

ICU MEDICAL INC/DE  
Form 10-K  
February 22, 2008

## **UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549



**FORM 10-K**

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



For the fiscal year ended December 31, 2007 or





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

**For the transition period from                      to**

**Commission File No. 0-19974**



**ICU MEDICAL, INC.**

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(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**33-0022692**

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

**951 Calle Amanecer**

**San Clemente, California**

(Address of principal executive offices)

**92673**

(Zip Code)

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



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

**Common Stock, \$0.10 par value**

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

**Preferred Stock Purchase Rights**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

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 the definitions 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  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, 2007, the last business day of registrant's most recently completed second fiscal quarter, was \$554,622,487\*.

The number of shares outstanding of registrant's common stock, \$.10 par value, as of February 15, 2008 was 13,755,261.



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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2008 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2007, are incorporated by reference into Part III of this Report.

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\* 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.

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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 infectious diseases through accidental needlesticks. We are also a leader in the production of custom I.V. systems and we incorporate our proprietary products into many of those custom I.V. systems. We are also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

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.

In 1993, we launched the CLAVE<sup>®</sup>, an innovative one-piece, needleless I.V. connection device that accounted for approximately 38% of our revenue in 2007, exclusive of CLAVEs incorporated into custom I.V. systems. We believe that the CLAVE offers superior infection control benefits for the patient and for healthcare providers a combination of safety, ease of use, reliability and cost effectiveness that is superior to any other protective I.V. connection system on the market. It allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE is a successor to our protected needle products first introduced in 1984. We designed the CLAVE to eliminate needles from certain applications in acute care hospitals, home healthcare, ambulatory surgical centers, nursing homes, convalescent facilities, physicians' offices, medical clinics, and emergency centers. Reduction in the use of needles not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal.

We are reducing our dependence on our current proprietary products by introducing new products and systems. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. Under one of our Hospira Agreements, we manufacture all new custom I.V. systems for sale by Hospira and jointly promote the products under the name SetSource<sup>®</sup>. A majority-owned subsidiary is developing a new medical device for use in detecting coronary heart disease; sales depend on the success of efforts to develop and market the device, and there can be no certainty that those efforts will succeed. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into the Manufacturing, Commercialization and Distribution Agreement (MCDAt) to produce Hospira's invasive monitoring, angiography products and certain other products they had manufactured at that facility. Custom I.V., custom critical care and custom oncology products accounted for approximately \$58.5 million or 31% of total revenue in 2007. Sales of critical care products, excluding custom critical care, were \$43.4 million in 2007. There is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

The principal products that we have introduced in recent years are the 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 . We will further expand our custom sets market and angiography market with various specialty components.

We currently sell substantially all of our products to I.V. product manufacturers and independent distributors. Hospira, our largest customer, accounted for 73% of our worldwide revenues in 2007.

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

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





**I.V. Products**



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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 led to significant federal and state legislation. The federal Needlestick Safety and Prevention Act, enacted in 2000, modified standards promulgated by the Occupational Safety and Health Administration ( OSHA ) to require employers to use needle-safe systems where appropriate to reduce risk of injury to employees from needlesticks. This was a significant expansion of the previous OSHA mandate that universal precautions be observed to minimize exposure to blood and other body fluids. In 1998, the State of California enacted the bloodborne pathogen standard under the state's occupational safety and health statute. This standard mandates use of needlestick prevention controls, including needleless systems. California was the first state to enact such legislation, and since then many other states have enacted similar legislation. Our devices will allow a healthcare provider to be compliant with any of these standards.

Hospital Acquired Infection (HAI) is a substantial concern for healthcare providers today. HAI can be caused by a variety of issues, one being having a vascular catheter which becomes contaminated with bacteria. The result is what is known as a Catheter Related Bloodstream Infection (CRBSI) and has a high rate of patient morbidity and mortality. In October 2008 The Centers for Medicare Services (CMS) will enact a ruling where they will cease reimbursement payment for HAI that are a result of Vascular Catheter Associated Infections. The average reported cost for treatment of a single CRBSI is \$60,000 and the ruling CMS will discontinue payment for these expenses 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

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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 can be administered through the CLAVE by using a standard syringe without a hypodermic needle attached. The CLAVE can be used with any conventional peripheral or central vascular access systems, both for venous and arterial applications. The resilience of the silicone compression seal permits repeated connections and disconnections without replacing the CLAVE.

The Y-CLAVE is designed to be integrated directly into primary and secondary I.V. sets, thus eliminating the need for special adapters, pre-slit injection ports, or metal needles when making piggyback I.V. connections. The Y-CLAVE will not replace CLAVE products used in non-piggyback connections. Unlike the original CLAVE site, the Y-CLAVE is marketed exclusively to I.V. set manufacturers, such as Hospira, to build directly into their I.V. sets or used by us in our custom I.V. sets.

The CLAVE is our largest selling product line, and accounted for \$72.3 million of our revenue in 2007. CLAVE products and Custom I.V. systems including one or more CLAVEs accounted for \$106.8 million of our revenue in 2007.

The MicroCLAVE<sup>®</sup> 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 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.

#### *Custom I.V. Systems*



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In the late 1990 s, we entered into 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, 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 2007, net sales of custom I.V. systems were approximately \$45.3 million, 39% of the custom I.V. sales were with domestic distributors, 40% with Hospira and the balance from international sales.

### *CLC2000*<sup>®</sup>

The CLC2000 is a one piece, swabbable connector used to connect I.V. lines to catheters, which is engineered to prevent the back-flow of blood into the catheter. The CLC2000 does not permit the use of needles, thereby ensuring compliance with needle-free policies of healthcare providers. The CLC2000 also contains no natural rubber latex. The CLC2000 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 \$5.2 million of our revenue in 2007.

### *1o2<sup>®</sup> Valve*

The 1o2 Valve is the first one-way or two-way drug delivery system. It functions as a single unit or in multiple ganged units as a manifold, for use primarily in anesthesia and critical care. It provides the safety features of an automatic one-way valve, yet allows aspiration, or two-way function by simply pushing a button. The 1o2 Valve can be used in place of products such as stopcocks and check valve manifolds. We actively commenced sales in April 2000. Our manufacturing focus has been on anesthesia and critical care usage and we are selling the 1o2 Valve only as part of I.V. sets that we manufacture. Sales of I.V. sets containing 1o2 Valves were approximately \$6.3 million in 2007 and are included in custom I.V. systems.

### **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. Our sales of critical care products were \$56.0 million in 2007. The products we manufacture, almost all of which are disposable, are the following.

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

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

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

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



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

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

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

*Custom Critical Care* A substantial portion of the invasive monitoring and angiography products are custom products designed to meet the specific needs of the customer. Most of the critical care products can be sold in custom systems containing specific components to meet the specific needs of the customer, and in some cases, custom made or acquired components. We believe we can significantly expand the market for custom invasive monitoring and angiography products through cost savings using our proprietary low-cost manufacturing techniques, although there is no assurance that we will succeed in this.

**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*



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We are developing several new products that we intend to introduce in 2008 and later. We believe innovative products continue to be important to maintaining and increasing our sales levels.

