ICU MEDICAL INC/DE

FORM 10-K
(Annual Report)

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Address	951 CALLE AMANECER SAN CLEMENTE, CA 92763
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Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES
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, 2008 or

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

For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0022692**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
951 Calle Amanecer **San Clemente, California**	**92673**
(Address of principal executive offices)	(Zip Code)

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

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

Title of each class	**Name of each exchange on which registered**
Common stock, par value $0.10 per share	The NASDAQ Stock Market LLC (Global Select Market)

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

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 (§ 229.405 of this chapter) 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, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Small reporting company ☐
(Do not check if a smaller reporting company)

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, 2008, the last business day of registrant's most recently completed second fiscal quarter, was $279,719,052*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2009 was 14,730,725.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2009 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within

120 days following registrant's fiscal year ended December 31, 2008, 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.

ICU Medical, Inc.
Form 10-K
For the Year Ended December 31, 2008

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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 diseases through accidental needlesticks or hazardous drugs. 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. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems. Our headquarters are in San Clemente, California.

In 1993, we launched the CLAVE, an innovative one-piece, needleless I.V. connection device that accounted for approximately 39% of our revenue in 2008, 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.

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 have furthered this effort to include all of our proprietary devices on all of our custom systems beyond the CLAVE.

We are reducing our dependence on our current proprietary products by introducing new products and systems. 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 CLAVE, custom I.V. systems and custom oncology products in the product offerings of those entities. In our Co-Promotion and Distribution Agreement with Hospira, we manufacture all new custom I.V. systems for sale by Hospira Inc. ("Hospira") and jointly promote the products under the name SetSource ®. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into the Manufacturing, Commercialization and Development Agreement ("MCDA") with Hospira to produce Hospira's invasive monitoring, angiography products and certain other products they had manufactured at that facility. Custom products, which include custom I.V. sets, custom oncology and custom critical care products, accounted for approximately $70.2 million or 34% of total revenue in 2008. Sales of critical care products, excluding custom critical care, were $36.5 million in 2008. T here 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 Spiros™ Closed Male Connector, Genie™ Closed Vial Access Device and a line of custom I.V. therapy sets specifically designed for use in Oncology. A DyePod™ Contrast Management System, TEGO™ Hemodialysis Connector, a new Y-CLAVE connector with integral check valve and the Orbit 90™ diabetes infusion set. We intend to further expand our custom sets market with various specialty components.

We currently sell substantially all of our products to I.V. product manufacturers, independent distributors and direct sales to the end user. Hospira, our largest customer, accounted for 69% of our worldwide revenues in 2008.

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, and amendments to those reports free of charge on our website as soon as reasonably practicable after filing them with the Securities and Exchange Commission. We also have our code of ethics posted on our website. The information on our website is not incorporated into this Annual Report.

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

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

Heightened awareness of the risk of infection from needlesticks and the substantial expense to healthcare providers of complying with regulatory protocols when needlesticks occur have led to growing demand for safe medical devices such as our needleless I.V. connectors. This awareness has also lead to significant federal and state legislation. 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.

Hospital Acquired Infection ("HAI") is a substantial concern for healthcare providers today. HAI can be caused by a variety of issues, one being a vascular catheter becoming contaminated with bacteria. This result is what is known as a Catheter Related Bloodstream Infection ("CRBSI") and has a high rate of patient morbidity and mortality. The Centers for Medicare Services ("CMS") discontinued payment for HAI that are a result of Vascular Catheter Associated Infections in late 2008. The reported cost for treatment of a single CRBSI can be as high as $60,000 and CMS will discontinue payment for these expenses commencing in fiscal year 2009. The CLAVE technology is designed to prevent bacterial contamination of the vascular catheter and will assist healthcare facilities in the effort to reduce these types of infections. We believe that the CLAVE has certain design features that are important for the prevention of CRBSI. Additionally, we believe that these important design features are not available in competitive products.

CLAVE Products

Prior to the introduction of needle-safe 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 an internal blunt cannula. As the luer tip enters the CLAVE housing, it depresses the silicone seal back into the housing and slides over the blunt cannula, which penetrates through the pre-slit silicone. Fluid channels in the blunt cannula 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 internal blunt cannula, 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 and I.V. fluids can be administered through the CLAVE by using a standard syringe without a hypodermic needle attached or various pre-filled syringe devices. 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. 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 MicroCLAVE ® 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 protocols without the risk of device failure and a saline flush regimen which reduces cost and exposure to the drug Heparin. The MicroCLAVE is intended for use on all peripheral and central catheters, which allows it to be used throughout the Hospital and reduces line items that the Hospital may need to carry and the educational burden of having multiple devices. The MicroCLAVE is being marketed as an extension of the CLAVE product line for use where the infection control, neutral displacement and saline flush features are advantageous.

CLAVE products are our largest selling product line, and accounted for $80.6 million of our revenue in 2008.

Custom I.V. Systems

In the late 1990's, we entered the market for 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 customers' order. This is a fraction of the time required by other custom set manufacturers. The use of sophisticated design, validation, 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.

Under a 2001 agreement with Hospira, 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 2008, net sales of custom I.V. systems were approximately $49.3 million, 43% of the custom I.V. sales were with domestic distributors, 41% with Hospira and 16% from international sales.

CLC2000 ®

The CLC2000 is a one piece, swabbable connector used to connect I.V. lines to catheters, which is engineered to have a positive displacement of fluid on disconnection which in turn will 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 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.

The CLC2000 is typically used on central venous catheters where catheter occlusion is most prevalent. Generally, when an I.V. line is disconnected from the catheter, there is a back-flow of blood from the patient's vein into the catheter. 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. 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 $6.0 million of our revenue in 2008.

Critical Care Products

Critical care products are used to monitor vital signs as well as specific physiological 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 we manufacture 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 at our Salt Lake City facility, 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. Our 2008 critical care sales, excluding custom critical care, were $36.5 million.

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. Our 2008 custom critical care sales were $11.8 million.

Other Products and Revenues

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 have recently introduced a number of new products: the TEGO for use in dialysis, a line of oncology products that includes the Spiros male luer connector device, the Genie vial access device, the Orbit 90 diabetes set and custom I.V. sets and ancillary products specifically designed for oncology therapy. Sales of these new products were $14.0 million in 2008.

We are developing several new products that we intend to introduce in 2009 and later. We believe innovative products continue to be important to maintaining and increasing our sales levels.

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 December 31, 2008, we employed 110 people in sales and marketing and expect this to increase in 2009. Our sales function includes product specialists worldwide who support our medical product manufacturing customers, our independent domestic distributors and end users of our products. 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 Product Manufacturers

We have a strategic supply and distribution relationship with Hospira, a major I.V. product supplier, which has a significant share of the U.S. 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, CLC2000, Lopez Valve, Spiros, Genie and Rhino products are purchased and packaged separately.

Under another agreement with Hospira that extends to 2014, we have the exclusive right to manufacture all new custom gravity I.V. sets for sale by Hospira, other than those custom sets that Hospira was manufacturing before we entered into the agreement in 2001. 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, we manufacture critical care products exclusively to Hospira. 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 worldwide.

Worldwide sales to Hospira accounted for approximately 69% of revenue in 2008. The loss of Hospira as a customer would have a significant adverse effect on our business and operating results.

Independent Domestic Distributors

As of December 31, 2008, we had 41 independent distributors in the United States and Canada who employ approximately 690 salespeople in the aggregate and which accounted for approximately 17% of our revenues in 2008. We include Canada as "domestic" for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

No single independent distributor accounted for more than two percent of revenue in 2008. 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 15%, 13% and10% of our revenues 2008, 2007 and 2006. As of December 31, 2008, we had approximately 42 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 five business development personnel serving Europe and seven serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add more business development personnel in 2009. Administrative operations are in Roncanova in northern Italy (at the site of our assembly plant) and San Clemente, California. Currently, all shipments from the United States are invoiced in U.S. dollars and sales from Italy are invoiced in Euros.

In December 2008, we signed an agreement to acquire a small manufacturing and distribution company based in Germany for €4.2 million. The products and distribution from this company are in the oncology market. Completion of this acquisition is contingent on final approval from the German court. We expect this process to conclude in the first half of 2009, however, there is no assurance that these expectations will be realized.

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 facility with approximately 450,000 square feet of state-of-the art manufacturing space. This building includes approximately 82,500 square feet of class 100,000 clean room area, 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. As of December 31, 2008, this facility was equipped with 64 injection molding machines and ancillary equipment and approximately 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, RF150 and some of our critical care products. The assembly systems are custom designed and manufactured for us. Our mold maintenance shop supports the repair and maintenance needs of our molding. 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, Mexico. This facility has approximately 241,000 square feet of production and warehousing space and an electron beam sterilizer. 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.

In 2007, we initiated a significant initiative to improve production processes, called the “ICU Production System” or “IPS”, which we believe will enable us to further improve our manufacturing efficiency. We started IPS in our Mexico facility in 2007 and in our Salt Lake City facility in 2008. These efforts are ongoing in both facilities and will continue in 2009.

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. 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 to date. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available.

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. We have 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.

We have a 21,000 square foot building in northern Italy where we assemble I.V. therapy systems. This facility also serves as our European distribution center.

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 Act ("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. However, certain of our new products may require a lengthier time for clearance than we have experienced in the past and there can be no assurance that a PMA application will not be required. Further, there is no assurance that other 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, ISO and European Council Directive 93/42/EEC ("Medical Device Directive") 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 and ISO inspections of manufacturing facilities. If an 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 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, oncology 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 Inc. ("Cardinal"), Becton Dickinson and others. Although we believe that our needleless devices have distinct advantages over competing systems, there is no assurance that they 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. The overall market for the critical care products we manufacture has been declining in recent years, and over that period, Hospira has lost market share to its competitors.

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, Fresenius 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 NAMIC, formerly part of 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 customers such as 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.

Cardinal manufactures a connector that competes with the CLAVE. Cardinal is the largest distributor of healthcare products in the United States, and has announced its intent to increase market share. We believe 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, Orbit 90, 1o2 Valve, TEGO, Click Lock technology, Custom Set Design and Manufacturing Methods. We have applications pending for additional United States and foreign patents on TEGO, Y-CLAVE with integral check value, Orbit 90, CLC2000, CLAVE, Spiros Closed Male Connector, Genie Closed Vial Access Device and Custom Set Design and Manufacturing Methods. The expiration dates of our patents range from 2009 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 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 or Click Lock 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.

United States patents related to our principal products expire as follows:

Product	Expiration dates
CLAVE® connector	12/2011 - 07/2016
CLC2000® connector	12/2016
Click Lock® connector	04/2010 - 07/2015
Custom Set Design and Manufacturing	01/2021
Orbit 90® infusion set	03/2022 - 11/2023

Hospira owns many 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 December 31, 2008 we had 1,829 full-time employees, consisting of 184 engaged in sales, marketing and administration, and 1,645 in manufacturing, molding, product development and quality control, including 1,165 in Mexico. We contract with independent temporary agencies to provide some production personnel who are not our employees. At December 31, 2008, we had 82 temporary production personnel.

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 depend on Hospira for a high percentage of our sales. The table below shows our total revenue and percentage of total revenue attributable to various types of customers for 2008 and 2007 (dollars in millions):

	Years Ended December 31,			
	2008		2007	
Hospira (U.S.)	$ 132.6	65%	$ 129.7	69%
Other manufacturers	3.7	2%	2.7	1%
Domestic distributors/direct sales	35.9	17%	29.5	16%
International customers	30.8	15%	23.7	13%
Other revenue	1.7	1%	2.5	1%

Our principal agreements with Hospira are the MCDA, a strategic supply and distribution agreement for most of our other medical devices in the domestic and international markets and an agreement to sell Hospira custom I.V. systems. The MCDA expires in 2025 and the latter two agreements expire in 2014.

The U.S. market for critical care products has been declining in recent years and our sales of critical care products to Hospira declined in 2008 compared to 2007. We expect further declines in 2009. If the market for critical care products continues to decline or if we have significant decreases in our prices to Hospira under the MCDA that are not offset by increased sales volume, our critical care product sales could continue to decline, resulting in a substantial reduction to 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, our sales and operations could be adversely affected.

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.

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.

