ICU MEDICAL INC/DE
Form 10-K/A
February 24, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

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, 2008 or
o	**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
	For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

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

Securities Registered Pursuant to Section 12(g) of the Act:
Preferred Stock Purchase Rights

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes x 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. o Yes x 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. x Yes o 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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

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

Indicated by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes x No

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2008, the last business day of registrant s most recently completed second fiscal quarter, was $279,719,052*.

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

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant s 2009 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant s fiscal year ended December 31, 2008, are incorporated by reference into Part III of this Report.

* Without acknowledging that any person other than Dr. George A. Lopez is an affiliate, all directors and executive officers have been included as affiliates solely for purposes of this computation.

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EXPLANATORY NOTE

ICU Medical, Inc. (the Company) is filing Amendment No. 1 to its Annual Report on 10-K for the fiscal year ended December 31, 2008 that was originally filed with the United States Securities and Exchange Commission on February 20, 2009 to correct two typographical errors that occurred in the EDGAR conversion process. The Company amends the first quarter of 2008 stock price under Part II, Item 5 and Cash and cash equivalents on the Consolidated Balance Sheet as of December 31, 2008. There are no other changes to the original Annual Report on Form 10-K filed on February 20, 2009 other than those described above, and this amendment does not otherwise amend, update or change the financial statements or disclosures in the original filing. The entire Annual Report on Form 10-K and exhibits are included in this amendment.

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ICU Medical, Inc.

Form 10-K

For the Year Ended December 31, 2008

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PART I

Item 1. Business.

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in vascular therapy applications. Our devices are designed to protect patients from catheter related bloodstream infections and healthcare workers from exposure to diseases through accidental needlesticks or hazardous drugs. We are also a leader in the production of custom I.V. systems and we incorporate our proprietary products into many of those custom I.V. systems. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems. Our headquarters are in San Clemente, California.

In 1993, we launched the CLAVE, an innovative one-piece, needleless I.V. connection device that accounted for approximately 39% of our revenue in 2008, exclusive of CLAVEs incorporated into custom I.V. systems. We believe that the CLAVE offers superior infection control benefits for the patient and for healthcare providers a combination of safety, ease of use, reliability and cost effectiveness that is superior to any other protective I.V. connection system on the market. It allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE is a successor to our protected needle products first introduced in 1984. We designed the CLAVE to eliminate needles from certain applications in acute care hospitals, home healthcare, ambulatory surgical centers, nursing homes, convalescent facilities, physicians offices, medical clinics, and emergency centers. Reduction in the use of needles not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal.

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE®. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom I.V. systems, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices on all of our custom systems beyond the CLAVE.

We are reducing our dependence on our current proprietary products by introducing new products and systems. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors. We also contract with group purchasing organizations and independent dealer networks for inclusion of our CLAVE, custom I.V. systems and custom oncology products in the product offerings of those entities. In our Co-Promotion and Distribution Agreement with Hospira, we manufacture all new custom I.V. systems for sale by Hospira Inc. (Hospira) and jointly promote the products under the name SetSource®. In 2005, we acquired Hospira s Salt Lake City manufacturing facility and entered into the Manufacturing, Commercialization and Development Agreement (MCDA) with Hospira to produce Hospira s invasive monitoring, angiography products and certain other products they had manufactured at that facility. Custom products, which include custom I.V. sets, custom oncology and custom critical care products, accounted for approximately $70.2 million or 34% of total revenue in 2008. Sales of critical care products, excluding custom critical care, were $36.5 million in 2008. 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 infusion set. We intend to further expand our

custom sets market with various specialty components.

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

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

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

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I.V. Products

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

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

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

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

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

CLAVE Products

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

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

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

The MicroCLAVE® is smaller than the standard CLAVE but is functionally similar. The MicroCLAVE has a feature where upon disconnection of an I.V. administration set or syringe, there is a neutral displacement of fluid. This allows clinicians to utilize known protocols without the risk of device failure and a saline flush regimen which reduces cost and exposure to the drug Heparin. The MicroCLAVE is intended for use on all peripheral and central catheters, which allows it to be used throughout the Hospital and reduces line items that the Hospital may need to carry and the educational burden of having multiple devices. The MicroCLAVE is being marketed as an extension of the CLAVE product line for use where the infection control, neutral displacement and saline flush features are advantageous.