We have a 94% interest in a company developing a new medical device for screening for heart disease. The device in the design stage, uses new technology, and completion of a marketable device is expected to take at least several years at a cost somewhat in excess of our current investment. There is no assurance that a functional device will be developed or as to the timing of or cost of completing a marketable device.

In 2006, we launched, the TEGO Connector product, a new connector for use as an infection control device for use with dialysis catheters. In 2006, we introduced the Orbit 90 diabetes set. In 2007, we introduced SPIROS, a novel male luer connection device, and a line of I.V. therapy products used primarily for the delivery of hazardous medications such as chemotherapy which, if released can have harmful effects to the healthcare worker and environment. Sales of these new products were only \$2.2 million in 2007 and were adversely impacted by constraints on production capacity. We expect to have adequate tooling and capacity in 2008. There is no assurance as to the levels of sales we will achieve with the new products or whether production will have adequate capacity for a successful launch of these products.

### **Marketing and Distribution**



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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, 2007, we employed 81 product specialists worldwide to support our medical product manufacturing customers and our independent domestic distributors. Our product specialists call on prospective customers, demonstrate products and support programs to train the salespeople and customers' staffs in the use of our products.

### *Medical Products Manufacturers*

We have a strategic supply and distribution relationship with Hospira, a major I.V. product supplier, which has a significant share of the 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, 1o2 Valve, CLC2000, Lopez Valve and Rhino products are purchased and packaged separately.

Under another agreement with Hospira that extends to December 2014, we have the exclusive right to manufacture all new custom 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 with Hospira, which runs to 2025, we manufacture produce for sale, exclusively to Hospira, substantially all the products that Hospira had manufactured at the Salt Lake City facility that we purchased from Hospira in 2005. The majority of the products under the MCDA are critical care products. Hospira retains commercial responsibility for the products we produce, including sales, marketing, distribution, pricing, customer contracts, customer service and billing. We manufacture all critical care products sold by Hospira in the United States and all catheters sold by Hospira worldwide.

Worldwide sales to Hospira accounted for approximately 73%, 77% and 74% of revenue in 2007, 2006 and 2005, respectively. The loss of Hospira as a customer would have a significant adverse effect on our business and operating results.



*Independent Domestic Distributors*





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As of December 31, 2007, we had approximately 38 independent distributors in the United States and Canada who employ approximately 675 salespeople in the aggregate and which accounted for approximately 16% of our revenues in 2007, 14% in 2006 and 16% in 2005. We include Canada as domestic for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

No single independent distributor accounts for more than three percent of revenue in 2007. 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*



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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 13%, 10% and 8% of our revenues in each of the years ended December 31, 2007, 2006 and 2005, respectively. As of December 31, 2007, 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 four business development personnel serving Europe and six serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add more business development personnel in 2008. Administrative operations are in Roncanova in northern Italy (at the site of our assembly plant) and San Clemente. Currently, all shipments from the United States are invoiced in U.S. dollars and sales from Italy are invoiced in Euros.

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

### **Manufacturing**



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

We own a fully integrated medical device manufacturing facility in Salt Lake City, Utah with approximately 450,000 square feet. This building includes approximately 82,500 square feet of class 100,000 clean room space, approximately 36,000 square feet of other manufacturing space, approximately 104,000 square feet of warehouse space and approximately 155,000 square feet of office space. We acquired the Salt Lake City manufacturing facility from Hospira in 2005. In 2006, we completed significant improvements to that facility and moved all production in San Clemente, consisting of molding and automated assembly of CLAVE and certain other products, to Salt Lake City. As of December 31, 2007, this facility was equipped with approximately 60 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, 1o2 Valve, RF150 and our critical care products, including catheters, angiography kits and cardiac monitoring systems. The assembly systems are custom designed and manufactured for us. A mold maintenance shop supports the repair and maintenance needs of our molding operation and manufactures some of our production molds. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment.

Most of our manual assembly is done at our facility in Ensenada, Baja California, Mexico. This facility 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 are starting it in our Salt Lake City facility in 2008.

Our state-of-the-art injection molding technology and highly automated assembly systems are designed to maintain a high level of product quality and achieve high volume production at low unit manufacturing costs. To achieve these advantages and to gain greater control over raw material and finished product delivery times, we mold our entire requirements of proprietary molded

components. The raw materials for our molding operation are principally resins and silicones, and these materials are available from several sources. Generic, off-the-shelf items are purchased from outside vendors unless significant cost savings can be achieved by molding in-house. We have no contracts with our suppliers beyond the terms of purchase orders issued.

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

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

We also have a 37,500 square foot facility in Vernon, Connecticut, where we previously manufactured the Punctur-Guard products, a product line we discontinued in January 2007. The building is currently leased to an unrelated company, and MedScanSonic, Inc, our 94% owned subsidiary, subleases a portion of the building. We expect to sell the building, but the timing of the sale, if any, is uncertain.

In 2008, we will begin building a manufacturing plant in China to use for molding components for products that will be sold in markets outside of China. We expect this facility to be operational in early 2009.

## **Government Regulation**

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

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We must comply with FDA and European Council Directive 93/42/EEC (ISO) regulations governing medical device manufacturing practices. The FDA, State, Foreign Agencies and ISO require manufacturers to register and subject manufacturers to periodic FDA, State, Foreign Agencies and ISO inspections of their manufacturing facilities. We are a FDA and ISO registered medical device manufacturer, and must demonstrate that we and our contract manufacturers comply with the FDA's current Quality System Regulations ( QSR ). Under these regulations, the manufacturing process must be regulated and controlled by the use of written procedures and the ability to produce devices that meet the manufacturer's specifications must be validated by extensive and detailed testing of every critical aspect of the process. They also require investigation of any deficiencies in the manufacturing process or in the products produced and detailed record keeping. Further, the FDA and ISO's interpretation and enforcement of these requirements has been increasingly strict in recent years and seems likely to be even more stringent in the future. Failure to adhere to QSR and ISO standards would cause the products produced to be considered in violation of the applicable law and subject to enforcement action. The FDA and ISO monitor compliance with these requirements by requiring manufacturers to register with the FDA and ISO, and by subjecting them to periodic FDA inspections of manufacturing facilities. If a FDA or ISO inspector observes conditions that might be violative, the manufacturer must correct those conditions or explain them satisfactorily, or face potential regulatory action that might include physical removal of the product from the marketplace.



We believe that our products and procedures are in compliance with all applicable FDA and ISO regulations. There is no assurance, however, that other products we are developing or products that we may develop in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the FDA, ISO or agencies in other jurisdictions. In addition, changes in FDA, ISO or other federal or state health, environmental or safety regulations or their applications could adversely affect our business.

To market our products in the European Community ( EC ), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of EN ISO 13485. Those quality standards are similar to the QSR regulations.

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

We have demonstrated conformity to the regulation of EN ISO 13485 and the Medical Device Directive and we affix the CE Mark to our device labeling for product sold in member countries of the EC.

We believe our products and systems are in compliance with all EC requirements. There can be no assurance, however, that other products we are developing or products that we may develop in the future will conform or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the EC.

## **Competition**



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

Our present and future products compete with needleless I.V. connection systems like those marketed by Baxter Healthcare Corporation, B. Braun Medical, Inc. ( B. Braun ), Cardinal Healthcare ( Cardinal ), Becton Dickinson (BD) and others. Although we believe that our needleless CLAVE has distinct advantages over competing systems, there is no assurance that it will be able to compete successfully with these products.