Our operating results may be adversely affected by unfavorable economic conditions which affect our customers' ability to buy our products and could affect our relationships with our suppliers.

Disruptions in financial markets worldwide and other worldwide macro-economic challenges may cause our customers and suppliers to experience cash flow concerns. If job losses and the resulting loss of health insurance and personal savings causes individuals to forgo or postpone treatment, decreased hospital use could affect the demand for our products. As a result, customers may modify, delay or cancel plans to purchase our products and suppliers may increase their prices, reduce their output or change terms of sales. Additionally, if customers' or suppliers' operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, customers may not be able to pay, or may delay payment of, accounts receivable owed to us and suppliers may impose different payment terms. Any inability of current and/or potential customers to pay us for our products or any demands by suppliers for different payment terms may adversely affect our earnings and cash flow.

If we are unable to substantially reduce 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, and recent declines in production volumes of critical care products because of reduced sales of those products to Hospira is offsetting some of the cost savings previously attained. 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. In 2007, we expanded our Mexico facility and anticipate further increases in volume at that facility, resulting in an increase to 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.

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.

In 2008, CLAVE products accounted for approximately 39% of our revenue. 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 moderate sales growth 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 needleless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline, we could lose market share, and we could encounter sustained price and profit margin erosion.

If our efforts to increase our custom products business are not successful or we cannot increase sales of other products and develop new, commercially successful products, our sales may not grow.

Our future success may be dependent both on the success of our strategic initiatives to substantially increase 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, custom oncology products and custom critical care products, were $70.2 million in 2008, compared with $58.5 million in 2007. Sales of custom I.V. products increased by 9% in 2008 over 2007, 15% in 2007 over 2006 and 24% in 2006 over 2005. Sales of custom critical care products declined in 2008 from 2007. The success of our custom product sales program will require a larger increase in sales in the future than was achieved in 2008 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 which may adversely affect our results of operations.

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 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 most of our products sold internationally from the United States and Mexico. Our principal competitors in international markets consist 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.

We distribute products in Europe through our subsidiary in northern Italy. 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 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 than us, 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 significantly shorten the time from customer order to delivery of finished product, or both. To reduce costs, we moved labor intensive assembly operations to our facility in Mexico. To shorten delivery times, we 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 are introducing many of the systems and procedures that we used in our I.V. systems operations into the production of critical care products. If we are unable to complete this process 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, which could happen with the loss of a customer or a change in product mix, it may be necessary for us recognize an impairment charge for the value of the production tooling because its cost may not be recovered through production of saleable product, which could adversely affect our financial condition.

We have been and will be ordering production molds for our new products such as the Spiros closed male luer and Genie vial access device. We have ordered a high speed automated assembly machine for the MicroCLAVE connector and expect to have it in production in the second half of 2009. We expect to order semi-automated or fully automated assembly machines for the other new products in 2009. If we do not achieve significant sales of these new products, it might be necessary for us to recognize an impairment charge for the value of the production tooling because it costs may not be recovered through production of saleable product, which could adversely affect our financial condition.

If we cannot obtain additional custom tooling and equipment on a timely basis to enable us 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 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 and could be adversely affected by any economic or political disruptions

We continue to expand our production in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations. In 2008, production costs in Mexico were approximately $58.2 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, 2008, we employed 1,165 people in our plant in Ensenada, Mexico and we expect this number to increase during 2009. Business activity in the Ensenada area has expanded significantly, providing increased 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 are resins, plastics and other material that depend upon oil or natural gas as their raw material. Crude oil markets are 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, or the cost to produce, our products. Also, crude oil and natural gas prices in 2008 reached record highs. Our suppliers have passed some of their cost increases on to us, and if such prices are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs have increased because of the effect of higher crude oil prices, and we believe most of these costs have been passed on to us. Our ability to recover these increased costs may depend upon our ability to raise prices on our products. 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 , or to otherwise recover these costs, 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 or as our key patents expire.

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 pending litigation against Alaris Medical Systems, Inc., 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 this or in other litigation we bring against third parties for violating our patents could adversely affect our sales.

We are substantially dependent upon the patents on our proprietary products to prevent others from manufacturing and selling products similar to ours. We generally have multiple patents covering various features of a product, and as each patent expires, the protection afforded by that patent is no longer available to us, even though protection of features that are covered by other unexpired patents may continue to be available to us. The loss of patent protection on certain features of our products may make it possible for others to manufacture and sell products with features similar to ours, which could adversely affect our business.

If others chose to manufacture and sell products similar to or substantially the same as our products, it could have a material adverse effect on our business through loss of unit volume or price erosion, or both, and could adversely affect our ability to secure new business.

In the past, we have faced patent infringement claims related to the CLAVE, the CLC2000 and TEGO. We believe these claims had no merit, and all have been settled or dismissed, although a case involving the CLC2000 is pending on appeal. 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.

For additional information regarding our pending litigation, see “Item 3. Legal Proceedings” in this document.

If we are unable to effectively manage 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 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.

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

Government regulation is a significant factor in the development, marketing and manufacturing of our products. Our products are subject to clearance by the United States Food and Drug Administration (“FDA”) under a number of statutes including the Food Drug and Cosmetics Act (“FDC Act”). Each of our current products has qualified, and we anticipate that any new products we are likely to market will qualify, for clearance under the FDA’s expedited pre-market notification procedure pursuant to Section 510(k) of the FDC Act. However, certain of our new products may require a longer time for clearance than we have experienced in the past and there can be no assurance that a PMA application will not be required. Further, there is no assurance that other 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 FDC 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 (2003). Those quality standards are similar to the FDA's Quality System Regulations. 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 expired in 2007 and our Board of Directors adopted an Amended and Restated Rights Agreement in July 2007. 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 $225 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board of Directors a great deal of flexibility in dealing with any takeover attempts and is designed to cause persons interested in acquiring us to deal directly with the Board of Directors, 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 2007 10-K filed with the Securities and Exchange Commission.

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 2007 through December 2008, our trading price ranged from a high of $45.02 per share to a low of $22.14 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; the recent macroeconomic downturn could depress our stock price for some time.

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 45% 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 December 31, 2008 was 1,317,651 shares, or approximately nine percent 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, 2008, we had outstanding stock options to purchase 2.7 million shares, 70% 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 significant 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 241,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico, a 17,000 square foot and a 21,000 square foot building in Roncanova, Italy.

Item 3. Legal Proceedings

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

In an action filed June 16, 2004 entitled ICU Medical, Inc. v. Alaris Medical Systems, Inc. in the United States District Court for the Central District of California, we alleged that Alaris infringes ICU's patent through 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, we amended our complaint to allege that Alaris infringes three additional patents. On July 17, 2006, the Court issued an order interpreting certain claims in the asserted patents in a manner that, if upheld, could significantly impair our ability to enforce those patents against Alaris and potentially others. The Court also issued partial summary judgment in favor of Alaris based on one of those interpretations. On January 22, 2007, the Court granted 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 remaining claims. The Court's order adjudicated only the asserted claims of the patents in suit, not other claims in the patents. Following entry of the judgment dismissing our case, the Court heard Alaris' motion to recover its fees, costs and expenses, and on April 16, 2007, the Court granted in part Alaris' motion. On June 28, 2007, the Court awarded Alaris $4.8 million in fees and costs, which were later increased to $5.0 million, plus post-judgment interest. We have appealed the Court's decisions, and oral argument has been heard by the Federal Circuit Court of Appeal on January 5, 2009. Because the award of fees and costs is a judgment against us and the outcome of the appeal is uncertain, we recorded a charge of $5.0 million in our financial statements for the year ended December 31, 2007. We have not paid the judgment, pending outcome of the appeal.

In an action filed July 6, 2006 entitled Medegen MMS, Inc. v. ICU Medical, Inc. filed in the United States District Court for the Central District of California, Medegen alleged that ICU Medical infringed one of its patents by offering for sale and selling the CLC2000 and TEGO. Medegen sought monetary damages and injunctive relief. In March 2007, Medegen withdrew its action as to the TEGO. On June 21, 2007, the Court issued an order interpreting certain terms and phrases of Medegen's patent in a manner that we believe supported our position. On September 14, 2007, the Court issued an order granting our summary judgment motion of non-infringement and entered judgment of non-infringement, dismissing Medegen's case with prejudice, on October 19, 2007. On October 19, 2007, the Court also dismissed, without prejudice, our counterclaims that the asserted patent is invalid and unenforceable due to inequitable conduct by Medegen before the United States Patent and Trademark Office. Medegen has appealed the Court's claim construction and summary judgment orders. By decision issued in November 2008, the Federal Circuit reversed the order granting summary judgment and remanded the case to the District Court. In December 2008, ICU filed a Petition for Rehearing En Banc with the Federal Circuit. The Petition remains pending. We intend to defend ourselves against Medegen's claims in this action.

In an action filed July 27, 2007 entitled ICU Medical, Inc. v. RyMed Technologies, Inc. ("RyMed"), in the United States District Court for the District of Delaware, we alleged that RyMed infringes certain of ICU's patents through the manufacture and sale of certain products, including its InVision-Plus valves. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. RyMed has denied our allegations and sued ICU in the United States District Court for the Central District of California seeking a declaratory judgment of non-infringement and invalidity of our patents and alleging that we have infringed RyMed's trademark and engaged in unfair competition and other improper conduct. RyMed seeks monetary damages and injunctive relief. The Central District Court has transferred the patent claims to Delaware. RyMed's trademark and unfair competition claims remain pending in the Central District of California. ICU will continue to defend itself in the California action, and vigorously pursue its patent infringement claims against RyMed in the Delaware 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.	61	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	36	Vice President of Marketing
Richard A. Costello	45	Vice President of Sales
Scott E. Lamb	46	Chief Financial Officer
Steven C. Riggs	49	Vice President of Operations

Dr. Lopez has served as our Chairman of the Board and Chief Executive Officer since his hire date in 1989. Ms. Burcar, the niece of Dr. Lopez, has served as our Vice President of Marketing since 2002, was our Marketing Operations Manager from 1998 to 2002 and held research and development project/program management positions from 1995 to 1998. Mr. Costello has served as our Vice President of Sales since 1997, was our National Sales Manager from 1996 to 1997 and was a Product Specialist from 1992 to 1996. Mr. Lamb has served as our Chief Financial Officer since 2008 and as our Controller from 2003 to 2008. Mr. Riggs has served as our Vice President of Operations since 2002, was Director of Operations from 1998 to 2002 and was Senior Manager of Quality Assurance and Quality Control from 1992 to 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 Global Select Market 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 NASDAQ:

2008	High	Low
First quarter	$ 38.0837.75	$ 24.19
Second quarter	30.00	22.14
Third quarter	33.65	22.69
Fourth quarter	35.11	24.32

2007	High	Low
First quarter	$ 41.32	$ 38.01
Second quarter	44.60	39.57
Third quarter	43.34	32.66
Fourth quarter	40.10	35.96

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 January 31, 2009, we had 102 stockholders of record and we believe we have approximately 10,200 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 and have a 2001 Directors' Stock Option Plan under which we may grant options to purchase our Common Stock to our directors. 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 also have an Employee Stock Purchase Plan. All plans were approved by our stockholders. Further information about the plans is in Note 2 to the Consolidated Financial Statements. Certain information about the plans at December 31, 2008, 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)
2,706,786	$27.70	1,759,586