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

Custom I.V. Systems

In the late 1990 s, we entered the market for custom I.V. systems. To promote the growth of the business, we have developed innovative software systems and manufacturing processes known as SetMaker that permits us to design a custom I.V. set to a hospital s or clinician s exact specifications, commence production in Mexico or Italy within less than a day after we receive the customer order and ship smaller orders of the custom I.V. sets to the customer within three days of receipt. While we are capable of meeting customer demand on this accelerated three-day schedule, in normal circumstances we ship within twenty-one to thirty days of receipt of the customers order. This is a fraction of the time required by other custom set manufacturers. The use of sophisticated design, validation, ordering and order tracking systems and streamlined assembly and distribution processes allows us to sell custom I.V. sets at prices substantially lower than those charged by other producers of custom I.V. sets.

Under a 2001 agreement with Hospira, we manufacture all new custom I.V. sets for sale by Hospira, and the two companies jointly promote the products under the name SetSource. The current term of the agreement extends to 2014. Sales of custom I.V. systems continue to increase as a result of the agreement and we expect further significant increases in sales of custom I.V. systems, although there is no assurance that such increases will be achieved.

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

custom I.V. systems, and we expect this to continue.

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

CLC2000®

The CLC2000 is a one piece, swabbable connector used to connect I.V. lines to catheters, which is engineered to have a positive displacement of fluid on disconnection which in turn will prevent the back-flow of blood into the catheter. The CLC2000 does not permit the use of needles, thereby ensuring compliance with needle-free policies of healthcare providers. The CLC2000 also contains no natural rubber latex. The CLC2000 was developed to reduce clotting of catheters because of back-flow when the I.V. line is disconnected. The CLC2000 consists of a T shaped cylindrical housing, which contains a poppet that is depressed as the luer tip enters the CLC2000. Fluid flows around the poppet and through the housing and into the catheter. When the luer is removed from the CLC2000, a portion of the fluid remaining in the housing is expelled out through the tip of the catheter while a constant positive pressure is maintained to prevent any back-flow into the catheter.

The CLC2000 is typically used on central venous catheters where catheter occlusion is most prevalent. Generally, when an I.V. line is disconnected from the catheter, there is a back-flow of blood from the patient s vein into the catheter. That blood in time coagulates and occludes the catheter. Occlusion (clotting off) of catheters requires expensive drugs and procedures to flush the catheter, or if those procedures are not effective, replacement of the catheter. We concentrate the marketing of the CLC2000 where its no back-flow features are of maximum benefit in patient care. These are generally therapies that use long-term indwelling central venous catheters such as oncology and long-term infusion of medication. CLC2000 accounted for $6.0 million of our revenue in 2008.

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Critical Care Products

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

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

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

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

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

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

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

We manufacture all critical care products sold by Hospira in the United States and all catheters sold by Hospira outside the United States. Our 2008 critical care sales, excluding custom critical care, were $36.5 million.

Custom Critical Care A substantial portion of the invasive monitoring and angiography products are custom products designed to meet the specific needs of the customer. Most of the critical care products can be sold in custom systems containing specific components to meet the specific needs of the customer, and in some cases, custom made or acquired components. Our 2008 custom critical care sales were $11.8 million.

Other Products and Revenues

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

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New Products

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

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

Marketing and Distribution

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

As of December 31, 2008, we employed 110 people in sales and marketing and expect this to increase in 2009. Our sales function includes product specialists worldwide who support our medical product manufacturing customers, our independent domestic distributors and end users of our products. Our product specialists call on prospective customers, demonstrate products and support programs to train the salespeople and customers staffs in the use of our products.

Medical Product Manufacturers

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

Hospira purchases CLAVE products packaged separately for distribution to healthcare providers and in bulk for assembly into Hospira s full range of I.V. products. The MicroCLAVE, CLC2000, Lopez Valve, Spiros, Genie and Rhino products are purchased and packaged separately.

Under another agreement with Hospira that extends to 2014, we have the exclusive right to manufacture all new custom gravity I.V. sets for sale by Hospira, other than those custom sets that Hospira was manufacturing before we entered into the agreement in 2001. Hospira and we jointly promote the products under the name SetSource. Hospira is the exclusive and non-exclusive distributor and co-promoter of SetSource products to certain categories of customers, including SetSource products containing both companies proprietary products.