The market for critical care devices is highly competitive. Competition is based on pricing, customer service and product features. The overall market for the critical care products we manufacture has been declining in recent years, and over that period, Hospira was losing market share to its competitors. Under the MCDA we have established specific resources to support the sales and marketing efforts of these products and are pursuing new products and new product features to increase the sales of these product lines. There is no assurance that these efforts will be successful.

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

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

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

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

### **Patents**



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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 valve, 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 2008 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:

<b>Product</b>	<b>Expiration dates</b>
CLAVE® connector	12/2011 - 07/2016
CLC2000® connector	12/2016
Click Lock® connector	11/2014 - 11/2015
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, 2007 we had 1,696 full-time employees, consisting of 162 engaged in sales, marketing and administration, and 1,534 in manufacturing, molding, product development and quality control, including 1,042 in Mexico. We contract with independent temporary agencies to provide some production personnel who are not our employees. At December 31, 2007, the number of temporary production personnel was 100.

### Item 1A. Risk Factors.

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

*Because we are 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. U.S. sales to Hospira were approximately \$129.7 million in the year ended December 31, 2007. The table below shows our total revenue and percentage of total revenue attributable to various types of customers for 2007 and 2006 (dollars in millions):

	Years Ended December 31,					
	2007			2006		
Hospira (U.S.)	\$	129.7	69%	\$	148.4	74%
Other manufacturers		2.7	1%		2.1	1%
Domestic distributors		29.5	16%		27.7	14%
International customers		23.7	13%		20.6	10%
Other revenue		2.5	1%		2.8	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 to Hospira; the latter two agreements extend through 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 2007 compared to 2006. We expect further declines in 2008. If the market for critical care 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 sales could continue to decline, resulting in a substantial reduction to our sales and profits.

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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.

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

The prices at which we sell products to Hospira and the gross margins that we realize under the MCDA depend on the cost savings that we expect to achieve in producing those products over Hospira's cost to manufacture the same products at the date we purchased the Salt Lake City facility from Hospira. Achieving substantial cost reductions requires moving manufacturing operations to lower-cost locations and the development and implementation of innovative manufacturing and assembly processes and techniques. While we have succeeded in reducing costs to date, there is no assurance of the longer term success of these efforts, 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.

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

We intend to continue to expand our marketing and distribution capability internally, by expanding our sales and marketing staff and resources and may expand it externally, by acquisitions both in the United States and foreign markets. We may also consider expanding our product offerings through further acquisitions of companies or product lines. We intend to build additional production facilities or contract for manufacturing in markets outside the United States, to reduce labor costs and eliminate transportation and other costs of shipping finished products from the United States and Mexico to customers outside North America. In 2008, we expect to begin building a manufacturing plant in China to use for molding components for products that will be sold in markets outside of China. We expect this facility to be operational in early 2009. 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.

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

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

For the year ended December 31, 2007, CLAVE products accounted for approximately 38% of our revenue and 57% of our revenue including custom I.V. systems incorporating a CLAVE. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. Most of our CLAVE sales are in the United States, where we expect our growth in sales to moderate in the future as further penetration of markets available to our existing customers in the United States becomes increasingly difficult. Future significant sales increases for CLAVE products may depend on increases in sales of custom I.V. systems, expansion in the international markets or acquisition of new customers in the United States. We cannot give any assurance that sales of CLAVE products will increase indefinitely or that we can sustain current profit margins on CLAVE products indefinitely.

We believe that the success of the CLAVE has motivated, and will continue to motivate, others to develop one piece needless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline as we lose market share, and/or we could encounter sustained price and profit margin erosion.

*If our efforts to increase 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 initiative to increase substantially our custom product business and develop significant market share on a profitable basis and on new product development. Our total sales of custom products including custom I.V. products, custom critical care products and custom oncology products, were \$58.5 million in the year ended December 31, 2007, compared with \$56.4 million in the year ended December 31, 2006. Sales of custom I.V. products increased by 15% in 2007 over 2006, 24% in 2006 over 2005, and 23% in 2005 over 2004. Sales of custom critical care products declined by \$4.2 million in 2007 to \$12.6 million. The success of our custom product sales program will require a larger increase in sales in the future than was achieved in 2007 and there is no assurance that such an increase will be achieved or sustained. Although we are seeking to continue to develop a variety of new products, there is no assurance that any new products will be commercially successful or that we will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers, with financial and distribution resources substantially greater than ours, have developed and are marketing products intended to fulfill the same functions as our products.

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

We have undertaken a program to increase significantly our international sales, and have distribution arrangements in all the principal countries in Western Europe, the Pacific Rim and Latin America, and in South Africa. We plan to sell in most other areas of the world. Currently, we export from the United States and Mexico most of our products sold internationally. Our principal competitors in international markets are a number of much larger companies as well as smaller companies already established in the countries into which we sell our products. Our cost structure is often higher than that of our competitors because of the relatively high cost of transporting product to the local market as well as our competitors' lower local labor costs in some markets. For these reasons, among others, we expect to open manufacturing facilities in foreign locations. In 2008, we expect to begin building a manufacturing plant in China. We expect this to be operational in early 2009. 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, we may be unable to maintain market share, in which case our sales may not grow and our profitability may be adversely affected.*

The market for I.V. products is intensely competitive. We believe that our ability to compete depends upon continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection and pricing. The ability to compete effectively depends on our ability to differentiate our products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as our ability to perceive and respond to changing customer needs. We encounter significant competition in our markets both from large established medical device manufacturers and from smaller companies. Many of these firms have introduced competitive products with protective features not provided by the conventional products and methods they are intended to replace. Most of our current and prospective competitors have economic and other resources substantially greater than ours and are well established as suppliers to the healthcare industry. Several large, established competitors offer broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply all of their I.V. product requirements. There is no assurance that our competitors will not substantially increase resources devoted to the development, manufacture and marketing of products competitive with our products. The successful implementation of such a strategy by one or more of our competitors could materially and adversely affect us.

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

We believe that the success of our I.V. systems operations will depend on our ability to lower per unit manufacturing costs and price our products competitively and on our ability to shorten significantly the time from customer order to delivery of finished product, or both. To reduce costs, we 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 successfully, we may not be successful in increasing sales of critical care products.

*If demand for our products were to decline significantly, we might not be able to recover the cost of our expensive automated molding and assembly equipment and tooling, which could have an adverse effect on our results of operations.*

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

We have been and will be ordering production molds for our new products such as the TEGO, Orbit 90, SPIROS closed male luer and Genie vial access device. We have ordered an automated assembly machine for the Y-CLAVE connector with integrated check valve and expect to have it in production in the first half of 2008, and expect to order semi-automated or fully automated assembly machines for the other new products in 2008. If we do not achieve significant sales of these new products, it might be necessary for us to account for impairment in value of the production tooling because it costs may not be recovered through production of saleable product.