Issuer Repurchase of Equity Securities

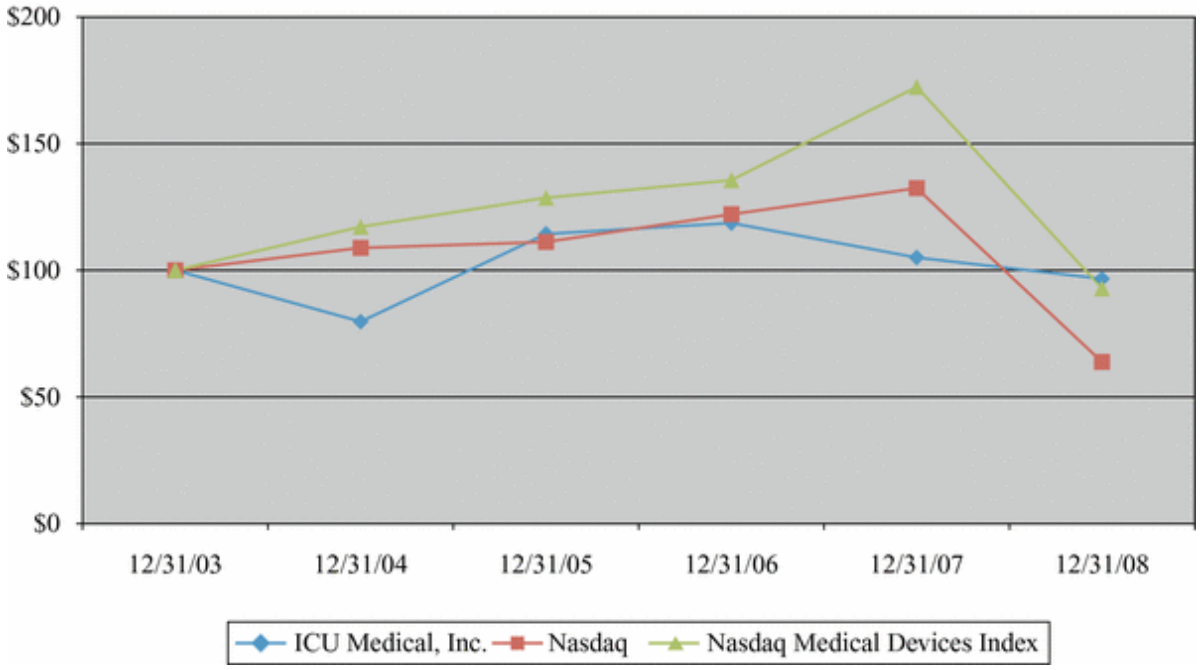
In July 2008, our Board of Directors authorized a program to purchase $40.0 million of our common stock. Actual purchases will depend on the stock price, prevailing market and business conditions and other considerations.

The following is a summary of our stock repurchasing activity during the fourth quarter of 2008:

Period	Shared 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
10/1/2008 - 10/31/2008	60,000	$ 33.34	60,000	$ 38,000,000
11/1/2008 - 11/30/2008	100,000	32.41	100,000	34,758,000
12/1/2008 - 12/31/2008	20,000	30.82	20,000	34,142,000
Fourth quarter 2008 total	180,000	$ 32.54	180,000	34,142,000

COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2004 TO DECEMBER 31, 2008 OF ICU MEDICAL, INC., NASDAQ AND NASDAQ MEDICAL DEVICES INDEX

The following graph shows the total stockholder return on our common stock based on the market price of the Common Stock from December 31, 2003 to December 31, 2008 and the total returns of the NASDAQ U.S. Index and NASDAQ Medical Devices, Instruments and Supplies, Manufacturers and Distributers Stocks Index for the same period.



	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08
ICU Medical, Inc.	$ 100.00	$ 79.73	$ 114.35	$ 118.64	$ 105.02	$ 96.65
Nasdaq	$ 100.00	$ 108.84	$ 111.16	$ 122.11	$ 132.42	$ 63.80
Nasdaq Medical Devices Index	$ 100.00	$ 117.16	$ 128.63	$ 135.58	$ 172.38	$ 92.84

Assumes $100 invested on December 31, 2003 in ICU Medical Inc.'s Common Stock, the NASDAQ U.S. Index and the Nasdaq Medical Devices, Instruments and Supplies, Manufacturers and Distributers Stocks Index.

Item 6. Selected Financial Data.

ICU MEDICAL, INC.
SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2008	2007	2006	2005	2004
INCOME DATA:					
Revenue					
Net sales	$ 203,026	$ 185,618	$ 198,788	$ 154,621	$ 72,704
Other	1,700	2,520	2,825	2,911	2,846
Total revenue	204,726	188,138	201,613	157,532	75,550
Cost of goods sold	114,910	109,895	120,929	88,128	39,853
Gross profit	89,816	78,243	80,684	69,404	35,697
Selling, general and administrative expenses	53,611	45,484	44,245	36,992	26,409
Research and development expenses	4,822	8,111	7,659	4,817	3,376
Gain on sale of building	—	—	(2,093)	—	—
Total operating expenses	58,433	53,595	49,811	41,809	29,785
Income from operations	31,383	24,648	30,873	27,595	5,912
Other income	4,695	8,698	4,462	2,721	1,579
Income before income taxes and minority interest	36,078	33,346	35,335	30,316	7,491
Provision for income taxes	(11,778)	(10,337)	(10,240)	(10,459)	(2,600)
Minority interest	—	70	565	417	109
Net income	$ 24,300	$ 23,079	$ 25,660	$ 20,274	$ 5,000
Net income per common share					
Basic	$ 1.72	$ 1.62	$ 1.78	$ 1.47	$ 0.37
Diluted	$ 1.67	$ 1.51	$ 1.64	$ 1.35	$ 0.33
Weighted average number of shares					
Basic	14,144	14,282	14,412	13,811	13,691
Diluted	14,565	15,265	15,599	15,040	14,960
Cash dividends per share	$ —	$ —	$ —	$ —	$ —
CASH FLOW DATA:					
Total cash flows from operations	$ 30,226	$ 41,512	$ 31,608	$ 27,342	$ 25,283
BALANCE SHEET DATA:					
Cash, cash equivalents, restricted cash and current and long-term investment securities	$ 129,153	$ 95,643	$ 116,918	$ 86,742	$ 87,341
Working capital	157,428	131,782	155,519	123,875	109,590
Total assets	283,434	242,594	244,248	204,537	164,768
Stockholders' equity	253,031	213,904	224,887	189,198	156,348

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 vascular therapy applications. Our devices are designed to protect patients from catheter related bloodstream infections and healthcare workers from exposure to diseases through accidental needlesticks or hazardous drugs. 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. In addition, we are 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: Investment securities consist of commercial paper and pre-refunded municipal bonds, which are classified as "available for sale" and auction rate securities which are classified as "trading." See Item 7A, Quantitative and Qualitative Disclosures about Market Risk. Under our current investment policies, our available for sale securities have no significant difference between the fair value and amortized cost. If there were to be a significant difference, this amount would be reflected as a separate component of stockholders' equity.

In January 2008, we adopted SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" (SFAS 159). SFAS 159 provides companies with an option to report selected financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date.

In October 2008, we accepted a release and settlement agreement (the "Agreement") from Morgan Stanley & Co. Incorporated ("Morgan Stanley") that requires Morgan Stanley to purchase $6.1 million of our existing auction rate securities at par value plus accrued interest at various dates from November 2008 — August 2009. As of December 31, 2008, $4.6 million of auction rate securities are left to be purchased by Morgan Stanley in accordance with the Agreement.

In October 2008, we accepted an offer from UBS AG ("UBS"), providing us with rights related to our auction rate securities held at UBS, (the "Rights"). The Rights permit us to require UBS to purchase our auction rate securities at par value plus accrued interest, at any time during the period June 30, 2010 through July 2, 2012. Conversely, UBS has the right, in its discretion, to purchase or sell our auction rate securities at any time until July 2, 2012, so long as we receive payment at par value upon any sale or disposition. We expect to sell our auction rate securities under the Rights.

The Agreement and Rights both represent a firm agreement in accordance with SFAS 133, which defines a firm agreement as an agreement with an unrelated party, binding on both parties and usually legally enforceable, with the following characteristics: a) the agreement specifies all significant terms, including the quantity to be exchanged, the fixed price, and the timing of the transaction, and b) the agreement includes a disincentive for nonperformance that is sufficiently large to make performance probable. The enforceability of both the Agreement and Rights results in put options and these should be recognized as free standing assets separate from the auction rate securities. Upon acceptance of the offers from Morgan Stanley and UBS, we recorded $0.5 million as the fair value of the put option assets, with a corresponding credit to other income. The put options do not meet the definition of a derivative instrument under SFAS 133. Therefore, we have elected to measure the put options at fair value under SFAS 159, which permits an entity to elect the fair value option for recognized financial assets, in order to match the changes in the fair value of the auction rate securities. As a result, unrealized gains and losses will be included in earnings in future periods. We expect that future changes in the fair value of the put options will approximate fair value movements in the related auction rate securities.

Revenue recognition : We record sales and related costs when ownership of the product transfers to the customer, persuasive evidence of an arrangement exists, collectibility is reasonably assured and the sales price is determinable. 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. Our customers are medical product manufacturers, distributors and 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 : Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on the age of the receivable or 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 : 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/depreciation : 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

In December 2007, the FASB issued SFAS 141R, “Business Combinations” (SFAS 141R). SFAS 141R amends the requirements for accounting for business combinations. SFAS 141R will be effective for financial statements issued for fiscal years beginning after December 15, 2008. The effect of this pronouncement could have a material impact on our consolidated financial statements if we engage in business combinations since acquisition related expenses that were previously capitalized will now be expensed.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities— an amendment of FASB Statement No. 133” (“SFAS 161”), which requires enhanced disclosures about an entity’s derivative and hedging activities. SFAS 161 will be effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We do not expect SFAS 161 to have a material impact on our results of operations, financial position or cash flows.

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 have furthered this effort to include all of our proprietary devices beyond the CLAVE.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In the years ended 2008, 2007 and 2006, our revenues from worldwide sales to Hospira were 69%, 73% and 77%, respectively, of total revenues. We expect this percentage will be maintained in the future as a result of sales of CLAVE products, custom I.V. systems, 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 worldwide.

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. Although overall pricing has been stable recently, the average price of our CLAVE products may decline in the future. 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. 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 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into the Manufacturing Commercialization and Development Agreement ("MCDA") with Hospira 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. We are expanding our custom products business through increased sales to medical product manufacturers, independent distributors and direct sales to the end users of our product. These expansions include our 2008 agreement with Premier and an agreement extension with MedAssets. Both organizations are U.S. healthcare purchasing networks. Custom products, which include custom I.V., custom oncology and custom critical care products, accounted for approximately $70.2 million or 34% of total revenue in 2008. We expect continued increases in sales of custom I.V. systems and custom oncology products. As part of this effort, we have recently introduced a number of new products: the TEGO for use in dialyses, the Orbit 90 diabetes set, and a line of oncology products including the Spiros male luer connector device, the Genie vial access device and custom I.V sets and ancillary products specifically designed for oncology therapy. T here is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products, that we will successfully integrate them into our existing business.

Custom products 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 modest growth rate. We also potentially face substantial increases in competition in our CLAVE business. 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 products and other products that lend themselves to customization and new products in the U.S. and international markets.

In 2005, we acquired Hospira's Salt Lake City manufacturing facility, related capital equipment and 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 U.S. market for most of the critical care products that we sell to Hospira has been declining in recent years. Under the MCDA, we manufacture the products and Hospira is responsible for sales to end customers, and we have little ability to directly influence Hospira's sales and marketing efforts, and our sales under the MCDA are subject to fluctuations over which we have little control.

We have also committed to fund certain research and development to improve critical care products and develop new products for sale to Hospira and to provide 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. There is no assurance as to the amounts of future sales or profits under the MCDA.

In December 2008, we signed an agreement to acquire a small manufacturing and distribution company based in Germany for €4.2 million. The products and distribution from this company are in the oncology market. Completion of this acquisition is contingent on final approval from the German court. We expect this process to conclude in the first half of 2009, however, there is no assurance that these expectations will be realized.

We believe that achievement of our growth objectives worldwide 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 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	2008	2007	2006
CLAVE	39%	38%	34%
Custom products	34%	31%	28%
Critical care	18%	23%	25%
Other products	8%	7%	12%
License, royalty and revenue share	1%	1%	1%
Total	100%	100%	100%

We sell our I.V. administration products to independent distributors, direct sales 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, 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.

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 molding in Salt Lake City and expanded our production facility in Mexico which took over the majority of our manual assembly previously done in Salt Lake City. In 2007, we began a significant initiative to improve production processes, called the "ICU Production System" or "IPS", which we believe will enable us to further improve our manufacturing efficiency. We started IPS in our Mexico facility in 2007 and in our Salt Lake City facility in 2008. These efforts are ongoing in both facilities and will continue in 2009. We may establish additional production facilities outside the U.S. There is no assurance as to the benefits of IPS or our success in establishing manufacturing facilities outside the U.S.