Under the MCDA, we manufacture critical care products exclusively to Hospira. The majority of the products under the MCDA are critical care products. Hospira retains commercial responsibility for the products we produce, including sales, marketing, distribution, pricing, customer contracts, customer service and billing. We manufacture all critical care products sold by Hospira in the United States and all catheters sold by Hospira worldwide.

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

Independent Domestic Distributors

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

No single independent distributor accounted for more than two percent of revenue in 2008. Although the loss of one or more of our larger distributors could have an adverse affect on our business, we believe we could readily locate other distributors in the same territories who could continue to distribute our products to the same customers.

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International

International distribution is concentrated principally in Europe, Asia Pacific, Southeast Asia, Latin America, South Africa and the Middle East. Foreign sales (excluding Canada) accounted for approximately 15%, 13% and10% of our revenues 2008, 2007 and 2006. As of December 31, 2008, we had approximately 42 international distributors. Customers in Europe are served by our distribution operation in Italy. We serve the rest of the world from our facilities in the U.S. and Mexico. We have five business development personnel serving Europe and seven serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add more business development personnel in 2009. Administrative operations are in Roncanova in northern Italy (at the site of our assembly plant) and San Clemente, California. Currently, all shipments from the United States are invoiced in U.S. dollars and sales from Italy are invoiced in Euros.

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

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

Manufacturing

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

We own a fully integrated medical device manufacturing facility in Salt Lake City, Utah facility with approximately 450,000 square feet of state-of-the art manufacturing space. This building includes approximately 82,500 square feet of class 100,000 clean room area, approximately 36,000 square feet of other manufacturing space, approximately 104,000 square feet of warehouse space and approximately 155,000 square feet of office space. As of December 31, 2008, this facility was equipped with 64 injection molding machines and ancillary equipment and approximately 40 automated or semi-automated assembly machines. These sophisticated, highly automated assembly systems are designed to minimize human intervention and assemble the CLAVE, Y-CLAVE, MicroCLAVE, CLAVE vial access spike, CLC2000, RF150 and some of our critical care products. The assembly systems are custom designed and manufactured for us. Our mold maintenance shop supports the repair and maintenance needs of our molding. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment.

Most of our manual assembly is done at our facility in Ensenada, Mexico. This facility has approximately 241,000 square feet of production and warehousing space and an electron beam sterilizer. Principal products assembled manually are I.V. therapy systems and custom angiography systems and kits, the Lopez Valve, and CLAVE ancillary products and accessories and critical care products.

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

Our state-of-the-art injection molding technology and highly automated assembly systems are designed to maintain a high level of product quality and achieve high volume production at low unit manufacturing costs. To achieve these advantages and to gain greater control over raw material and finished product delivery times, we mold our entire requirements of proprietary molded components. The raw materials for our molding operation are principally resins and silicones, and these materials are available from several sources. Generic, off-the-shelf items are purchased from outside vendors unless significant cost savings can be achieved by molding in-house. We have no contracts with our suppliers beyond the terms of purchase orders issued. Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material to date. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available.

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The majority of the non-critical care products we manufacture are sterilized in processes which use electron beam (e-beam) radiation. Most critical care products and other certain products are currently sterilized in processes using gamma radiation or ethylene oxide gas (EO). The products we assemble in Italy are sterilized using gamma radiation. We have our own sterilization facility at our plant in Mexico that is used to sterilize most of the product assembled in Mexico. All other sterilization is done by independent contractors.

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

Government Regulation

Government regulation is a significant factor in the development, marketing and manufacturing of our products. The Food and Drug Administration (FDA) regulates medical product manufacturers and their products under a number of statutes including the Food, Drug and Cosmetic Act (FDC Act), and we and our products are subject to the regulations of the FDA. The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, under which the manufacturer gives the FDA a pre-market notification of the manufacturer s intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the Section 510(k) procedure, the manufacturer must file a pre-market approval (PMA) application. This requires substantially more extensive pre-filing testing than the Section 510(k) procedure and involves a significantly longer FDA review process. FDA approval of a PMA application occurs only after the applicant has established safety and efficacy to the satisfaction of the FDA. Each of our current products has qualified, and we anticipate that any new products that we are likely to market will qualify, for the expedited Section 510(k) clearance procedure. However, certain of our new products may require a lengthier time for clearance than we have experienced in the past and there can be no assurance that a PMA application will not be required. Further, there is no assurance that other new products we develop or any manufacturers that we might acquire, or claims that we may make concerning those products, will qualify for expedited clearance rather than the more time consuming PMA procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. All of the regulated products that we currently manufacture are classified as Class II medical devices by the FDA. Class II medical devices are subject to performance standards relating to one or more aspects of the design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

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

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

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

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

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

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

Competition

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

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

The market for critical care devices is highly competitive. Competition is based on pricing, customer service and product features. The overall market for the critical care products we manufacture has been declining in recent years, and over that period, Hospira has lost market share to its competitors.