*If we cannot obtain additional custom tooling and equipment on a timely enough basis to meet demand for our products, we might be unable to increase our sales or might lose customers, in which case our sales could decline.*

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

*We are increasingly dependent on manufacturing in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations*

We continue to expand our production in Mexico. In 2007, production costs in Mexico were approximately \$51.1 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, 2007, we employed 1,042 people in our plant in Ensenada, Mexico and we expect this to increase in the number of employees in Mexico during 2008. 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 is resins, plastics and other material that depend upon oil or natural gas as their raw material. Crude oil markets are being affected by political uncertainty in the Middle East, and there is no assurance that there will not be an interruption in crude oil supplies. Any such interruption could have an adverse effect on our ability to produce our products. Also, crude oil and natural gas prices in 2007 reached record highs, and continue to be substantially above historical levels. Our suppliers have passed some of their cost increases on to us, and if such prices are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs have increased because of the effect of higher crude oil prices, and we believe most of these costs have been passed on to us. Our ability to recover those higher costs may depend upon our ability to raise prices to our customers. In the past, we have rarely raised prices and it is uncertain that we would be able to raise them to recover higher prices from our suppliers. Our inability to raise prices in those circumstances could have an adverse effect on our profitability.

*We could be adversely affected by turbulence in the credit markets*

Developments in the credit markets may have an adverse effect on the liquidity of the tax-exempt debt securities and corporate preferred securities that we own. Auctions of these securities are conducted at prescribed intervals, and the securities are bought or sold depending on the interest or dividend rates bid for the securities; these securities are generally called auction rate securities. Investment banks generally purchased these securities for their own account if auction demand was not sufficient to complete the auction or customers desired to sell securities between auction dates. Investment banks are reported to have recently stopped purchasing these securities for their own account; this has adversely affected liquidity of these securities. In auctions at which the interest or dividend rates are reset, if there is not enough demand to sell the entire issue, the auction fails. Holders desiring to sell their securities cannot sell them at auction, and the interest or dividend rate generally resets to a penalty rate. Without participation by investment banks, there is only a very limited secondary market for these securities. If an auction fails, the ability of the holder of the security to liquidate the security would depend on the success of a subsequent auction, whether the issuer raises other financing to redeem the securities, or whether the holder is able to sell the securities to another party; there is no assurance that any of these events will occur. At February 11, 2008, we had \$87.9 million of auction rate securities; through February 20, 2008, we sold \$6.4 million of them at auction, and auctions on \$12.5 million of them failed and we continue to hold the securities. Auctions for more of our auction rate securities are likely to fail in the future. All of our securities are investment grade, and we do not expect any credit losses, but we may not be able to sell the securities, if necessary, to meet working capital needs. There can be no assurance as to when we will be able to sell additional securities and whether we will be able to sell them without incurring losses.

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

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 may make it possible for others to manufacture and sell products similar to ours, even if our remaining patents would prevent others from manufacturing and selling a product substantially the same as ours until those patents expire.

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 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.

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

Government regulation is a significant factor in the development, marketing and manufacturing of our products. Our products are subject to clearance by the United States Food and Drug Administration ( FDA ) under a number of statutes including the Food Drug and Cosmetics ( FDC ) Act. Each of our current products has qualified, and we anticipate that any new products we are likely to market will qualify, for clearance under the FDA s expedited pre-market notification procedure pursuant to Section 510(k) of the FDC Act. 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.

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The FDA has broad discretion in enforcing the FDC Act, and noncompliance with the Act could result in a variety of regulatory actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal penalties. If the FDA determines that we have seriously violated applicable regulations, it could seek to enjoin us from marketing our products or we could be otherwise adversely affected by delays or required changes in new products. In addition, changes in FDA, or other federal or state, health, environmental or safety regulations or in their application could adversely affect our business.

To market our products in the European Community ( EC ), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of ISO 13485 (2003). Those quality standards are similar to the FDA's Quality System Regulations but incorporate the quality requirements for product design and development. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC ( Medical Device Directive ) and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the CE Mark may be affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. 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 a great deal of flexibility in dealing with any attempted takeover of and will cause persons interested in acquiring us to deal directly with the Board, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire us.

Investors should refer to the description of the Plan in this Report to 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 December 2006 through December 2007, our trading price ranged from a high of \$45.02 per share to a low of \$31.96 per share. In mid-February 2008, it declined to \$27.48. We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts' expectations and actual quarterly and annual results, new product introductions by us or our competitors, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders and substantial product orders could contribute to the volatility in the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles and changing interest rates may also adversely affect the market price of our common stock.

Most of our common stock is held by, or included in accounts managed by, institutional investors or managers. Several of those institutions own or manage a significant percentage of our outstanding shares, with the ten largest interests accounting for 63% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate its position in our common stock, it could cause a decrease in the price of the common stock that could be significant.

For the past several years there has been a significant short position in our common stock, consisting of borrowed shares sold, or shares sold for future delivery which may not have been borrowed. We do not know whether any of these short positions are covered by long positions owned by the short seller. The short position, as reported by the Nasdaq Stock Market on January 31, 2008 was 2,752,154 shares, or approximately 20% 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, 2007, we had outstanding stock options to purchase 3.7 million shares, 90% 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. In addition, we anticipate that 1,125,000 options, which will expire on January 2, 2009, will be exercised and the underlying shares will be sold prior to the end of 2008.

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

The Sarbanes-Oxley Act of 2002 imposed significant new requirements on public companies. We have complied with most of these without undue effort or expense. However, compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requiring management to document and report on the effectiveness of internal controls over financial reporting and our independent registered public accounting firm to audit and report on the design and effectiveness of our internal controls over financial reporting has been extremely expensive. Further, there is no certainty that we will continue to receive unqualified reports on our internal controls over financial reporting from our independent registered public accounting firm and what actions might be taken by securities regulators or investors if we are unable to obtain an unqualified report.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

We own a 39,000 square foot building and a 28,000 square foot building in San Clemente, California, a 450,000 square foot building in Salt Lake City, Utah, a 37,500 square foot building in Vernon, Connecticut, a 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 affected 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. 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 \$4.8 million in our financial statements for the quarter ended June 30, 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. We intend to defend ourselves in the appeal and to vigorously pursue our claims against Medegen.

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 us 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. ICU has moved to dismiss RyMed's California case and will continue to defend ourselves vigorously in this action.

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

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

Not Applicable.

**Executive Officers of Registrant**

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

	<b>Age</b>	<b>Office Held</b>
George A. Lopez, M.D.	60	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	35	Vice President of Marketing
Richard A. Costello	44	Vice President of Sales
Scott E. Lamb	45	Controller
Francis J. O'Brien	65	Chief Financial Officer
Steven C. Riggs	49	Vice President of Operations

Dr. Lopez, Mr. Costello, Mr. O'Brien, Mr. Riggs and Ms. Burcar have been employed by us in their current positions for more than five years. Ms. Burcar is the niece of Dr. Lopez.

Mr. Lamb became Controller in April 2003. Prior to joining ICU, he held various finance positions. The last two were at GE Medical Systems Information Technologies and Vitalcom, Inc.



**Part II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.**

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

<b>2007</b>		<b>High</b>		<b>Low</b>
First quarter	\$	41.32	\$	38.01
Second quarter		44.60		39.57
Third quarter		43.34		32.66
Fourth quarter		40.10		35.96

  

<b>2006</b>		<b>High</b>		<b>Low</b>
First quarter	\$	43.09	\$	33.72
Second quarter		43.90		33.48
Third quarter		46.81		39.79
Fourth quarter		48.51		39.88

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, 2008, we had 108 stockholders of record and we believe we have approximately 12,500 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, 2007, is as follows:**

We have a 2003 Stock Option Plan under which we may grant options to purchase our Common Stock to our employees.



