recorded as reductions to the income tax provision. The effect of the adoption SFAS 123R on the Company's basic and diluted earning per share was an increase of \$.08 and \$0.07 per share, respectively, for the year ended December 31, 2006. The number of options that are anti-dilutive because their exercise price exceeded the average market price of the Company's common stock approximated 17,000, 791,000 and 1,117,000 in 2006, 2005 and 2004, respectively.

Stock Option Plans

The 2003 Stock Option Plan (2003 Plan) has 1,500,000 shares of common stock 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 on the exercise of the option 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 the exercise of an incentive stock option. The 2003 Plan includes conditions whereby options not vested are cancelled if employment is terminated. To date, all options granted under the 2003 Plan are nonstatutory stock options.

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.

The Company also has the 2001 Directors' Stock Option Plan (the Directors' Plan), which had 750,000 shares reserved for issuance to members of the Company's Board of Directors. Options not vested terminate if the directorship is terminated. All further grants under the Director's Plan have been suspended.

The fair value of stock grants is calculated using the Black-Scholes option valuation model. Grants for 2005 and 2004 were valued using the following weighted-average assumptions: risk-free interest rate of 4.3 percent and 3.2 percent, respectively, expected option life of 4.0 years and 4.4 years, respectively, expected volatility of 52 percent and 51 percent, respectively and no dividends. The weighted average exercise price for 2005 and 2004 option grants was \$33.04 and \$31.55, respectively. The Company granted 40,000 options in 2006, valued at \$0.7 million. These grants were valued using the following weighted-average assumptions: risk-free interest rate of 4.9 percent, expected option life of 6.0 years, expected volatility of 36 percent and no dividends. The expected term was based on expected future employee behavior. The Company estimates the volatility of its common stock at the date of grant based on the historical volatility of its common stock. As of December 31, 2006, the Company has \$0.7 million of unamortized stock compensation cost of which approximately \$0.2 million will amortize in 2007 and \$0.1 million will amortize annually from 2008 through 2011. As of December 31, 2005, the Company had one unvested performance based grant of 15,000 options and four unvested time-based grants totaling 18,335. As of December 31, 2006, the Company has one unvested performance based grant of 15,000 options and four unvested time-based grants totaling 40,668 options, which vest between 2007 and 2011. Vested and expected to vest stock options equal the Company's total outstanding options at December 31, 2006.

A summary of the Company's stock option activity for the year ended December 31, 2006 is as follows:

	Shares	Exercise Price		Weighted Average
		Range		
Outstanding at December 31, 2005	4,019,958	\$ 5.08	\$ 39.56	\$ 19.26
Granted	40,000	40.96	41.96	41.46
Exercised	(604,240)	5.08	39.56	14.06
Forfeited	(2,011)	13.13	39.04	34.23
Outstanding at December 31, 2006	3,453,707	\$ 5.08	\$ 41.96	\$ 20.41
Exercisable at December 31, 2006	3,398,039	\$ 5.08	\$ 39.56	\$ 20.15
Available for grant at December 31, 2006:				
2003 Plan	1,211,000			
Director's Plan	513,750			
	1,724,750			

The intrinsic value of stock options exercised in the year ended December 31, 2006, 2005 and 2004 was \$17.1 million, \$12.4 million and \$5.2 million, respectively. The intrinsic value of options outstanding and options exercisable at December 31, 2006 was \$70.0 million and \$69.8 million, respectively. The above intrinsic values are before applicable taxes, based on the Company's closing stock price of \$40.68 on December 31, 2006. The weighted average remaining contractual term of options outstanding and options exercisable at December 31, 2006, was 4.9 years and 4.8 years, respectively.

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

A summary of the Company's weighted average fair value for stock option activity in 2006 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2005	33,335	\$ 8.04
Granted	40,000	18.11
Vested	(17,667)	12.40
Forfeited		
Nonvested at December 31, 2006	55,668	\$ 13.89

The weighted average grant date fair value of options granted in 2006, 2005 and 2004 was \$18.11, \$13.68 and \$13.57, respectively. The total fair value of shares at grant date vested in 2006, 2005 and 2004 was \$0.2 million in 2006, \$2.9 million in 2005 and \$17.3 million in 2004, respectively.