We distribute products through three distribution channels. Product revenues for each distribution channel as a percentage of total channel product revenue were as follows:

Channel	2008	2007	2006
Medical product manufacturers	67%	71%	76%
Independent domestic distributors/direct sales	18%	16%	14%
International customers	15%	13%	10%
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		
	2008	2007	2006
Revenue			
Net sales	99%	99%	99%
Other	1%	1%	1%
Total revenues	100%	100%	100%
Gross profit	44%	42%	40%
Selling, general and administrative expenses	26%	24%	22%
Research and development expenses	2%	5%	3%
Gain on sale of building	—%	—%	1%
Total operating expenses	28%	29%	24%
Income from operations	16%	13%	16%
Other income	2%	5%	2%
Income before income taxes and minority interest	18%	18%	18%
Income taxes	6%	6%	5%
Minority interest	0%	0%	0%
Net income	12%	12%	13%

Comparison of 2008 to 2007

Revenues were $204.7 million in 2008, compared to $188.1 million in 2007.

Distribution channels: Net U.S. sales to Hospira in 2008 were $132.6 million, compared to net sales of $129.7 million in 2007. The $2.9 million increase was primarily comprised of a $5.4 million increase in CLAVE sales, a $2.5 million increase in custom product sales, a $0.9 million increase in oncology sales, partially offset by a $7.0 million decrease in critical care product sales. The increase in CLAVE sales was from higher unit sales due to increased market share through Hospira. The unit growth in custom I.V. sets and custom oncology products more than offset the decline we experienced in custom critical care sales. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. The decrease in critical care sales was due to lower prices charged under the MCDA and lower unit sales of certain critical care products. We expect a modest growth in sales to Hospira in 2009 from 2008 from increased sales of CLAVE, custom I.V. systems, custom oncology products and new products offsetting declines in critical care and custom critical care products, although there is no assurance that these expectations will be realized.

Net sales to domestic distributors/direct in 2008 (including Canada) were $35.9 million compared to $29.5 million in 2007, an increase of $6.4 million or 22%. The increase was primarily from increased sales in custom products of $4.9 million and CLAVE of $1.1 million. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. We expect comparable increases in domestic distributor sales in 2009 that were experienced in 2008, principally from growth in our custom products and CLAVE products and new product sales, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were $30.8 million in 2008, compared with $23.7 million in 2007. The increased sales were primarily from $4.2 million of increased custom product sales and $1.5 million of increased CLAVE sales. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. Approximately 55% of the increase was attributable to increased sales in Europe and 24% of the increase was attributable to increased sales in the Pacific Rim. We expect modest increases in international customer sales in 2009, primarily from increased custom product sales and oncology product sales, although there is no assurance that these expectations will be realized.

Product and other revenue: Net sales of CLAVE products increased from $72.3 million in 2007 to $80.6 million in 2008, an increase of $8.3 million or 11%. This increase was from increased sales in all channels from increased market share and demographic growth, including $5.4 million in sales to Hospira. We expect increases in CLAVE product sales in 2009 compared to 2008, although there is no assurance that these expectations will be realized.

Net sales of custom products, which include custom I.V., systems, custom oncology products and custom critical care products, were $70.2 million in 2008 compared to $58.5 million in 2007. This increase was comprised of increased sales of custom oncology products of $8.5 million and custom I.V. systems of $4.0 million, partially offset by a $0.8 million decline in custom critical care sales. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. The decrease in custom critical care revenue was due to lower unit sales and lower prices to Hospira under the MCDA. We expect increases in custom I.V. system sales and new custom oncology sales. We expect decreases in custom critical care sales from unit volume decreases in 2009 compared to 2008.

Critical care product sales were $36.5 million in 2008 compared to $43.4 million in 2007. This decrease was due to lower unit sales and lower prices to Hospira under the MCDA. We expect further unit volume decreases in 2009 compared to 2008.

Our new oncology product sales, including custom oncology, were $11.8 million in 2008 compared to $0.9 million in 2007.

Other revenue consists of license, royalty and revenue share income and was approximately $1.7 million in 2008 and $2.5 million in 2007. We may receive other license fees or royalties in the future for the use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Gross margins for 2008 and 2007 were 44% and 42%, respectively. The margin improvement is attributed to a favorable product mix, improved efficiencies and productivity gains at our Mexico manufacturing facility and an increase in production volumes, offset by an increase in raw material and transportation costs and a decrease in pricing for critical care.

We estimate our gross margin in 2009 will approximate 43-44%. There is no assurance that these expectations will be realized.

Selling, general and administrative expenses **("SG&A")** were $53.6 million and 26% of revenues in 2008, compared with $45.5 million and 24% of revenues in 2007. The increase was primarily from increased compensation and benefits of $2.9 million, stock compensation expense of $0.8 million, sales and marketing promotional costs of $2.1 million and outside services of $1.4 million. The increase in compensation and benefits is primarily in incentive compensation and higher salary costs. We expect SG&A in 2008 to be approximately 26-27% of revenue with the increase principally from the addition of sales personnel, increased travel related expenses, and increased compensation and stock compensation expense. There is no assurance that these expectations will be realized.

Research and development expenses **("R&D")** were $4.8 million and two percent of revenue in 2008 compared to $8.1 million and four percent of revenue in 2007. The decrease is primarily due to our increased focus on our core projects in the latter half of 2008. We expect R&D in 2009 to be one to two percent of revenue, although there is no assurance that these expectations will be realized.

Other income decreased $4.0 million to $4.7 million in 2008 compared to $8.7 million in 2007. Other income in 2008 is primarily comprised of $3.0 million in interest income and $1.8 million of payments from a settlement agreement. Other income in 2007 includes $4.4 million of interest income, an $8.0 million payment to us for a settlement of litigation against a law firm that formerly represented us in patent litigation, and $1.0 million of payment under another settlement agreement, partially offset by a $5.0 million charge for an award against us in our litigation with Alaris Medical Systems. The decrease in interest income was primarily due to lower interest rates.

Income taxes were accrued at an effective tax rate of 33% in 2008 compared to 31% in 2007. The 2008 rate differed from the statutory corporate rate of 35% because of tax credits, tax exempt interest and dividends, Domestic Production Activities exclusions and foreign taxes. We expect our effective tax rate to be approximately 36% in 2009.

Comparison of 2007 to 2006

Revenues were $188.1 million in 2007, compared to $201.6 million in 2006. Revenues in 2006 included $14.6 million of sales from a product we discontinued manufacturing under the MCDA in October 2006 and sales of the Punctur Guard product line that was discontinued in January 2007. Revenues for 2007 and 2006, excluding discontinued products, were $188.1 million and $187.0 million.

Distribution channels: Net U.S. sales to Hospira in 2007 were $129.7 million, compared to net sales of $148.4 million in 2006, a decrease of $18.7 million or 13%. Sales in 2006 include $10.1 million from discontinued product sales. Excluding these sales, 2006 sales were $138.3 million compared to $129.7 million in 2007, a decrease of $8.6 million. The change in revenue was primarily from a decrease in critical care sales of $10.9 million, partially offset by increased custom I.V. system sales of $2.0 million. Of the decrease, $6.1 million was in critical care products, excluding custom products, and $4.8 million was in custom critical care products. The decreases in critical care and custom critical care sales were due to lower unit sales in most products and lower prices under the MCDA. The increased sales in custom I.V. systems were due to increased unit volumes. Custom I.V. system sales were $18.4 million in 2007 compared to $16.3 million in 2006, an increase of 13%. CLAVE sales to Hospira were $53.1 million in 2007, relatively unchanged from $52.8 million in 2006.

Net sales to independent domestic distributors in 2007 (including Canada) were $29.5 million compared to $27.7 million in 2006. Sales in 2006 include $3.1 million of Punctur Guard sales. Excluding Punctur Guard sales, 2006 sales were $24.6 million, for a $4.9 million or 20% increase in 2007. The increased sales were primarily from increases of $3.3 million in custom product sales, $0.9 million in new product sales of TEGO and oncology products and $0.5 million in CLAVE product sales. The increases in custom product and CLAVE sales were due to increased unit volumes.

Net sales to international customers (excluding Canada) were $23.7 million in 2007, compared with $20.6 million in 2006. Sales in 2006 include $1.4 million of Punctur Guard sales. Excluding Punctur Guard sales, 2006 sales were $19.2 million, for a $4.5 million or 24% increase in 2007. The increased sales were primarily from increases of $2.9 million in CLAVE product sales and $1.1 million in custom product sales. These increases were due to increased unit volumes. Approximately 76% of the increase was attributable to increased sales in Europe and 13% of the increase was attributable to increased sales in the Pacific Rim.

Product and other revenue: Net sales of CLAVE products increased from $68.4 million in 2006 to $72.3 million in 2007, an increase of $3.9 million or six percent. This increase was primarily due to increased international sales of $2.9 million and increased domestic distributor sales of $0.5 million.

Net sales of custom products were $58.5 million in 2007 compared to $56.4 million in 2006. Custom I.V. system sales were $45.3 million in 2007, or an increase of $5.8 million from 2006 sales of $39.5 million. This increase was due to increased unit sales across all channels. Custom critical care sales decreased by $4.2 million in 2007 from 2006. This decrease was due to lower unit sales and lower prices to Hospira under the MCDA.

Critical care product sales were $43.4 million in 2007 compared to $49.5 million in 2006. This decrease was due to lower unit sales and lower prices to Hospira under the MCDA.

Sales of other products were $11.4 million and $24.5 million in 2007 and 2006, respectively. The 2006 sales include $9.4 million of sales of a product we no longer manufacturer under the MCDA and $5.2 million of Punctur-Guard product sales (excluding royalties), which was terminated in January 2007.

Other revenue consists of license, royalty and revenue share income and was approximately $2.5 million in 2007 and $2.8 million in 2006. We may receive other license fees or royalties in the future for the use of our technology.

Gross margins for 2007 and 2006 were 42% and 40%, respectively. Production and gross margins were relatively stable in the first and second quarters of 2006. In the third and fourth quarters of 2006, gross margins declined to 39% and 33%, respectively. The decline was caused by temporary production inefficiencies at our factory in Salt Lake City and production inefficiencies at our factory in Mexico because of increased production volumes, turnover of new personnel and changes in production processes and certain non-recurring charges. The production inefficiencies in Salt Lake City and Mexico were reduced in 2007. Gross margin was favorably impacted by certain government incentives and unfavorably impacted by a decrease in production volumes.

Selling, general and administrative expenses **("SG&A")** were $45.5 million and 24% of revenues in 2007, compared with $44.2 million and 22% of revenues in 2006. The increase in costs was primarily due to increased sales and marketing compensation and benefits of $0.9 million, increased stock compensation expense of $0.6 million, increased sales and marketing travel costs of $1.1 million, increased sales and marketing promotional costs, such as trade shows, of $0.9 million, offset by decreased litigation expenses of $2.8 million.

Research and development expenses **("R&D")** were $8.1 million and four percent of revenue in 2007 compared to $7.7 million and three percent of revenue in 2006.

Other income increased $4.2 million to $8.7 million in 2007 compared to $4.5 million in 2006. Other income in 2007 includes $4.4 million of interest income, an $8.0 million payment to us for a settlement of litigation against a law firm that formerly represented us in patent litigation, and $1.0 million of payment under another settlement agreement, partially offset by a $5.0 million charge for an award against us in our litigation with Alaris Medical Systems. Other income in 2006 includes $3.7 million of interest income and $0.8 million of payment under a settlement agreement. The increase in interest income was due to an increase in average invested funds and higher yield rates.

Income taxes were accrued at an effective tax rate of 31% in 2007 compared to 29% in 2006. The 2007 rate differed from the statutory corporate rate of 35% because of tax credits, tax exempt interest and dividends and Domestic Production Activities exclusions.

Liquidity and Capital Resources

During 2008, our cash, cash equivalents, restricted cash and current and long-term investment securities increased by $33.5 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 and the timing of tax payments.

During 2008, our cash provided by operations was $30.2 million, which was mainly comprised of net income of $24.3 million, depreciation and amortization of $14.2 million, stock compensation expense of $1.9 million, offset by changes in our operating assets and liabilities. The $12.4 million increase in Accounts Receivable was the largest contributor to the change in our operating assets and liabilities. The increase was primarily due to higher sales in the fourth quarter of 2008 compared to 2007.