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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) 3,698,879	(b) \$21.59	(c) 2,020,705

**Issuer Repurchase of Equity Securities**



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We had a stock repurchase program, originally announced in July 2006. In August 2006, our Board of Directors authorized a program to purchase \$14.0 million of our common stock. This program was terminated in January 2007 after purchasing shares with a cost of approximately \$8.0 million. Also in January 2007, we announced an expanded program to purchase up to \$20 million of our common stock. The January repurchase program was completed in September 2007. In September 2007, we announced a new program to purchase up to \$20.0 million of our common stock. The September 2007 repurchase program was completed in November 2007. Additional share repurchases may be made as we deem appropriate based upon prevailing market and business conditions.

The following is a summary of our stock repurchasing activity during the fourth quarter of 2007:

Period	Shares purchased	Average price paid per share	Shares purchased as part of a publicly announced program	Approximate dollar value that may yet be purchased under the program
10/1/2007 - 10/31/2007	310,111	\$ 38.51	310,111	\$ 3,323,900
11/1/2007 - 11/30/2007	84,999	39.11	84,999	
12/1/2007 - 12/31/2007				
Fourth quarter 2007 total	395,110	\$ 38.64	395,110	

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COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2003 TO DECEMBER 31, 2007 AMOUNT ICU MEDICAL, INC., THE 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, 2002 to December 31, 2007 and the total returns of the Nasdaq Stock Market Tier Index and NASDAQ Medical Devices Index for the same period.

	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07
ICU Medical, Inc.	\$ 100.00	\$ 91.93	\$ 73.30	\$ 105.12	\$ 109.06	\$ 96.54
Nasdaq	\$ 100.00	\$ 149.52	\$ 162.72	\$ 166.18	\$ 182.57	\$ 197.98
Nasdaq Medical Devices Index	\$ 100.00	\$ 147.95	\$ 173.33	\$ 190.30	\$ 200.58	\$ 255.03

Assumes \$100 invested on December 31, 2002 in ICU Medical Inc.'s Common Stock, the Nasdaq Stock Market National Market Tier Index and the Nasdaq Medical Devices Index.





**Item 6. Selected Financial Data.**



ICU MEDICAL, INC.SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2007	2006	2005	2004	2003
<b>INCOME DATA:</b>					
Revenue					
Net sales	\$ 185,618	\$ 198,788	\$ 154,621	\$ 72,704	\$ 102,726
Other	2,520	2,825	2,911	2,846	4,628
Total revenue	188,138	201,613	157,532	75,550	107,354
Cost of goods sold	109,895	120,929	88,128	39,853	48,444
Gross profit	78,243	80,684	69,404	35,697	58,910
Selling, general and administrative expenses	45,484	44,245	36,992	26,409	23,029
Research and development expenses	8,111	7,659	4,817	3,376	1,757
Gain on sale of building		(2,093)			
Total operating expenses	53,595	49,811	41,809	29,785	24,786
Income from operations	24,648	30,873	27,595	5,912	34,124
Other income	8,698	4,462	2,721	1,579	1,123
Income before income taxes and minority interest	33,346	35,335	30,316	7,491	35,247
Provision for income taxes	(10,337)	(10,240)	(10,459)	(2,600)	(12,950)
Minority interest	70	565	417	109	
Net income	\$ 23,079	\$ 25,660	\$ 20,274	\$ 5,000	\$ 22,297
<b>Net income per common share</b>					
Basic	\$ 1.62	\$ 1.78	\$ 1.47	\$ 0.37	\$ 1.62
Diluted	\$ 1.51	\$ 1.64	\$ 1.35	\$ 0.33	\$ 1.48
<b>Weighted average number of shares</b>					
Basic	14,282	14,412	13,811	13,691	13,753
Diluted	15,265	15,599	15,040	14,960	15,050
Cash dividends per share	\$	\$	\$	\$	\$
<b>CASH FLOW DATA:</b>					
Total cash flows from operations	\$ 41,512	\$ 31,608	\$ 27,342	\$ 25,283	\$ 22,829
<b>BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 95,643	\$ 116,918	\$ 86,742	\$ 87,341	\$ 73,137
Working capital	131,782	155,519	123,875	109,590	102,932
Total assets	242,594	244,248	204,537	164,768	164,288
Stockholders' equity	213,904	224,887	189,198	156,348	156,003

**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 infectious diseases through accidental needlesticks. We are also a leader in the production of custom I.V. systems and we incorporate our proprietary products into many of those custom I.V. systems. We are also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

**Critical Accounting Policies**



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

Investment securities are all marketable and considered available for sale. See Item 7A. Quantitative and Qualitative Disclosures about Market Risk. Under our current investment policies, the securities in which we invest have no significant difference between cost and fair value. If our investment policies were to change, and there were differences between cost and fair value, that difference, net of tax effect, would be reflected as a separate component of stockholders' equity.

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

Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on 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 are stated at the lower of cost (first in, first out) or market. We need to carry many components to accommodate our rapid product delivery, and if we misestimate demand or if customer requirements change, we may have components in inventory that we may not be able to use. Most finished products are made only after we receive orders except for certain standard (non-custom) products which we will carry in inventory in expectation of future orders. For finished products in inventory, we need to estimate what may not be saleable. We regularly review inventory for slow moving items and write off all items we do not expect to use in manufacturing, or finished products we do not expect to sell. If actual usage of components or sales of finished goods inventory is less than our estimates, we could be required to write off additional inventory, which could have an adverse effect on our operating results in the period in which the write-off occurs.

Property and equipment is carried at cost and depreciated on the straight-line method over the estimated useful lives. The estimates of useful lives are significant judgments in accounting for property and equipment, particularly for molds and automated assembly machines that are custom made for us. We may retire them on an accelerated basis if we replace them with larger or more technologically advanced tooling. The remaining useful lives of all property and equipment are reviewed regularly and lives are adjusted or assets written off based on current estimates of future use. As part of that review, property and equipment is reviewed for other indicators of impairment. An unexpected shortening of useful lives of property and equipment that significantly increases depreciation provisions, or other circumstances causing us to record an impairment loss on such assets, could have an adverse effect on our operating results in the period in which the related charges are recorded.

## **New Accounting Pronouncements**

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

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

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. Accordingly, any business combinations we engage in will be recorded and disclosed following existing accounting principles until December 31, 2008.

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.

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 2007, 2006 and 2005, our revenues from worldwide sales to Hospira were 73%, 77% and 74%, 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

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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 2004, we made our initial investment in a company developing a new medical device. Sales depend on the success of efforts to develop and market the device, and there can be no certainty that those efforts will succeed. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into the MCDA to produce their invasive monitoring, angiography products and certain other products they had manufactured at that facility. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors. Custom I.V., custom oncology and custom critical care products accounted for approximately \$58.5 million or 31% of total revenue in 2007. We expect continued increases in sales of custom 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



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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. There is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

Custom I.V. systems and new products will be of increasing importance to us in future years. We expect continued growth in our CLAVE products in the U.S., but at a 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 I.V. systems and other products that lend themselves to customization and new products in the U.S. and international markets, and increasing our emphasis on markets outside the U.S.