A majority-owned subsidiary of the Company adopted a stock option plan under which 300,000 shares were initially reserved for issuance to employees and directors. This plan was increased to 400,000 in the fourth quarter of 2006. The terms are similar to the Company's 2003 Plan. The subsidiary granted 256,000 options with exercise prices equal to the fair market value at the date of grant and granted 140,750 options with exercise prices that are greater than the fair market value at the date of grant. Total option grants of 396,750 represent approximately 13.0% of the outstanding shares of the subsidiary. As of December 31, 2006, 396,750 stock options are outstanding under this plan and 232,916 are exercisable. All outstanding and exercisable stock options have an exercise price of \$2.00 and a weighted average remaining contractual life of 8.8 years. During the year ended December 31, 2006 there were 140,750 options granted at an exercise price of \$2.00, and an average grant date fair value of \$0.06. There were no forfeitures and no exercises under this plan. The average grant date fair value of the 161,000 and 163,834 non-vested options at December 31, 2005 and 2006 was \$0.94 and \$0.33, respectively. The total fair value of options at grant date which vested during the years ended December 31, 2006 and 2005 was \$0.1 million and \$0.1 million, respectively. There were no options that vested in 2004.

Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan (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 is subject to an annual increase. The Board of Directors determined that the annual increases due January 1, 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 45,206, 20,266 and 20,881 shares of Common Stock under the ESPP Plan in the years ended December 31, 2006, 2005 and 2004, respectively. As of December 31, 2006, there are 641,154 shares available for future issuance.

The fair value of rights to purchase shares under the ESPP shares is calculated using the Black-Scholes option valuation model. Rights for the 2006, 2005 and 2004 purchase periods were valued using the following weighted average assumptions: risk-free interest rate of 4.8 percent, 2.3 percent and 1.0 percent, respectively; expected option life of 0.5 years, expected volatility of 28 percent, 34 percent and 53 percent, respectively, which is based on the historical volatility of the Company's stock, and no dividends. As of December 31, 2006, the Company has less than \$0.1 million of unamortized stock compensation expense from the ESPP which will be recognized in the first quarter of 2007. The intrinsic value of ESPP shares at their date of purchase by employees in 2006, 2005 and 2004 was \$0.3 million, \$0.1 million and \$0.1 million, respectively.

Note 4: 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 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 moved all molding and automated assembly from its San Clemente location to its Salt Lake City location. In addition, the Company has expanded its production facility in Mexico to take over substantially all manual assembly previously done in its Salt Lake City facility. Most of these changes are expected to be completed by Spring 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 that are involuntarily terminated within two years of the May 1, 2005 date of purchase. The Company expensed the costs of relocating personnel to Salt Lake City, and moving machinery to and installing it in Salt Lake City as these costs were incurred. The Company paid one-time termination benefits to certain employees in San Clemente and expects to pay termination benefits to certain Connecticut employees who are involuntarily terminated because of the move to Salt Lake City if they continue to render service until terminated. The liability for such benefits is being accrued ratably over the employees' expected service period in accordance with Statement of Financial Accounting Standards No. 146 Accounting for Costs Associated with Exit or Disposal Activities. As of December 31, 2005, the Company had \$0.6 million accrued for these exit costs. During 2006, the Company paid \$0.9 million in severance costs and adjusted the accrual by \$0.5 million, bringing the December 31, 2006 accrual to \$0.2 million. The accrual adjustments were due to changes in the length of employment for the designated employees and changes in the affected employees. The total estimated exit costs associated with these terminations is \$1.1 million. Costs of moving production to Mexico are capitalized or charged to expense immediately, as appropriate. Relocation costs to Mexico are not expected to be material. Total facility moving costs, relocation costs and termination benefit costs charged to expense in the year ended December 31, 2006 and 2005 were approximately \$1.8 million and \$1.0 million, respectively and are included in cost of good sold.