Investing Activities: During 2008, cash provided by investing activities was $3.6 million. This was primarily comprised of net investment sales of $20.3 million and proceeds on finance loan repayment of $0.6 million, partially offset by restricted cash of $6.0 million, cash paid for purchases of property and equipment of $11.4 million which were primarily for equipment and mold additions.

In connection with our existing auction rate securities, we have entered into arrangements with each of Morgan Stanley and UBS pursuant to which they will either purchase certain of our existing auction rate securities or sell them, in both cases at a price at least at par value, pursuant to the terms of such arrangements. For additional information, see Investment Securities under our Critical Accounting Policies at the beginning of Item 7 in this report.

We estimate that our capital expenditures in 2009 will approximate $15.0 million. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Cash provided by financing activities was $14.0 million in 2008. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was $19.9 million from the sale of 1,221,161 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

In July 2008, we announced program to purchase up to $40.0 million of our common stock. We purchased $5.9 million in the fourth quarter of 2008. Additional share repurchases may be made as we deem appropriate and based upon prevailing market and business conditions.

We have a substantial cash and investment security 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, cash equivalents and investment securities 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, and that we will be able to secure credit if needed because of illiquidity in our investment securities.

Off Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify our officers and directors 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 Hospira and to provide sales specialists focused on critical care. We believe that our existing cash and investment securities 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. We have excluded from the table below, the FASB Interpretation No. 48 , "Accounting for Uncertainty in Income Taxes," an interpretation of FASB Statement no. 109 ("FIN 48") noncurrent liability of $4.4 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the FIN 48 liabilities.

	2009 (in thousands)
MCDA	$ 8,693
Property and equipment	2,313
Total	$ 11,006

Forward Looking Statements

This Annual Report on Form 10-K contains statements relating to ICU Medical, Inc. (including certain projections and business trends) that are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and are subject to the "safe harbor" created by those sections. All statements included in this Annual Report on Form 10-K, other than those that are purely historical, are forward-looking statements. Words such as "expect," "believe," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "seek," "estimate," "should," "may," "assume" and "continue," as well as variations of such words and similar expressions, also identify forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, without limitation, statements regarding:

- 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, selling, general and administrative expense, research and development expense, expanding our workforce, our effective tax rate, future employee behavior, payment of dividends, 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, transportation costs, 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, changes in supply and prices of raw materials, effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies, business seasonality and fluctuations in quarterly results, operation of certain production equipment, financial health of our distributors, customer ordering patterns, competitive advantages of our current products, cost of compliance with new regulations, 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, consolidation of the healthcare provider market and downward pressure on selling prices, future purchases of treasury stock, loss of Dr. Lopez's services, working capital requirements, liquidity and realizable value of our investment securities, securing of credit lines, future investment alternatives, unexpected property and equipment depreciation, foreign currency denominated financial instruments, foreign exchange risk, our expectations regarding liquidity and capital resources over the next twelve months, investment strategy, capital expenditures, acquisitions of other businesses or product lines, indemnification liabilities, contractual liabilities, sale of our stock by certain individuals and entities, effect of our Stockholder Rights Plan and certain provisions of our Charter and Bylaws.

- general economic and business conditions, both in the U.S. and internationally;

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

- competitive factors, such as product innovation, quality, reliability and convenience of our products, 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.

The forward-looking statements in this report are subject to additional risks and uncertainties, including those set forth in Item 1A — "Risk Factors" and those detailed from time to time in our other filings with the Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof and, except as required by law, we undertake no obligation to update or revise any of them, whether as a result of new information, future events or otherwise.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We had a portfolio of corporate preferred stocks, federal-tax exempt state and municipal government debt securities, commercial paper and put options of $67.4 million as of December 31, 2008. The put options are enforceable, non-transferrable rights and agreement to purchase our existing auction rate securities at par value plus accrued interest. The securities are all "investment grade" and we believe that we have minimal exposure to credit risk. As of December 31, 2008, $44.4 million of our marketable securities were invested in pre-refunded municipal securities, $15.4 million were invested in "auction rate securities", $7.1 million were invested in commercial paper and $0.5 million were in put option assets related to auction rate securities. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk. For most of the auction rate securities, dividend and interest rates reset at auction at seven to forty-nine day intervals. As of December 31, 2008, we had declines of $0.5 million in the market values of the auction rate securities. The commercial paper investments are short-term debt issued by corporations with top-tier ratings of P-1/A-1.

Up until early February 2008, the market for our auction rate securities was highly liquid. However, as a result of liquidity issues in the global credit and capital markets, auctions for all of our auction rate securities failed beginning in February 2008 when sell orders exceeded buy orders. The failures of these auctions do not affect the value of the collateral underlying the auction rate securities, and we continue to earn and receive interest on our auction rate securities at pre-determined formula with spreads tied to particular interest rate indexes. Liquidity has been substantially impaired since February 2008 and accordingly we have substantially reduced our position in these types of investments since that time. We intend to continue our investment objectives of avoiding credit and market risk in the future.

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, commercial paper and corporate preferred stocks in our 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 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 asset position at December 31, 2008 and 2007 were approximately €9.1 million and €4.4 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 to date. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available.

Item 8 . Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ICU Medical, Inc.

San Clemente, CA

We have audited the accompanying consolidated balance sheet of ICU Medical, Inc. and subsidiaries (the "Company") as of December 31, 2008, and the related consolidated statements of income, stockholders' equity and comprehensive income, and cash flows for the year then ended. Our audit also included the financial statement schedule as of and for the year ended December 31, 2008 listed in the Index at Item 15. We also have audited the Company's internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and financial statement schedule and an opinion on 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 the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the ICU Medical, Inc. and subsidiaries as of December 31, 2008 and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ Deloitte & Touche, LLP

Costa Mesa, California
February 20, 2009

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ICU Medical, Inc.

We have audited the accompanying consolidated balance sheet of ICU Medical, Inc. and subsidiaries as of December 31, 2007, and the related consolidated statements of income, stockholders' equity and comprehensive income and cash flows for each of the two years in the period ended December 31, 2007. Our audits also included the financial statement schedules of ICU Medical, Inc. listed in Item 15(a). These financial statements and schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedules 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, 2007, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ McGladrey & Pullen, LLP
Irvine, California
February 21, 2008

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	December 31, 2008	December 31, 2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 55,6966	$ 7,873
Investment securities	56,093	87,770
Cash, cash equivalents and investment securities	111,789	95,643
Accounts receivable, net of allowance for doubtful accounts of $320 in 2008 and $655 in 2007	38,423	26,115
Inventories	17,930	19,504
Prepaid income taxes	4,544	2,740
Prepaid expenses and other current assets	3,471	4,746
Deferred income taxes — current portion	3,231	4,509
Total current assets	179,388	153,257
PROPERTY AND EQUIPMENT, net	69,897	72,708
PROPERTY HELD FOR SALE	940	—
RESTRICTED CASH	6,014	—
INVESTMENT SECURITIES — non-current portion	11,350	—
INTANGIBLE ASSETS, net	10,780	11,884
DEFERRED INCOME TAXES — non-current portion	3,855	2,432
INCOME TAXES RECEIVABLE — non-current portion	1,210	1,848
OTHER ASSETS	—	465
	283,434	$ 242,594
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,879	$ 8,439
Accrued liabilities	14,081	13,036
Total current liabilities	21,960	21,475
COMMITMENTS AND CONTINGENCIES	—	—
DEFERRED INCOME TAXES — non-current portion	4,007	4,325
INCOME TAXES PAYABLE — non-current portion	4,436	2,890
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 14,783,668 shares in 2008 and 14,746,951 shares in 2007, outstanding 14,730,725 shares in 2008 and 13,689,450 shares in 2007	1,478	1,475
Additional paid-in capital	50,970	74,805
Treasury stock, at cost — 52,943 shares in 2008 and 1,057,501 shares in 2007	(1,623)	(40,776)
Retained earnings	201,304	177,004
Accumulated other comprehensive income	902	1,396
Total stockholders' equity	253,031	213,904
	$ 283,434	$ 242,594

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,		
	2008	2007	2006
REVENUES:			
Net sales	$ 203,026	$ 185,618	$ 198,788
Other	1,700	2,520	2,825
TOTAL REVENUE	204,726	188,138	201,613
COST OF GOODS SOLD	114,910	109,895	120,929
Gross profit	89,816	78,243	80,684
OPERATING EXPENSES:			
Selling, general and administrative	53,611	45,484	44,245
Research and development	4,822	8,111	7,659
Gain on sale of building	—	—	(2,093)
Total operating expenses	58,433	53,595	49,811
Income from operations	31,383	24,648	30,873
OTHER INCOME	4,695	8,698	4,462
Income before income taxes and minority interest	36,078	33,346	35,335
PROVISION FOR INCOME TAXES	(11,778)	(10,337)	(10,240)
MINORITY INTEREST	—	70	565
NET INCOME	$ 24,300	$ 23,079	$ 25,660
NET INCOME PER COMMON SHARE			
Basic	$ 1.72	$ 1.62	$ 1.78
Diluted	$ 1.67	$ 1.51	$ 1.64
Weighted average number of shares			
Basic	14,144,245	14,281,696	14,411,699
Diluted	14,564,893	15,265,108	15,599,132

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							
	Number of Shares Outstanding	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income	Total	Comprehensive Income
BALANCE, December 31, 2005	14,136,298	$ 1,416	$ 60,154	$ (609)	$ 128,265	$ (28)	$ 189,198	
Purchase of treasury stock	(165,323)	—	—	(6,986)	—	—	(6,986)	
Exercise of stock options, including excess income tax benefits of $6,512	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
Purchase of treasury stock	(1,062,922)	—	—	(41,000)	—	—	(41,000)	
Exercise of stock options, including excess income tax benefits of $551	89,252	—	(1,106)	3,746	—	—	2,640	
Proceeds from employee stock purchase plan	42,699	—	(459)	1,861	—	—	1,402	
Stock compensation	—	—	1,052	—	—	—	1,052	
Minority interest share transfer	—	—	289	—	—	—	289	
Research and development tax credit originating from stock options and other tax benefits	—	—	540	—	—	—	540	
Comprehensive income								
Net income	—	—	—	—	23,079	—	23,079	$ 23,079
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $(472)	—	—	—	—	—	1,015	1,015	1,015
BALANCE, December 31, 2007	13,689,450	1,475	74,805	(40,776)	177,004	1,396	213,904	$ 24,094
Purchase of treasury stock	(180,000)	—	—	(5,858)	—	—	(5,858)	
Exercise of stock options, including excess income tax benefits of $8,996	1,162,456	3	(24,794)	42,706	—	—	17,915	
Proceeds from employee stock purchase plan	58,819	—	(932)	2,305	—	—	1,373	
Stock compensation	—	—	1,891	—	—	—	1,891	
Comprehensive income								
Net income	—	—	—	—	24,300	—	24,300	$ 24,300
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $74	—	—	—	—	—	(494)	(494)	(494)
BALANCE, December 31, 2008	14,730,725	$ 1,478	$ 50,970	$ (1,623)	$ 201,304	$ 902	$ 253,031	$ 23,806