Manufacturers of products with which we currently compete, or might compete in the future, include large companies with an established presence in the healthcare products market and substantially greater financial, marketing and distribution, managerial and other resources. In particular, Baxter, Cardinal, Hospira, Fresenius and B. Braun are leading distributors of I.V. therapy systems, Edwards Life Sciences has a significant share of the critical care catheter market, invasive monitoring disposables market and arterial blood sampling system market, while NAMIC, formerly part of Boston Scientific, and Merit Medical are competitive in the angiography kit market. Several of these competitors have broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply substantially all of

their product requirements in these areas. In order to achieve greater market penetration or maintain our existing market position, we have established strategic relationships with customers such as Hospira.

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

Cardinal manufactures a connector that competes with the CLAVE. Cardinal is the largest distributor of healthcare products in the United States, and has announced its intent to increase market share. We believe Cardinal could adversely affect our market share and the prices for our CLAVE products.

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

Patents

We have United States and certain foreign patents on the CLAVE, CLC2000, Orbit 90, 1o2 Valve, TEGO, Click Lock technology, Custom Set Design and Manufacturing Methods. We have applications pending for additional United States and foreign patents on TEGO, Y-CLAVE with integral check value, Orbit 90, CLC2000, CLAVE, Spiros Closed Male Connector, Genie Closed Vial Access Device and Custom Set Design and Manufacturing Methods. The expiration dates of our patents range from 2009 to 2023. While we no longer manufacture and sell the Click Lock and Piggy Lock, the patents have considerable value for potential use in other devices.

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

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

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

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

The fact that a patent is issued to us does not eliminate the possibility that patents owned by others may contain claims that are infringed by our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which would result in substantial cost to us and in diversion of our resources, may be necessary to defend us against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. Adverse determinations in such litigation could subject us to significant liabilities to third parties or could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using our products, any of which could have a material adverse effect on our business. In addition, we have initiated litigation, and will continue to initiate litigation in the future, to enforce our intellectual property rights against those we believe to be infringing on our patents. Such litigation could result in substantial cost and diversion of resources.

Employees

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

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Item 1A. Risk Factors.

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

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

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

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

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

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

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

In 2004, Hospira substantially reduced its purchases of CLAVE products because it was reducing its inventories of our products. This caused a significant reduction in our sales and led to a net loss in the third and fourth quarters of 2004. If the steps we have taken to monitor and control the amount of Hospira s inventory of CLAVE products to avoid future inventory reductions are not successful we could experience sharp

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

Our ability to maintain and increase our market penetration depends on the success of our arrangement with Hospira and Hospira s arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. Our business could be materially adversely affected if Hospira terminates its arrangement with us, negotiates lower prices, sells more competing products, whether manufactured by themselves or others, or otherwise alters the nature of its relationship with us. Although we believe that Hospira views us as a source of innovative and profitable products, there is no assurance that our relationship with Hospira will continue in its current form.

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

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

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

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

The prices at which we sell products to Hospira and the gross margins that we realize under the MCDA depend on the cost savings that we expect to achieve in producing those products over Hospira s cost to manufacture the same products at the date we purchased the Salt Lake City facility from Hospira. Achieving substantial cost reductions requires moving manufacturing operations to lower-cost locations and the development and implementation of innovative manufacturing and assembly processes and techniques. While we have succeeded in reducing costs to date, there is no assurance of the longer term success of these efforts, and recent declines in production volumes of critical care products because of reduced sales of those products to Hospira is offsetting some of the cost savings previously attained. If we are unable to achieve the cost savings that we expect, our profits on products manufactured under the MCDA will be adversely affected.