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	\$ 14,902
Inventory	10,195
Intangible asset - MCDA	8,571
Liabilities assumed	(1,062)
Total	\$ 32,606

Note 5: Asset Disposition

As a result of the relocation of manufacturing from the Company's San Clemente location to its Salt Lake City location (Note 4), one building in San Clemente was no longer needed. On September 1, 2006, the Company sold the San Clemente manufacturing building for \$6.1 million, net of fees and expenses. The net book value of the land and building was \$4.0 million, resulting in a gain on the sale of the land and building of \$2.1 million.

In the fourth quarter of 2006, the Company decided to discontinue production on the blood collection needle products purchased in 2002. Accordingly, depreciation and amortization were accelerated for the fixed assets, patents and other intangibles related to those products. This resulted in a \$0.4 million charge to cost of goods sold for deprecation and a \$0.2 million charge to selling, general and administrative expenses for the intangible amortization. The building and a royalty agreement remain as assets. The Company has not yet determined what to do with the building in Connecticut, but does not anticipate a loss in the event of a sale of the Connecticut building.

Note 6: 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% and in February 2007, the Company increased its ownership to 94% (see Note 15). 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, mostly that of 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 \$1.7 million, \$1.0 million in 2006 and 2005, respectively and \$0.3 million from September through December 2004.

Note 7: 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:

	2006	2005
Corporate preferred stocks	\$ 18,425	\$ 17,425
Federal tax-exempt debt securities	84,125	60,700
United States treasury bill	1,215	1,763
	\$ 103,765	\$ 79,888

The scheduled maturities of the debt securities are: \$1.2 million in 2007, \$10.1 million between 2012-2019, \$29.1 million between 2020-2029 and \$44.9 million from 2030-2040.

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

	2006	2005	2004
Corporate dividends	\$ 621	\$ 505	\$ 263
Tax-exempt interest	2,616	1,300	799
Other interest	474	392	517
	\$ 3,711	\$ 2,197	\$ 1,579

Note 8: Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2006	2005
Salaries and benefits	\$ 3,564	\$ 3,479
Professional fees	1,024	1,105
Incentive compensation	1,844	2,548
Other	1,357	1,677
	\$ 7,789	\$ 8,809

Note 9: 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.

Note 10: Income Taxes

The provision (benefit) for income taxes for the years ended December 31, 2006, 2005, 2004 is as follows:

	2006	2005	2004
Current:			
Federal	\$ 7,410	\$ 12,206	\$ (524)
State	2,135	502	(418)
Foreign	(175)		
	9,370	12,708	(942)
Deferred:			
Federal	3,998	(1,629)	3,430
State	(2,798)	103	112
Foreign	(330)	(723)	0
	870	(2,249)	3,542
	\$ 10,240	\$ 10,459	\$ 2,600

Current income taxes payable were reduced from the amounts in the above table by \$6.5 million, \$4.3 million, and \$2.0 million in 2006, 2005, and 2004, 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 for tax contingencies for potential tax assessments, and in 2006 has recognized a \$0.6 million net reduction of accruals made in prior years which are no longer deemed necessary of which \$0.4 million relates to state tax reserves.

During 2006, the Company has recognized a (benefit) of \$0.3 million for foreign tax net operating losses (NOL) originating in prior years that may be carried forward indefinitely.