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	For the years ended December 31,		
	2008	2007	2006
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 24,300	$ 23,079	$ 25,660
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	14,220	11,796	11,231
Provision for doubtful accounts	(270)	331	(273)
Stock compensation expense	1,891	1,052	487
Minority interest	—	(70)	(565)
Loss (gain) on disposal or sale of property and equipment or property held for sale	653	(130)	(2,093)
Cash provided (used) by changes in operating assets and liabilities, net of assets purchased			
Accounts receivable	(12,375)	523	(2,353)
Inventories	1,447	(3,033)	(785)
Prepaid expenses and other assets	197	(240)	(1,504)
Accounts payable	(525)	250	3,034
Accrued liabilities	1,093	5,144	(1,141)
Prepaid and deferred income taxes	(404)	2,810	(90)
Net cash provided by operating activities	30,227	41,512	31,608
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(11,351)	(23,645)	(19,612)
Proceeds from sale of assets	—	504	6,062
Cash paid for acquired assets	—	(3,224)	—
Proceeds from finance loan repayments	646	73	2,881
Change in restricted cash	(6,014)	—	—
Purchases of investment securities	(62,945)	(38,863)	(43,724)
Proceeds from sale of investment securities	83,272	54,858	19,847
Net cash provided by (used in) investing activities	3,608	(10,297)	(34,546)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	9,471	2,090	8,497
Proceeds from employee stock purchase plan	1,373	1,402	1,252
Excess tax benefits from exercise of stock options	8,996	551	6,512
Purchase of treasury stock	(5,859)	(41,000)	(6,986)
Net cash provided by (used in) financing activities	13,981	(36,957)	9,275
Effect of exchange rate changes on cash	7	462	(38)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	47,823	(5,280)	6,299
CASH AND CASH EQUIVALENTS, beginning of year	7,873	13,153	6,854
CASH AND CASH EQUIVALENTS, end of year	$ 55,696	$ 7,873	$ 13,153
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for income taxes	$ 3,073	$ 7,476	$ 4,001

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, 2008, 2007 and 2006
(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 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 equivalents are 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:

	2008	2007
Raw material	$ 12,531	$ 15,622
Work in process	2,577	1,712
Finished goods	2,822	2,170
Total	$ 17,930	$ 19,504

d. Property and Equipment

Property and equipment consist of the following at December 31:

	2008	2007
Machinery and equipment	$ 50,337	$ 45,503
Land, building and building improvements	48,715	48,546
Molds	16,791	14,029
Computer equipment and software	9,890	8,927
Furniture and fixtures	1,983	1,982
Construction in progress	3,479	4,900
Total property and equipment, cost	131,195	123,887
Accumulated depreciation	(61,298)	(51,179)
Net property and equipment	$ 69,897	$ 72,708

All property and equipment are stated at cost. 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 $12.4 million, $10.1 million and $9.4 million in the years ended December 31, 2008, 2007 and 2006, 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.

e. Intangible Assets

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

		December 31, 2008		
	Amortization Life in Years	Cost	Accumulated Amortization	Net
Patents and licenses	10	$ 7,763	$ 2,411	$ 5,352
MCDA contract *	10	8,571	3,143	5,428
Royalty agreements	6	1,399	1,399	—
Non compete agreement	5	818	818	—
Total		$ 18,551	$ 7,771	$ 10,780

		December 31, 2007		
	Amortization Life in Years	Cost	Accumulated Amortization	Net
Patents and licenses	10	$ 7,044	$ 1,742	$ 5,302
MCDA contract *	10	8,571	2,286	6,285
Royalty agreements	6	1,399	1,184	215
Non compete agreement	5	818	736	82
Total		$ 17,832	$ 5,948	$ 11,884

*MCDA contract: Manufacturing, Commercialization and Development Agreement with Hospira, Inc, dated May 1, 2005.

Amortization expenses in 2008, 2007 and 2006 was $1.8 million, $1.7 million and $1.8 million, respectively, including $0.2 million in 2006 for impairment related to the blood collection needle products. Estimated annual amortization for each of the next five years is approximately $1.6 million for 2009, $1.6 million for 2010, $1.5 million for 2011, $1.5 million for 2012 and $1.5 million for 2013.

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, which requires impairment losses to be recorded on long-lived assets used in operations when indicators of impairment, such as reductions in demand or significant economic slowdowns in the industry, are present.

The Company periodically evaluates the recoverability of long-lived assets whenever events and changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. When indicators of impairment are present, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book value of the underlying asset is adjusted to fair value if the sum of the expected discounted cash flows is less than book value. Fair values are based on estimates of market prices and assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

No impairment charges, other than those discussed in Note 1 and Note 4, were recorded in the years ended December 31, 2008, 2007 and 2006.

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.

	Fiscal year ended (in thousands, except per share data)		
	December 31, 2008	December 31, 2007	December 31, 2006
Net income	$ 24,300	$ 23,079	$ 25,660
Weighted average shares outstanding	14,144	14,282	14,412
Dilutive effect of employee stock options	421	983	1,187
Diluted weighted average shares outstanding	14,565	15,265	15,599
Basic net income per common share	$ 1.72	$ 1.62	$ 1.78
Diluted net income per common share	$ 1.67	$ 1.51	$ 1.64

There were no potentially dilutive securities excluded from the computation of diluted earnings per share for these periods if their effect would have been antidilutive.

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, 2008 and 2007, 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 has adopted the new requirements in its fiscal first quarter of 2007. The adoption of FIN 48 did not have a material effect on the Company's consolidated financial condition or results of operations.

The Company recognizes interest and penalties related to unrecognized tax benefits and penalties in the tax provision. The Company has not recorded any material interest or penalties during any of the years presented.

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. 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, persuasive evidence of an arrangement exists, collectibility is reasonably assured and the sales price is determinable. 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 other than its Section 401(k) retirement plan for employees. Company contributions to the plan in 2008, 2007and 2006 were approximately $0.9 million, $0.8 million and $0.3 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 December 2007, the FASB issued SFAS 141R, "Business Combinations" (SFAS 141R). SFAS 141R amends the requirements for accounting for business combinations. SFAS 141R will be effective for financial statements issued for fiscal years beginning after December 15, 2008. The effect of this pronouncement could have a material impact on the Company's consolidated financial statements if the Company engages in business combinations since acquisition related expenses that were previously capitalized will now be expensed.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities— an amendment of FASB Statement No. 133" ("SFAS 161"), which requires enhanced disclosures about an entity's derivative and hedging activities. SFAS 161 will be effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company does not expect SFAS 161 to have a material impact on its results of operations, financial position or cash flows.

Note 2: Share Based Awards

At December 31, 2008, 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. Shares to be issued to satisfy future stock option exercises or stock purchase rights under the ESPP will be issued either from authorized but unissued shares or from treasury shares.

Total stock-based compensation cost recognized in the years ended December 31, 2008, 2007 and 2006 was $1.9 million, $1.1 million and $0.5 million, respectively, for stock options and the ESPP. The tax benefit from the stock-compensation cost recognized in 2008 was $3.3 million, consisting of $0.6 million benefit from stock compensation expense and $2.7 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 as a reduction of income tax expense in 2008 as permitted by interpretation of SFAS 123R. The effect of adopting SFAS 123R on the Company's basic and diluted earnings per share was an increase of $0.08 and $0.07 per share, respectively, for the year ended December 31, 2006.

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.

The Company also has the 2001 Directors' Stock Option Plan (the "Directors' Plan"), which has 750,000 shares reserved for issuance to members of the Company's Board of Directors. Options not vested terminate if the directorship is terminated.

The fair value of stock grants is calculated using the Black-Scholes option valuation model. 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 granted 302,500 options in 2007, valued at $5.3 million. These grants were valued using the following weighted-average assumptions: risk-free interest rate of 4.5 percent, expected option life of 7.6 years, expected volatility of 37 percent and no dividends. The expected term was based on expected future employee behavior. The Company granted 230,800 options in 2008, valued at $3.0 million. These grants were valued using the following weighted-average assumptions: risk-free interest rate of 3.5 percent, expected option life of 8.0 years, expected volatility of 36.5 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, 2008, the Company has $6.5 million of unamortized stock compensation cost of which approximately $1.8 million will amortize annually in 2009 and 2010, $1.6 million will amortize in 2011, $1.1 million will amortize in 2012 and $0.2 million will amortize in 2013. As of December 31, 2008, the Company had one unvested performance based grant of 15,000 options and 127 unvested time-based grants totaling 515,050 options, which vest between 2010 and 2013. Vested and expected to vest stock options equal the Company's total outstanding options at December 31, 2008.

A summary of the Company's stock option activity for the as of and for the year ended December 31, 2008 is as follows:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2007	3,666,953	$ 21.58
Granted	230,800	27.32
Exercised	(1,162,456)	8.15
Forfeited or expired	(28,511)	34.37
Outstanding at December 31, 2008	2,706,786	$ 27.70
Exercisable at December 31, 2008	2,176,736	$ 26.66
Available for grant at December 31, 2008:		
2003 Plan	784,200	
Director's Plan	435,750	
	1,219,950	

The intrinsic value of stock options exercised in the year ended December 31, 2008, 2007 and 2006 was $23.7 million, $1.5 million and $17.1 million, respectively. The intrinsic value of options outstanding and options exercisable at December 31, 2008 was $15.6 million and $14.1 million, respectively, based on the Company's closing stock price of $33.14 on December 31, 2008. The above intrinsic values are before applicable taxes. The weighted average remaining contractual term of options outstanding and options exercisable at December 31, 2008, was 5.2 years and 4.3 years, respectively.

The number of options that are anti-dilutive because their exercise price exceeded the average market price of the Company's common stock approximated 1,490,000, 55,000 and 17,000 in 2008, 2007 and 2006, respectively.

A summary of the Company's weighted average fair value for stock option activity in 2008 is as follows:

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2007	337,500	$ 17.49
Granted	230,800	13.03
Vested	(12,750)	12.56
Forfeited	(25,000)	17.55
Nonvested at December 31, 2008	530,550	$ 15.67

The weighted average grant date fair value of options granted in 2008, 2007 and 2006 was $13.03, $17.42 and $18.11, respectively. The total fair value of shares vested in 2008, 2007 and 2006 was $0.2 million, $0.1 million and $0.2 million, respectively.

Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan ("ESPP") under which U.S. employees may purchase up to $25,000 annually of Common Stock at 85% of its fair market value at the beginning or the end of a six-month offering period, whichever is lower. There are 750,000 shares of Common Stock reserved for issuance under the ESPP, which is subject to an annual increase of the lesser of 300,000 shares or two percent of the shares outstanding or such a number as determine by the Board. To date, there have been no increases. The ESPP is intended to constitute an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. Employees purchased 58,819, 42,699 and, 45,206 shares of Common Stock under the ESPP Plan in the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008, there were 539,636 shares available for future issuance.

The fair value of rights to purchase shares under the ESPP is calculated using the Black-Scholes option valuation model. Rights for the 2008, 2007 and 2006 purchase periods were valued using the following weighted average assumptions: risk-free interest rate of 2.1 percent, 4.7 percent and 4.8 percent, respectively; expected option life of 0.5 years, expected volatility of 39 percent, 25 percent and 28 percent, respectively, which is based on the historical volatility of the Company's stock, and no dividends. As of December 31, 2008, 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 2009. The intrinsic value of ESPP shares at their date of purchase by employees in 2008, 2007 and 2006 was $0.3 million, $0.2 million and $0.3 million, respectively.

Note 3: Fair Value Measurement :

The Company adopted SFAS No. 157, "Fair Value Measurements" "SFAS 157", on January 1, 2008. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. This statement applies under other accounting pronouncements that require or permit fair value measurements. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2008:

	Fair value measurements at December 31, 2008 using			
	Total carrying value at December 31, 2008	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Available for sale securities	$ 51,518	$ —	$ 51,518	$ —
Trading securities	15,925	—	—	15,925
	$ 67,443	$ —	$ 51,518	$ 15,925

The Company's investment securities, which are considered "available for sale", and trading consist principally of corporate preferred stocks, federal-tax-exempt state and municipal government debt. The Company has $51.5 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities and commercial paper and have observable inputs. The Company has $15.9 million of its investment securities as Level 3 assets due to the unobservable inputs caused by the lack of liquidity in the recent auctions. The valuation of these securities was based on quotes received from our brokers which were derived from their internally developed models. In determining a discount factor for each auction rate security, the model weights various factors, including assessments of credit quality, duration, insurance wraps, discount rates, overall capital market liquidity and comparable securities, if any. They are carried at fair value.

The following tables summarize the change in the fair values for Level 3 items for the year ended December 31, 2008:

Level 3 changes in fair value (pre-tax):

	Year ended December 31, 2008
Beginning balance	$ —
Transfer into Level 3	87,770
Sales	(71,845)
Unrealized holding loss, included in other comprehensive income	—
Ending balance	$ 15,925

In January 2008, the Company adopted SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" (SFAS 159) for its auction rate securities. SFAS 159 provides companies with an option to report selected financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date. As of December 31, 2008, the Company had $15.4 million of auction rate securities. These are recorded at fair value which resulted in a $0.5 million charge against other income in the Company's consolidated statement of income in 2008.