On May 1, 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.

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	2007	2006	2005
CLAVE	38%	34%	40%
Custom products	31%	28%	27%
Critical care (excluding custom products)	23%	25%	20%
CLC2000	3%	3%	3%

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Other products	4%	9%	8%
License, royalty and revenue share	1%	1%	2%
Total	100%	100%	100%

Critical care, including critical care custom products and excluding products we no longer manufacture, accounted for 30%, 33% and 26% of total revenue for the years ended December 31, 2007, 2006 and 2005, respectively. Custom I.V. systems, excluding critical care custom products, were 24%, 20% and 20% of total revenues for the years ended December 31, 2007, 2006 and 2005, respectively.

Most custom I.V. systems include one or more CLAVES. Total CLAVE sales including custom I.V. systems with at least one CLAVE were \$106.8 million or 57% of total revenue in 2007, \$97.9 million or 49% of total revenue in 2006 and \$86.0 million or 55% of total revenue in 2005.

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

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Agreements ). Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors and the CLC2000. Under a 2001 agreement, we sell custom I.V. systems to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. Under the MCDA, a 2005 agreement, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. The terms of the MCDA extend to 2025. We also sell certain other products to a number of other medical product manufacturers.

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

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 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 are starting it in our Salt Lake City facility in 2008. We plan to begin building a manufacturing facility in China in 2008 to manufacture components for products that will be sold in domestic and international markets. We expect this facility will be operational in early 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 in China and elsewhere 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	2007	2006	2005
Medical product manufacturers	71%	76%	76%
Independent domestic distributors	16%	14%	16%
International customers	13%	10%	8%
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.

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	Percentage of Revenues		
	2007	2006	2005
Revenue			
Net sales	99%	99%	98%
Other	1%	1%	2%
Total revenues	100%	100%	100%
Gross profit	42%	40%	44%
Selling, general and administrative expenses	24%	22%	23%
Research and development expenses	5%	3%	3%
Gain on sale of building	%	1%	%
Total operating expenses	29%	24%	26%
Income from operations	13%	16%	18%
Other income	5%	2%	2%
Income before income taxes and minority interest	18%	18%	20%
Income taxes	6%	5%	7%
Minority interest	0%	0%	0%
Net income	12%	13%	13%

**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 all critical care products of \$10.9 million from \$66.2 million to \$55.3 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. We expect our 2008 sales to Hospira will be comparable to 2007 as increased sales from sales of CLAVE, custom I.V. systems and new oncology products are offset by declines in critical care and custom critical care products, although there is no assurance that these expectations will be realized.

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. We expect significant increases in domestic distributor sales in 2008 principally from growth in our custom I.V. system business and new product sales, although there is no assurance that these expectations will be realized.

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

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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. We expect significant increases in international customer sales across all areas in 2008, primarily from increased CLAVE and custom product sales and new oncology product sales, although there is no assurance that these expectations will be realized.

**Product and other revenue:** Net sales of CLAVE products (excluding custom CLAVE I.V. systems) increased from \$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. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$106.8 million in 2007 compared with \$97.9 million in 2006. This increase was due to increased unit sales of CLAVE and custom CLAVE products in all our distribution channels. We expect moderate increases in CLAVE product sales in 2008 compared to 2007.

Critical care product sales, excluding custom critical care products and products we no longer manufacture, 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. We expect further price decreases in 2008 and 2009 compared to 2007 and further unit volume decreases in 2008 compared to 2007.

Net sales of custom products, including custom critical care products and custom oncology 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 to \$12.6 million. This decrease 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 price decreases and unit volume decreases in 2008 compared to 2007. We also expect price decreases in 2009 for custom critical care products.

Net sales of CLC2000 in 2007 were \$5.2 million compared to \$5.4 million in 2006. The decrease was from modest decreases in purchases from Hospira and domestic distributors, partially offset by higher international sales.

Sales of other products were \$6.2 million and \$19.1 million in 2007 and 2006, respectively. The 2006 sales include \$9.4 million of sales of a product we no longer manufacture 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. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

**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.

We estimate our gross margin in 2008 will approximate 45%. There is no assurance that these expectations will be realized.

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**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. We expect SG&A in 2008 to be approximately 26% of revenue with the increase principally from the addition of sales personnel, including travel, and increased compensation and stock compensation expense. There is no assurance that these expectations will be realized.

**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. We expect R&D in 2008 to be four to five percent of revenue, although there is no assurance that these expectations will be realized.

**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.



**Minority interest** was \$0.1 million in 2007 compared to \$0.6 million in 2006 and represents the minority interest share of the net loss of the company developing a new medical device for use in screening heart disease. The minority interest has been insignificant since our interest in the company increased to 94% in February 2007.

**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. We expect our effective rate to be approximately 31% in 2008.

### **Comparison of 2006 to 2005**

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

**Distribution channels:** Net U.S. sales to Hospira in 2006 were \$148.4 million, compared to net sales of \$115.0 million in 2005, an increase of \$33.4 million or 29%. Net sales of CLAVE products to Hospira, excluding custom CLAVE I.V. systems, increased to \$52.7 million in 2006 from \$49.2 million in 2005, an increase of 7% on increased unit volume. Sales to Hospira under the SetSource program approximated \$15.8 million in 2006 compared to \$14.3 million in 2005, an increase of 11%. The SetSource increase is attributed to unit sales increases in the custom set market. Sales to Hospira under the MCDA, which began in May 2005, were \$75.8 million or 38% of total revenue in 2006 and were \$46.7 million or 30% of total revenue in 2005. This includes sales of \$9.4 million and \$5.7 million in 2006 and 2005, respectively, for a product we discontinued manufacturing of under the MCDA in October 2006.

Net sales to independent domestic distributors (including Canada) were \$27.7 million, an increase of approximately \$3.3 million or 13%, from \$24.4 million in 2005. Independent domestic distributors had a 14% or \$1.9 million increase in custom I.V. systems and a 15%, or \$0.8 million, increase in CLAVE product sales. Both increases are principally because of an increase in unit volume.

Net sales to international customers (excluding Canada) were \$20.6 million in 2006, compared with \$13.0 million in 2005, an increase of 58%. Approximately 87% of the increase was attributable to increased sales in Europe, 9% of the increase was attributable to increased sales in South Africa. The principal product lines showing increases were custom I.V. systems and CLAVE, both on increased unit volumes.

**Product and other revenue:** Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) increased from \$62.5 million in 2005 to \$68.4 million in 2006, an increase of \$5.9 million or 10%. This increase was primarily due to increased sales to Hospira of \$3.5 million from 2005 and increased international sales of \$1.9 million. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$97.9 million in 2006 compared with \$85.9 million in 2005. This increase was due to increased purchases of CLAVE and custom CLAVE products in all our distribution channels.

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

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

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

Sales of other products were \$19.1 million and \$14.1 in 2006 and 2005, respectively. The 2006 and 2005 sales include \$9.4 million and \$5.7 million of sales of a product we no longer manufacturer under the MCDA. Other product sales also include net sales of Punctur-Guard products (excluding royalties) of \$5.3 million in 2006 and \$4.2 million in 2005, which was phased out of production in the first quarter of 2007.