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 tax rate is as follows:

	2006		2005		2004			
	Amount	Percent	Amount	Percent	Amount	Percent		
Federal tax at the expected statutory rate	\$ 12,360	35.0	% \$ 10,611	35.0	% \$ 2,622	35.0	%	
State income tax, net of federal effect	(243)	-0.7	933	3.1	266	3.5		
Tax credits	(1,463)	-4.2	(1,038)	-3.4	(418)	-5.6		
Tax-exempt interest and dividends	(1,033)	-2.9	(530)	-1.7	(371)	-4.9		
Domestic production activities/other	521	1.5						
Loss of domestic subsidiary not consolidated for tax purposes	602	1.7	483	1.5	501	6.7		
Foreign income tax	(504)	-1.4						
	\$ 10,240	29.0	% \$ 10,459	34.5	% \$ 2,600	34.7	%	

Tax credits in 2006 consist principally of research and developmental tax credits. In 2006, the effect of nonstatutory stock options exercised during the year on research and development tax credits and other tax credits was recorded as a reduction of the effective tax provision as permitted by interpretations of FAS 123(R). In prior years, such benefits were recorded in additional paid-in-capital.

The components of the Company's deferred income tax provision for the years ended December 31, 2006, 2005, and 2004, are as follows:

	2006	2005	2004
Allowance for doubtful accounts	\$ 148	\$ 100	\$ (30)
Inventory reserves	(282)	(344)	(244)
Accruals	(305)	(236)	496
State income taxes	1,577	(1,575)	605
Acquired future tax deductions	(86)	322	269
Depreciation and amortization	1,814	207	2,446
Net operating loss carryforward	(330)	(723)	
Tax credits	(1,666)		
	\$ 870	\$ (2,249)	\$ 3,542

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

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

	2006	2005
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts	\$ 99	\$ 247
Inventory reserves	1,146	864
Accruals	1,277	1,021
Tax credits	300	
Foreign	102	
State income taxes	(48)	1,341
	\$ 2,876	\$ 3,473
Non-current deferred tax asset:		
State income taxes	\$ (225)	\$
Tax credits state	2,050	
Net operating loss carry forwards	2,106	1,571
Valuation allowance	(1,053)	(848)
	\$ 2,878	\$ 723
Non-current deferred tax liability:		
Depreciation	\$ (4,899)	\$ (2,674)
Acquired future tax deductions	2,549	2,130
State income taxes	(651)	
SFAS 123 (R)	29	
Foreign currency translation adjustments	(112)	15
	\$ (3,084)	\$ (529)

Acquired future tax deductions are the tax benefits included in the Company's consolidated income tax returns originating in Bio-Plexus, Inc., an entity purchased in 2002, prior to its acquisition by the Company. They consist of: (a) the net tax benefit of items expensed for financial statement purposes but capitalized and amortized for tax purposes of \$1.9 million at acquisition date, less \$1.0 million realized since acquisition; most of the balance of \$0.9 million will be realized in approximately equal amounts over the next six years; (b) the tax benefited portion of Bio-Plexus's NOL carryforward of \$1.8 million, less \$0.7 million realized since acquisition, which will be realized in approximately equal amounts over the next sixteen years, and (c) by the tax effect of non-amortizable basis differences of \$0.5 million.

Under Section 382 of the Internal Revenue Code, certain ownership changes limit the 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 NOLs 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 the 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 (royalty rights) until that amount is reduced to zero, with any excess then recognized as a reduction in tax expense.

A domestic subsidiary not consolidated for tax return purposes has a NOL of \$3.0 million expiring in 2024, 2025 and 2026. The realization of the approximate benefit of this NOL is uncertain and has been offset by a valuation allowance.

A foreign subsidiary has a NOL carryforward of approximately \$3.2 million with an indefinite expiration period. 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.

Note 11: 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 \$68.4 million of revenues in 2006, \$62.5 million of revenues in 2005 and \$35.4 million of revenues in 2004. Custom I.V. systems, many of which incorporate the CLAVE connector, accounted for \$39.4 million of revenues in 2006, \$31.8 million of revenues in 2005 and \$26.2 million of revenues in 2004. Total critical care products, including custom critical care products but excluding products that we no longer manufacture under the MCDA, accounted for \$66.6 million of revenues in 2006 and \$41.0 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, 2006, 2005 and 2004, the Company had sales to one manufacturer, Hospira, of 77%, 74% and 53%, respectively, of consolidated revenue. As of December 31, 2006 and 2005, the Company had accounts receivable from Hospira of 61% and 75%, respectively, of consolidated accounts receivable.