In October 2008, the Company accepted a release and settlement agreement (the "Agreement") from Morgan Stanley & Co. Incorporated ("Morgan Stanley") that requires Morgan Stanley to purchase $6.1 million of the Company's existing auction rate securities at par value plus accrued interest at various dates from November 2008 — August 2009. As of December 31, 2008, $4.6 million of auction rate securities are left to be purchased by Morgan Stanley in accordance with the Agreement.

In October 2008, the Company accepted an offer from UBS AG ("UBS"), providing the Company with rights related to its auction rate securities held at UBS, (the "Rights"). The Rights permit the Company to require UBS to purchase the Company's auction rate securities at par value plus accrued interest, at any time during the period June 30, 2010 through July 2, 2012. Conversely, UBS has the right, in its discretion, to purchase or sell the Company's auction rate securities at any time until July 2, 2012, so long as the Company receives payment at par value upon any sale or disposition. The Company's management expects to sell its auction rate securities under the Rights.

The Agreement and Rights both represent a firm agreement in accordance with SFAS 133, which defines a firm agreement as an agreement with an unrelated party, binding on both parties and usually legally enforceable, with the following characteristics: a) the agreement specifies all significant terms, including the quantity to be exchanged, the fixed price, and the timing of the transaction, and b) the agreement includes a disincentive for nonperformance that is sufficiently large to make performance probable. The enforceability of both the Agreement and Rights results in put options and these should be recognized as free standing assets separate from the auction rate securities. Upon acceptance of the offers from Morgan Stanley and UBS, the Company recorded $0.5 million as the fair value of the put option assets, with a corresponding credit to other income. The put options do not meet the definition of a derivative instrument under SFAS 133. Therefore, the Company elected to measure the put options at fair value under SFAS 159, which permits an entity to elect the fair value option for recognized financial assets, in order to match the changes in the fair value of the auction rate securities. As a result, unrealized gains and losses will be included in earnings in future periods. The Company's management expects future changes in the fair value of the put options will approximate fair value movements in the related auction rate securities.

Note 4: Asset Dispositions or Held for Sale

In 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. In 2006, this resulted in a $0.4 million charge to cost of goods sold for depreciation 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. In December 2008, the building became classified as a held for sale asset and was marked down to its fair market value less estimated selling costs on the balance sheet as of December 31, 2008, resulting in a charge to sales, general and administrative expense of $0.6 million in the year ended December 31, 2008. The fair market value was based on an offer from a potential buyer in January 2009. In December 2007, the Company sold the inventory and machinery and equipment from the discontinued blood collection needle products line for $1.1 million, net of costs, $0.5 million payable at closing and $0.6 million that was payable in 2008. The Company did not receive the balance that was due in 2008 and adjusted the related receivable against the deferred revenue.

As a result of the relocation of manufacturing from the Company's San Clemente location to its Salt Lake City location in 2006, 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.

Note 5: Litigation Matters

In January 2007, the Company received $8.0 million in settlement of litigation against a law firm that formerly represented the Company in patent litigation matters. This is included in Other Income in the Consolidated Statements of Income for the year ended December 31, 2007.

On June 28, 2007 the United States District Court for the Central District of California ordered ICU Medical, Inc. to pay Alaris Medical Systems, Inc. (now part of Cardinal Health, Inc.), $4.8 million of fees and costs, which was later increased to $5.0 million, plus post judgment interest. The Court's decision was pursuant to a motion brought by Alaris for reimbursement of legal fees following dismissal of the Company's claim of patent infringement against Alaris. The Company has appealed the Court's judgment dismissing the Company's claims in the patent case and award of attorneys' fees. Because the order is a judgment against the Company and the outcome of the appeal is uncertain, the Company recorded a charge of $5.0 million in Other Income in the Consolidated Statement of Income for the year ended December 31, 2007. The Company has not paid the judgment, pending outcome of the appeal and accrued $0.2 million of interest expense in 2008.

Note 6: MedScanSonics, Inc.

As of December 31, 2007, the Company had a 94% interest in MedScanSonics, Inc. ("MSS"). This subsidiary was dedicated to the development of a new medical device for use in detecting coronary heart disease. Clinical trials determined the failure of the technology, resulting in the subsidiary ceasing operations in 2008. The Company recorded a $1.1 million tax benefit from the closure of this subsidiary. There were no other material effects on the Company's consolidated financial statements.

Note 7: Investment Securities

The Company's investment securities consist of corporate preferred stocks, federal-tax exempt state and municipal government debt securities, commercial paper and "puts". All investment securities are considered "available for sale" except for the auction rate securities and puts which are considered "trading". All of the securities are "investment grade", carried at fair value and there have been no gains or losses on their disposal. Balances consist of the following at December 31:

	2008	2007
Corporate preferred securities	$ 5,042	$ 19,250
Federal tax-exempt debt securities	54,694	67,625
Commercial paper	7,158	-
United States government securities	-	895
Puts	549	-
	$ 67,443	$ 87,770

The scheduled maturities of the debt securities are between 2009 and 2012.

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

	2008	2007	2006
Corporate dividends	$ 471	$ 521	$ 621
Tax-exempt interest	2135	3,347	2,616
Other interest	385	491	474
	$ 2,991	$ 4,359	$ 3,711

Note 8: Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2008	2007
Salaries and benefits	$ 4,031	$ 3,478
Professional fees	962	785
Legal judgment plus interest (Note 5)	5,351	5,149
Incentive compensation	2,517	1,891
Other	1,220	1,733
	$ 14,081	$ 13,036

Note 9: Stockholder Rights Plan

In July 1997, the Board of Directors adopted a Stockholder Rights Plan. This plan expired in 2007 and in July 2007, the Board of Directors adopted an Amended and Restated Rights Agreement. 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% 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 $225. In the event a third party or group were to acquire 15% 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 8, 2017.

Note 10: Income Taxes

Income from continuing operations before taxes for the years ended December 31, 2008, 2007, 2006 is as follows:

	2008	2007	2006
United States	$ 33,111	$ 32,168	$ 35,096
Foreign	2,967	1,178	239
	$ 36,078	$ 33,346	$ 35,335

The provision (benefit) for income taxes for the years ended December 31, 2008, 2007, 2006 is as follows:

	2008	2007	2006
Current:			
Federal	$ 9,576	$ 9,688	$ 7,410
State	2,203	712	2,135
Foreign	389	353	(175)
	12,168	10,753	9,370
Deferred:			
Federal	(376)	(856)	3,998
State	(1,841)	200	(2,798)
Foreign	1,827	240	(330)
	(390)	(416)	870
	$ 11,778	$ 10,337	$ 10,240

Current income taxes payable were reduced from the amounts in the above table by $9.0 million, $0.5 million and $6.5 million in 2008, 2007, and 2006, respectively, equal to the direct 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 2008 has recognized a $1.2 million net increase of accruals of which $0.5 million relates to state tax reserves.

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

	2008		2007		2006	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 12,619	35.0%	$ 11,671	35.0%	$ 12,360	35.0%
State income tax, net of federal effect	849	2.4	448	1.3	(243)	(0.7)
Tax credits	(1,903)	(5.3)	(833)	(2.5)	(1,463)	(4.2)
Tax-exempt interest and dividends	(842)	(2.3)	(1,360)	(4.1)	(1,033)	(2.9)
Domestic production activities/other	(131)	(0.5)	(285)	(0.8)	521	1.5
Loss of domestic subsidiary not consolidated for tax purposes	—	—	102	0.3	602	1.7
Foreign income tax	1,186	3.3	594	1.8	(504)	(1.4)
	$ 11,778	32.6%	$ 10,337	31.0%	$ 10,240	29.0%

Tax credits in 2008, 2007 and 2006 consist principally of research and developmental tax credits. In 2008 and 2007, the indirect effect of nonstatutory stock options exercised on research and development tax credits and other tax credits were recorded as reductions of the effective tax provision as permitted by interpretations of FAS 123R.

The components of the Company's deferred income tax provision for the years ended December 31, 2008, 2007 and 2006, are as follows:

	2008	2007	2006
Allowance for doubtful accounts	$ 66	$ 11	$ 148
Inventory reserves	339	113	(282)
Accruals	(245)	(1,680)	(305)
State income taxes	786	(225)	1,577)
Acquired future tax deductions	300	300	(86)
Depreciation and amortization	(417)	497	1,814
Net operating loss ("NOL") carryforward	577	476	(330)
Tax credits	(1,796)	92	(1,666)
	$ (390)	$ (416)	$ 870

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

	2008	2007
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts	$ 22	$ 88
Inventory reserves	695	1,034
Accruals	3,481	2,942
Tax credits	100	300
Foreign	(1,035)	101
State income taxes	(32)	44
	$ 3,231	$ 4,509
Non-current deferred tax asset:		
State income taxes	$ (221)	$ (340)
Tax credits state	3,953	1,958
Net operating loss carry forwards	—	1,732
Valuation allowance	—	(1,156)
Foreign	123	238
	$ 3,855	$ 2,432
Non-current deferred tax liability:		
Depreciation	$ (5,065)	$ (5,575)
Acquired future tax deductions	1,948	2,248
State income taxes	(1,231)	(405)
SFAS 123(R)	856	—
Foreign currency translation adjustments	(515)	(593)
	$ (4,007)	$ (4,325)

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 $1.7 million realized since acquisition; most of the balance of $0.2 million will be realized in approximately equal amounts over the next six years, and (b) by the tax benefited portion of Bio-Plexus's NOL carryforward of $2.0 million, less $1.2 million realized since acquisition, which will be realized in approximately equal amounts over the next 14 years. 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.

MedScanSonics, Inc., a domestic subsidiary, was liquidated in December 2008. A tax benefit of $1.1 million was realized.

A Mexican subsidiary recorded a deferred tax liability of $1.1 million as a result of newly enacted tax legislation.

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

Undistributed foreign earnings of the Company are primarily considered to be indefinitely reinvested. Upon distribution of those earnings in the form of dividends or otherwise, some portion of the distribution would be subject to both foreign withholding taxes and U.S. income taxes. Determination of the potential amount of unrecognized deferred federal and state income tax liability and foreign withholding taxes is not practicable because of the complexities associated with its hypothetical calculation; however, unrecognized foreign tax credits would be available to reduce some portion of the federal liability.

The Company adopted the provisions of FIN 48 on January 1, 2007. The total gross amount of unrecognized tax benefits as of the date of adoption was $2.5 million and as of December 31, 2008 was $4.9 million that, if recognized, would affect the effective tax rate. The Company does not anticipate that unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. The Company's United States federal income tax returns for tax years since 2007 are subject to examination by the Internal Revenue Service. The Internal Revenue Service recently concluded their examination of tax years through 2006. The Company's principal state income tax returns for tax years since 1998 are subject to examination by the state tax authorities.

The following table summarizes our cumulative gross unrecognized tax benefits under FIN 48:

	2008	2007
Beginning balance	$ 3,555	2,532
Increases to prior year tax positions	34	1,375
Increases to current year tax positions	1,908	150
Decrease related to lapse of statute of limitations	(138)	—
Decrease related to settlements	(472)	(502)
Ending balance	$ 4,887	3,555

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 $80.6 million, $72.3 million and $68.4 million of revenues in 2008, 2007 and 2006, respectively. Custom products, which include custom I.V. sets, custom oncology products and custom critical care, accounted for $70.2 million, $58.5 million and $56.5 million of revenues in 2008, 2007 and 2006, respectively. Critical care products accounted for $36.5 million, $43.4 million and $49.5 million of revenues in 2008, 2007 and 2006, respectively.

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, 2008, 2007 and 2006, the Company had worldwide sales to one manufacturer, Hospira, of 69%, 73% and 77%, respectively, of consolidated revenue. As of December 31, 2008 and 2007, the Company had accounts receivable from Hospira of 66% and 53%, respectively, of consolidated accounts receivable.

Export sales and sales outside the United States and Canada accounted for 15%, 13% and 10% of total revenue in 2008, 2007 and 2006, respectively.

As of December 31, 2008, approximately $44.0 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately $38.0 million in Mexico and approximately $6.0 million in Italy. As of December 31, 2007, approximately $41.3 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately $35.0 million in Mexico and approximately $6.3 million in Italy.