Other revenue consists of license, royalty and revenue share income and was approximately \$2.8 million in 2006 and \$2.9 million in 2005.

**Gross margins** for 2006 and 2005 were 40% and 44%, respectively. Production and gross margins were relatively stable in the first two quarters of 2006 and reflected further costs savings at our Salt Lake City and Mexico plants. In the third quarter, the margin was negatively impacted by approximately \$3.0 million of non-recurring costs including unabsorbed overhead as the San Clemente plant was shut down and production commenced in Salt Lake City, costs of moving machinery, and severance costs in San Clemente. While all costs directly related to the move from San Clemente to Salt Lake City were complete by the end of the third quarter, we incurred temporary production inefficiencies in the fourth quarter. Those inefficiencies and lower production scheduling through the holiday seasons in the fourth quarter negatively impacted our gross margin by approximately \$2.8 million.

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

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

**Selling, general and administrative expenses ( SG&A )** increased by \$7.3 million to \$44.2 million, and were 22% of revenues in 2006, compared with 23% in 2005. The increase in costs was partially due to \$4.1 million of increased compensation and benefit expenses, including the addition of new sales personnel, increased bonuses and increased pay rates. Travel expense increases accounted for \$1.1 million of the increase. Computer related costs, which includes software expenses, maintenance costs and hosting costs, increased by \$1.0 million as we continued to upgrade our systems and network. Amortization of intangibles accounted for \$0.5 million of the increase.

**Research and development expenses ( R&D )** were \$7.7 million and three percent of revenue in 2006 compared to \$4.8 million and three percent of revenue in 2005. This increase was primarily from R&D activity associated with a \$2.9 million increase in R&D on critical care products.

**Gain on sale of building** of \$2.1 million was from the sale of one of our buildings in San Clemente in 2006. The building was used for manufacturing prior to moving the manufacturing to our Salt Lake City facility.

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

**Minority interest** was \$0.6 million in 2006 compared to \$0.4 million in 2005 and represents the minority interest share of the net loss of the company developing a new medical device for use in screening heart disease.

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*Income taxes* were accrued at an effective tax rate of 29.0% in 2006 compared to 34.5% in 2005. The 2006 rate differed from the statutory corporate rate of 35% because of tax credits that are higher than expected on a recurring basis, tax exempt interest and dividends, and because of tax benefits of foreign tax losses, partially offset by state taxes and tax losses of a company not included in our consolidated tax return.

### **Liquidity and Capital Resources**

During 2007, our cash, cash equivalents and marketable securities decreased by \$21.3 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 2007, 2006 and 2005, cash provided by operations was \$41.5 million, \$31.6 million and \$27.4 million, respectively. The 2007 operating cash was mainly comprised of net income of \$23.1 million, depreciation and amortization of \$11.8 million, \$1.1 million of stock compensation expense, offset by changes in our operating assets and liabilities.

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**Investing Activities:** During 2007, we used cash of \$10.3 million in investing activities. This was primarily comprised of cash paid for acquired assets of \$3.2 million, purchases of property and equipment of \$23.6 million which were primarily for the building expansion of our Mexico facility, equipment additions and mold additions, offset by net investment sales of \$16.0 million.

We estimate that capital expenditures in 2008, will be approximately \$20.0 million. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

**Financing Activities:** During 2007, we used cash of \$37.0 million. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$4.0 million from the sale of 131,951 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

In January 2007, we announced an expanded program to purchase up to \$20.0 million of our common stock. In September 2007, we announced another program to purchase up to an additional \$20.0 million of our common stock. The full amount from each program was purchased, along with \$1.0 million from a 2006 program for a total 2007 purchase of \$41.0 million of our common stock. Additional share repurchases may be made as we deem appropriate and based upon prevailing market and business conditions.

We have a substantial cash and marketable 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.

Most of our marketable securities are invested in auction rate securities. Our auction rate securities are tax exempt debt securities and corporate preferred securities. Auctions of these securities are conducted generally at seven to forty-nine day intervals, depending on the terms of the security, and the securities are bought or sold depending on the interest or dividend rates bid for the securities. Up until February 2008, the auction rate securities market was highly liquid. During the week of February 11, 2008, a substantial number of auctions failed, meaning that there was not enough demand to sell the entire issue at auction; the immediate effect of a failed auction is that holders cannot sell the securities and the interest or dividend rate on the security generally resets to a penalty rate. If an auction fails, the ability of the holder of the security to liquidate the security would depend on the success of a subsequent auction, whether the issuer raises other financing to redeem the securities, or whether the holder is able to sell the securities to another party; there is no assurance that any of these events will occur. See Part I, Item 1A. Risk Factors *We could be adversely affected by turbulence in the credit markets.* All of our securities are investment grade, and the Company does not expect any credit losses, but we may not be able to sell our securities to meet working capital needs. We have succeeded in selling some of these securities at par and are attempting to sell more at par, but there can be no assurance as to when we will be able to sell additional securities and whether we will be able to sell them without incurring losses. We plan to secure credit lines to provide working capital if necessary, but there is no assurance we will be able to secure credit and if we can, whether terms will be acceptable.

We are considering investment alternatives for the future. We intend to continue our objectives of avoiding credit and market risk, but there is no assurance that investment yield will be comparable, on an after-tax basis, to the yields on auction rate securities.

We believe that our existing cash, cash equivalents and marketable 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 marketable 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 liquid investments along with funds expected to be generated from future operations will provide us with sufficient funds to meet commitments under all of our contractual obligations. There are no obligations past 2009. (In thousands)

	2008		2009
MCDA	\$ 8,801	\$	5,500
Property and equipment	2,428		
Total	\$ 11,229	\$	5,500

### Forward Looking Statements

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

- future operating results and various elements of operating results, including future expenditures on sales and marketing and product development, future sales and unit volumes of products, future license, royalty and revenue share income, production costs, gross margins, litigation expense, SG&A, R&D expense, future costs of expanding our custom I.V. systems business, income, losses, cash flow, changes in working capital items such as receivables and inventory, selling prices, and income taxes;
- factors affecting operating results, such as shipments to specific customers, reduced dependence on current proprietary products, expansion in international markets, selling prices, future increases or decreases in sales of certain products and in certain markets and distribution channels, increases in systems capabilities, introduction and sales of new products, warranty claims, rebates, product returns, bad debt expense, inventory requirements, manufacturing efficiencies and cost savings, unit manufacturing costs; 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, effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies, business seasonality and fluctuations in quarterly results, customer ordering patterns and the effects of new accounting pronouncements;
- new or extended contracts with manufacturers and buying organizations, dependence on a small number of customers, effect of the acquisition of Hospira's Salt Lake City manufacturing facility and the manufacture of products for Hospira under the MCDA, cost savings and use of our systems and procedures under the MCDA, and the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices; future purchases of treasury stock; working capital requirements; liquidity and realizable value of our marketable securities, outcome of future auctions of auction rate securities, securing of credit lines, future investment alternatives, foreign currency denominated financial instruments; capital expenditures; acquisitions of other businesses or product lines; indemnification liabilities; contractual liabilities.