Export sales and sales outside the United States and Canada accounted for 10%, 8% and 12% of total revenue in 2006, 2005 and 2004, respectively.

As of December 31, 2006, approximately \$28.9 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately \$23.4 million in Mexico and approximately \$5.5 million in Italy. 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.

Note 12: 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. As of December 31, 2006, the Company has one loan outstanding. Scheduled maturity of this loan is \$0.1 million in 2007 and \$0.6 million in 2008. Weighted average maturity (principal and interest) at December 31, 2006 was 1.5 years and the weighted average interest rate was 9.8%. There were no unfunded commitments at December 31, 2006.

Note 13: 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.

Note 14: Quarterly Financial Data - Unaudited

	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
2006				
Total revenue	\$ 48,781	\$ 51,425	\$ 48,600	\$ 52,807
Gross profit	21,350	23,074	18,850	17,410
Net income	6,366	6,292	6,142	6,860
Net income per share:				
Basic	\$ 0.45	\$ 0.44	\$ 0.42	\$ 0.47
Diluted	\$ 0.41	\$ 0.40	\$ 0.39	\$ 0.44
2005				
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

Note 15: Subsequent Events

On January 2007, the Company settled litigation against its former attorneys for \$8.0 million. Payment was received in January 2007.

On February 10, 2007, the Company and its subsidiary, MedScanSonics, Inc. (MSS), settled litigation with the founders of MSS under which the founders transferred all of their shares in MSS to MSS. The effect of this was to increase the Company's ownership in MSS to 94%.

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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

Management's Annual Report on Internal 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, 2006 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.

Item 9B. Other Information

None

60

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, 2006, 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, 2006, 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, 2006, 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, 2006, 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 February 28, 2007 expressed an unqualified opinion.

/s/ McGladrey & Pullen, LLP

Irvine, California

February 28, 2007

61

PART III

Item 10. Directors and Executive Officers of Registrant and Corporate Governance.

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, 2006 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, 2006, and such information is incorporated herein by this reference.

62

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.

	Form 10-K Page No.
Reports of Independent Registered Public Accounting Firm	39-40
Consolidated Balance Sheets at December 31, 2006 and 2005	41
Consolidated Statements of Income for the Years Ended December 31, 2006, 2005 and 2004	42
Consolidated Statements of Stockholders' Equity and Comprehensive Income for the Years Ended December 31, 2006, 2005 and 2004	43
Consolidated Statements of Cash Flows for the Years Ended December 31, 2006, 2005 and 2004	44
Notes to Consolidated Financial Statements	45-59

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

67

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)
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)

63

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 (16)
- 10.18 Form of Employment Agreements between Registrant and its Executive Officers effective January 1, 2007
- 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)
- 10.21 Settlement and Release Agreement dated as of January 2, 2007 between ICU Medical, Inc. and Fulwider Patton Lee & Utecht, LLP.
- 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

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.

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

(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

(16) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2006, and incorporated herein by reference

65

SIGNATURES

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

ICU MEDICAL, INC.

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

Dated: March 1, 2007

SIGNATURES

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

Signature	Title	Date
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	March 1, 2007
/s/ Francis J. O'Brien Francis J. O'Brien	Chief Financial Officer (Principal Financial Officer)	March 1, 2007
/s/ Scott E. Lamb Scott E. Lamb	Controller (Principal Accounting Officer)	March 1, 2007
/s/ Jack W. Brown Jack W. Brown	Director	March 1, 2007
/s/ John J. Connors John J. Connors	Director	March 1, 2007
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	March 1, 2007
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	March 1, 2007
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	March 1, 2007
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	March 1, 2007

ICU MEDICAL, INC.VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands)

Description	Balance at Beginning of Period	Additions Charged to Costs and Expenses	Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
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
For the year ended December 31, 2006:					
Allowance for doubtful accounts	\$ 593	\$ (273)	\$	\$ (10)	\$ 310

67