Note 12: Treasury Stock

The Company has a plan, authorized by its board of directors, to purchase up to $40 million of its common stock. As of December 31, 2008, $5.9 million has been purchased.

Note 13: Commitments and Contingencies

In an action filed July 6, 2006 entitled Medegen MMS, Inc. v. ICU Medical, Inc. filed in the United States District Court for the Central District of California, Medegen alleged that ICU Medical infringed one of its patents by offering for sale and selling the CLC2000 and TEGO. Medegen sought monetary damages and injunctive relief. In March 2007, Medegen withdrew its action as to the TEGO. On June 21, 2007, the Court issued an order interpreting certain terms and phrases of Medegen's patent in a manner that we believe supported our position. On September 14, 2007, the Court issued an order granting our summary judgment motion of non-infringement and entered judgment of non-infringement, dismissing Medegen's case with prejudice, on October 19, 2007. On October 19, 2007, the Court also dismissed, without prejudice, our counterclaims that the asserted patent is invalid and unenforceable due to inequitable conduct by Medegen before the United States Patent and Trademark Office. Medegen has appealed the Court's claim construction and summary judgment orders. By decision issued in November 2008, the Federal Circuit reversed the order granting summary judgment and remanded the case to the District Court. In December 2008, ICU filed a Petition for Rehearing En Banc with the Federal Circuit. The Petition remains pending. The Company intends to defend itself against Medegen's claims in this action.

The Company is from time to time involved in various other legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the other 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
2008				
Total revenue	$ 44,654	$ 48,592	$ 54,735	$ 56,745
Gross profit	17,771	20,804	24,947	26,294
Net income	2,898	4,772	7,645	8,985
Net income per share:				
Basic	$ 0.21	$ 0.34	$ 0.53	$ 0.62
Diluted	$ 0.20	$ 0.33	$ 0.52	$ 0.61
2007				
Total revenue	$ 48,833	$ 48,890	$ 44,868	$ 45,547
Gross profit	19,216	20,638	19,366	19,023
Net income	9,815	2,544	4,707	6,013
Net income per share:				
Basic	$ 0.67	$ 0.18	$ 0.33	$ 0.44
Diluted	$ 0.63	$ 0.16	$ 0.31	$ 0.41

Note 15: Subsequent Events: Restricted Cash/ Business Acquisition

In December 2008, the Company signed an agreement to acquire a small manufacturing and distribution company based in Germany for €4.2 million or an estimated $6.0 million. Completion of this acquisition was contingent on final approval from the German court, therefore the purchase price was held in escrow and was reflected as restricted cash as of December 31, 2008. The Company's received final approval from the German Court and closed this acquisition in February 2009.

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-15(e) and 15(d)-15(e) 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 was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

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, 2008 based on the criteria in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The Company's independent registered public accounting firm that audited the December 31, 2008 financial statements included in this Annual Report on Form 10-K has issued to the Company an attestation report on the Company's internal control over financial reporting .

Item 9B. Other Information

None

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, 2008 and such information is incorporated herein by reference. Pursuant to Instruction G(3) to Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K, information about Registrant's executive officers called for by Item 10, Part III of Form 10-K is set forth in Part I of this Report in a separate item captioned "Executive Officers of Registrant."

Items 11 though 14.

The information called for by Part III of Form 10-K (Item 11 — Executive Compensation, Item 12 — Security Ownership of Certain Beneficial Owners and Management 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, 2008, and such information is incorporated herein by this reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

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

1. Financial Statements

2. Financial Statement Schedules

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

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.

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. (11)
2.2	Letter Agreement dated May 1, 2005 between Registrant and Hospira, Inc. (11)
2.3	Real Estate Purchase Agreement dated February 25, 2005 between Registrant and Hospira, Inc. (11)
2.4	Transition Services Agreement dated May 1, 2005 between Registrant and Hospira, Inc. (11)
2.5	List of schedules and exhibits to Asset Purchase Agreement, Letter Agreement, Real Estate Purchase Agreement and Transition Services Agreement. (11)
2.6	Letter Agreement dated July 13, 2005 between Registrant and Hospira, Inc. re: Asset Purchase Agreement dated February 25, 2005. (12)
3.1	Registrant's Certificate of Incorporation, as amended. (1)
3.2	Registrant's Bylaws, as amended. (1)
10.1	Form of Indemnity Agreement with Executive Officers.(1)
10.2	Registrant's Amended and Restated 1993 Incentive Stock Plan.(2)*
10.3	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B. Braun, Inc. relating to the Protected Needle product.(3)
10.4	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(4)
10.5	Amended and Restated Rights Agreement dated October 18, 2007 between Registrant and American Stock Transfer & Trust Company as Rights Agent.(14)
10.6	SafeLine Agreement effective October 1, 1999 by and between Registrant and B.Braun Medical, Inc.(5)
10.7	Amendment to April 3, 1995 Supply and Distribution Agreement, dated January 1, 1999, between Registrant and Abbott Laboratories.(6)
10.8	Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories.(7)
10.9	Registrant's 2001 Directors' Stock Option Plan.(8)*
10.10	Registrant's 2002 Employee Stock Purchase Plan.(8)*
10.11	Registrant's 2003 Stock Option Plan.(9)*
10.12	Amendment to April 3, 1995 Supply and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories.(10)

10.13	Amendment to February 27, 2001 Co-Promotion and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories.(10)
10.14	Manufacturing, Commercialization and Development Agreement between Registrant and Hospira, Inc. effective May 1, 2005. (12)
10.15	Employment Agreement between Registrant and George A. Lopez, M.D. effective January 1, 2008. (15)*
10.16	Form of ICU Medical, Inc. 2005 Long Term Retention Plan. (11)
10.17	Letter Agreement dated July 8, 2005 between Registrant and Hospira, Inc. re: Manufacturing, Commercialization and Development Agreement effective May 1, 2005. (12)
10.18	Settlement and Release Agreement dated as of January 2, 2007 between ICU Medical, Inc. and Fulwider Patton Lee & Utecht, LLP. (13)
10.19	Retention Agreement between Registrant and Richard A. Costello, effective September 30, 2008 (16)*
10.20	Retention Agreement between Registrant and Steven C. Riggs, effective September 30, 2008 (16)*
10.21	Retention Agreement between Registrant and Scott E. Lamb, effective September 30, 2008 (16)*
10.22	Retention Agreement between Registrant and Alison Burcar, effective September 30, 2008 (16)*
10.23	Executive officer compensation*
10.24	Non-employee director compensation*
10.25	2008 Performance-Based Incentive Plan. (17)*
21	Subsidiaries of Registrant.
23.1	Consent of Deloitte & Touche LLP
23.2	Consent of McGladrey & Pullen 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

*Executive compensation plan or other arrangement

Exhibit 100.INS	XBRL Instance Document
Exhibit 100.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 100.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 100.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 100.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 100.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(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 Current Report on Form 8-K dated June 18, 1999, and incorporated herein by reference.

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

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

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

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

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

(11) 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.

(12) 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.

(13) Filed as an Exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2006, and incorporated herein by reference.

(14) Filed as an Exhibit to Registrant's Registration Statement on Form 8-A/A dated October 18, 2007, 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, 2008, and incorporated herein by reference.

(16) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated October 2, 2008 and incorporated herein by reference.

(17) Filed as Exhibit A to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 10, 2008 and incorporated herein by reference.

SIGNATURES

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

ICU MEDICAL, INC.

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

Dated: February 20, 2009

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)	February 20, 2009
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	February 20, 2009
/s/ Kevin J. McGrody Kevin J. McGrody	Controller (Principal Accounting Officer)	February 20, 2009
/s/ Jack W. Brown Jack W. Brown	Director	February 20, 2009
/s/ John J. Connors John J. Connors	Director	February 20, 2009
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	February 20, 2009
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	February 20, 2009
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	February 20, 2009
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	February 20, 2009

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands)		Additions			
Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
For the year ended December 31, 2006:					
Allowance for doubtful accounts	$ 593	$ (273)	$ —	$ (10)	$ 310
For the year ended December 31, 2007:					
Allowance for doubtful accounts	$ 310	$ 345	$ —	$ —	$ 655
For the year ended December 31, 2008:					
Allowance for doubtful accounts	$ 655	$ (270)	$ —	$ (65)	$ 320

Exhibit 10.23

Executive Officer Compensation

The annual base salaries for our executive officers as of January 1, 2009 are as follows:

Name	Title	Annual Base Salary
George A. Lopez, M.D.	Chairman of the Board, President and Chief Executive Officer	$ 500,000
Alison D. Burcar	Vice President of Marketing	$ 195,000
Richard A. Costello	Vice President of Sales	$ 260,000
Scott E. Lamb	Chief Financial Officer	$ 250,000
Steven C. Riggs	Vice President of Operations	$ 260,000

2008 Discretionary Bonuses:

In July 2008, the Compensation Committee of the Board of Directors approved payment of discretionary bonuses to the above named officers for the first half of 2008, and in January 2009, the Compensation Committee approved discretionary bonuses to each of the above named officers for the second half of 2008. In addition, Dr. Lopez was awarded a bonus by the Compensation Committee in January 2009, consistent with the terms of the 2008 Performance-Based Incentive Plan. The amount of the bonuses for the first half of 2008 were previously reported in the Current Report on Form 8-K filed with the SEC on July 24, 2008, and the amount of the bonuses for the second half of 2008, excluding Ms. Burcar, were previously reported in the Current Report on Form 8-K filed with the SEC on February 5, 2009, each of which reports are incorporated herein by reference.

Exhibit 10.24

Non-Employee Director Compensation

We currently pay our non-employee directors annual retainer of $24,000, plus $1,000 per day for attendance at meetings of the Board of Directors or $500 if the meeting is telephonic. Pay for attendance at meetings of Committees of the Board of Directors is $750 per day or $375 if the meeting is telephonic. Each Chairperson of a Committee of the Board of Directors also receives an annual retainer. The annual retainer is $7,500.

Our non-employee directors receive an option to purchase 1,500 shares of our common stock quarterly on the date that is two days after the public announcement of our earnings for the immediately preceding quarter. Such options become exercisable in four equal annual installments commencing one year after the grant date and expire ten years after the grant date.

Exhibit 21

Subsidiaries of Registrant

Name	State of Incorporation
ICU Medical Sales, Inc.	Delaware
ICU Finance, Inc.	California
Budget Medical Products, Inc.	California
ICU Medical de Mexico, S.A. de C.V.	Mexico
ICU Medical Europe S.r.l.	Italy
ICU Medical (Utah), Inc.	Delaware
ICU World, Inc.	Delaware
ICE Rink, Inc.	Delaware
ICU (Yantai) Medical Material Co. Ltd. (in liquidation)	China

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-04171, 333-58024, 333-90462, 333-90464, 333-115654, 333-115653, and 333-04167 on Form S-8 of our reports dated February 20, 2009, relating to the financial statements and financial statement schedule of ICU Medical, Inc. and subsidiaries as of and for the year ended December 31, 2008 and the effectiveness of ICU Medical, Inc. and subsidiaries' internal control over financial reporting, appearing in this Annual Report on Form 10-K of ICU Medical, Inc for the year ended December 31, 2008.

/s/ Deloitte and Touché, LLP

Cost Mesa, California
February 20, 2009

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement (Nos. 333-04171, 333-58024, 333-90462, 333-90464, 333-115654, 333-115653, and 333-04167) on Form S-8 of ICU Medical, Inc. of our report dated February 21, 2008 relating to our audits of the consolidated financial statements and the financial statement schedule of ICU Medical, Inc. for the years ended December 31, 2007 and 2006, which appears in this Annual Report on Form 10-K.

/s/ McGladrey & Pullen, LLP

Irvine, California
February 20, 2009

Exhibit 31.1

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

I, George A. Lopez, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 20, 2009

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

Exhibit 31.2

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

I, Scott E. Lamb, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 20, 2009

/s/ Scott E. Lamb
Chief Financial Officer

Exhibit 32

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

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George A. Lopez, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

February 20, 2009

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

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

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott E. Lamb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

February 20, 2009

/s/ Scott E. Lamb
Scott E. Lamb