The kinds of statements described above and similar forward looking statements about our future performance are subject to a number of risks and uncertainties which one should consider in evaluating the statements. First, one should consider the factors and risks described in the

statements themselves. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.



Second, one should read the forward looking statements in conjunction with the Risk Factors in Item 1A of this Annual Report to the Securities and Exchange Commission. Also, our actual future operating results are subject to other important factors that we cannot predict or control, including among others the following:

- general economic and business conditions;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

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

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

We have a portfolio of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities. The securities are all investment grade and we believe that we have virtually no exposure to credit risk. Dividend and interest rates reset at auction for most of the securities at seven to forty-nine day intervals so we have very little market risk, that is, risk that the fair value of the security will change because of changes in market interest rates. As of December 31, 2007 and 2006, we had no declines in the market values of these securities.

Up until early February 2008, the market for our securities was highly liquid. Liquidity has been substantially impaired since then. See Part I, Item 1A. Risk Factors *We could be adversely affected by turbulence in the credit markets* and Part I, Item 7. Management Discussion and Analysis of Financial Condition and Results of Operations, Liquidity and Capital Resources, *Financing Activities*. We intend to continue our 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 and corporate preferred stocks in the portfolio and market conditions specific to the securities in which we invest.

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable and accounts payable, is not significant to our financial statements. Sales from the U.S. and Mexico to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the Euro 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, 2007 and 2006 were approximately 4.4 million and 2.7 million. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

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

**Item 8. Financial Statements and Supplementary Data.**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

ICU Medical, Inc.

We have audited the consolidated balance sheets of ICU Medical, Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of income, stockholders' equity and comprehensive income and cash flows for each of the three years in the period ended December 31, 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 2006, and the results of their operations and their cash flows for each of the three 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ICU Medical, Inc.'s and subsidiaries' internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 21, 2008 expressed an unqualified opinion on the effectiveness of ICU Medical Inc.'s and subsidiaries' internal control over financial reporting.

/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)

	2007	December 31,	2006
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents	\$ 7,873	\$	13,153
Marketable securities	87,770		103,765
Cash, cash equivalents and marketable securities	95,643		116,918
Accounts receivable, net of allowance for doubtful accounts of \$655 in 2007 and \$310 in 2006	26,115		26,533
Inventories	19,504		16,315
Prepaid income taxes	2,740		4,541
Prepaid expenses and other current assets	4,746		4,255
Deferred income taxes - current portion	4,509		2,876
Total current assets	153,257		171,438
PROPERTY AND EQUIPMENT, net	72,708		59,037
INTANGIBLE ASSETS, net	11,884		9,781
DEFERRED INCOME TAXES - non current portion	2,432		2,878
TAXES RECEIVABLE non-current portion	1,848		
OTHER ASSETS	465		1,114
	\$ 242,594	\$	244,248
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Accounts payable	\$ 8,439	\$	8,130
Accrued liabilities	13,036		7,789
Total current liabilities	21,475		15,919
<b>COMMITMENTS AND CONTINGENCIES</b>			
DEFERRED INCOME TAXES - non current portion	4,325		3,084
INCOME TAXES PAYABLE - non current portion	2,890		
MINORITY INTEREST			358
<b>STOCKHOLDERS EQUITY:</b>			
Convertible preferred stock, \$1.00 par value Authorized 500,000 shares; Issued and outstanding none			
Common stock, \$0.10 par value - Authorized 80,000,000 shares; Issued 14,746,951 shares in 2007 and 2006, outstanding 13,689,450 and 14,620,421 shares in 2007 and 2006, respectively	1,475		1,475
Additional paid-in capital	74,805		74,489
Treasury stock, at cost 1,057,501 and 126,530 shares in 2007 and 2006, respectively	(40,776)		(5,383)
Retained earnings	177,004		153,925
Accumulated other comprehensive income	1,396		381
Total stockholders equity	213,904		224,887
	\$ 242,594	\$	244,248

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,		
	2007	2006	2005
<b>REVENUES:</b>			
Net sales	\$ 185,618	\$ 198,788	\$ 154,621
Other	2,520	2,825	2,911
<b>TOTAL REVENUE</b>	<b>188,138</b>	<b>201,613</b>	<b>157,532</b>
<b>COST OF GOODS SOLD</b>			
Gross profit	109,895	120,929	88,128
	78,243	80,684	69,404
<b>OPERATING EXPENSES:</b>			
Selling, general and administrative	45,484	44,245	36,992
Research and development	8,111	7,659	4,817
Gain on sale of building		(2,093)	
Total operating expenses	53,595	49,811	41,809
Income from operations	24,648	30,873	27,595
<b>OTHER INCOME</b>			
Income before income taxes and minority interest	8,698	4,462	2,721
	33,346	35,335	30,316
<b>PROVISION FOR INCOME TAXES</b>	<b>(10,337)</b>	<b>(10,240)</b>	<b>(10,459)</b>
<b>MINORITY INTEREST</b>	<b>70</b>	<b>565</b>	<b>417</b>
<b>NET INCOME</b>	<b>\$ 23,079</b>	<b>\$ 25,660</b>	<b>\$ 20,274</b>
<b>NET INCOME PER COMMON SHARE</b>			
Basic	\$ 1.62	\$ 1.78	\$ 1.47
Diluted	\$ 1.51	\$ 1.64	\$ 1.35
<b>Weighted average number of shares</b>			
Basic	14,281,696	14,411,699	13,810,516
Diluted	15,265,108	15,599,132	15,039,890

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

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

(Amounts in thousands, except share data)

	Common Stock					Accumulated Other Comprehensive Income		Comprehensive Income
	Number of Shares Outstanding	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings		Total	
BALANCE, December 31, 2004	13,574,969	\$ 1,416	\$ 61,751	\$ (15,290)	\$ 107,991	\$ 480	\$ 156,348	\$ 5,303
Exercise of stock options and related income tax benefits	541,063		(2,421)	14,137			11,716	
Proceeds from employee stock purchase plan	20,266		(63)	544			481	
Research and development tax credit originating from stock options			887				887	
Comprehensive income								
Net income					20,274		20,274	\$ 20,274
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of \$262						(508)	(508)	(508)
BALANCE, December 31, 2005	14,136,298	1,416	60,154	(609)	128,265	(28)	189,198	\$ 19,766
Purchase of treasury stock	(165,323)			(6,986)			(6,986)	
Exercise of stock options and related income tax benefits	604,240	57	13,528	1,282			14,867	
Proceeds from employee stock purchase plan	45,206	2	320	930			1,252	
Stock compensation			487				487	
Comprehensive income								
Net income					25,660		25,660	\$ 25,660
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of \$(127)						409	409	409
BALANCE, December 31, 2006	14,620,421	\$ 1,475	\$ 74,489	\$ (5,383)	\$ 153,925	\$ 381	\$ 224,887	\$ 26,069
Purchase of treasury stock	(1,062,922)			(41,000)			(41,000)	
Exercise of stock options and related income tax benefits	89,252		(566)	3,746			3,180	
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	
Comprehensive income								
Net income					23,079		23,079	\$ 23,079
Other comprehensive income, net of tax benefit:								

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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

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,		
	2007	2006	2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 23,079	\$ 25,660	\$ 20,274
Adjustments to reconcile net income to net cash provided by operating activities:			