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

In the fourth quarter of 2006, we experienced significant production inefficiencies following a large increase in production volume in Mexico and the transfer of San Clemente production to Salt Lake City. In 2007, we expanded our Mexico facility and anticipate further increases in volume at that facility, resulting in an increase to the workforce. Turnover among new employees is unusually high in Mexico, and the additional time spent in classroom training and on the job training could create production inefficiencies in Mexico in the future. The addition of new products will require additional molding in Salt Lake City, manual assembly work in Mexico and eventually additional automated assembly work in Salt Lake City. The effect of any inefficiencies can be particularly expensive in Salt Lake City because of the high fixed costs in this highly automated facility. Expansions of our production capacity will require significant management attention to avoid inefficiencies of the type experienced in 2006.

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

In 2008, CLAVE products accounted for approximately 39% of our revenue. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. Most of our CLAVE sales are in the United States, where we expect moderate sales growth in the future as further penetration of markets available to our existing customers in the United States becomes increasingly difficult. Future significant sales increases for CLAVE products may depend on increases in sales of custom I.V. systems, expansion in the international markets or acquisition of new customers in the United States. We cannot give any assurance that sales of CLAVE products will increase indefinitely or that we can sustain current profit margins on CLAVE products indefinitely.

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

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

Our future success may be dependent both on the success of our strategic initiatives to substantially increase our custom product business and develop significant market share on a profitable basis and on new product development. Our total sales of custom products including custom I.V. products, custom oncology products and custom critical care products, were $70.2 million in 2008, compared with $58.5 million in 2007. Sales of custom I.V. products increased by 9% in 2008 over 2007, 15% in 2007 over 2006 and 24% in 2006 over 2005. Sales of custom critical care products declined in 2008 from 2007. The success of our custom product sales program will require a larger increase in sales in the future than was achieved in 2008 and there is no assurance that such an increase will be achieved or sustained. Although we are seeking to continue to develop a variety of new products, there is no assurance that any new products will be commercially successful or that we will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers, with financial and distribution resources substantially greater than ours, have developed and are marketing products intended to fulfill the same functions as our products which may adversely affect our results of operations.

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

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

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

We distribute products in Europe through our subsidiary in northern Italy. Sales and most other transactions by this subsidiary are denominated in Euros. As the Euro-denominated sales increase in relation to our total sales, a decline in the value of the Euro in relation to the U.S. dollar could have an adverse effect on our reported operating results. There is no assurance as to the growth of this subsidiary or its future operating results.

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

Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid and other payers to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for us to sell our products at current prices. In the event that the market will not accept current prices for our products, our sales and profits could be adversely affected. We believe that our ability to increase our market share and operate profitably in the long term may depend in part on our ability to reduce manufacturing costs on a per unit basis through high volume production using highly automated molding and assembly systems. If we are unable to reduce unit manufacturing costs, we may be unable to increase our market share for CLAVE products or may lose market share to alternative products, including competitors products. Similarly, if we cannot reduce unit manufacturing costs of new products as production volumes increase, we may not be able to sell new products profitably or gain any meaningful market share. Any of these results would adversely affect our future results of operations.

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

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

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

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

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

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

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

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

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

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

We are increasingly dependent on manufacturing in Mexico and could be adversely affected by any economic or political disruptions

We continue to expand our production in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations. In 2008, production costs in Mexico were approximately $58.2 million. Most of the material we use in manufacturing is imported into Mexico, and substantially all the production in Mexico is exported. We depend on our ability to move goods across the border quickly. Any disruption in the free flow of goods across the border could have an adverse effect on our business.

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As of December 31, 2008, we employed 1,165 people in our plant in Ensenada, Mexico and we expect this number to increase during 2009. Business activity in the Ensenada area has expanded significantly, providing increased employment opportunities. This could have an adverse effect on our ability to hire or retain necessary personnel and result in an increase in labor rates. We continue to take steps to compete for labor through attractive employment conditions and benefits, but there is no assurance that these steps will continue to be successful or that we will not face increasing labor costs in the future.

Increases in the cost of petroleum-based and natural gas-based products or loss of supply could have an adverse effect on our profitability.

Most of the material used in our products are resins, plastics and other material that depend upon oil or natural gas as their raw material. Crude oil markets are affected by political uncertainty in the Middle East, and there is no assurance that there will not be an interruption in crude oil supplies. Any such interruption could have an adverse effect on our ability to produce, or the cost to produce, our products. Also, crude oil and natural gas prices in 2008 reached record highs. Our suppliers have passed some of their cost increases on to us, and if such prices are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs have increased because of the effect of higher crude oil prices, and we believe most of these costs have been passed on to us. Our ability to recover these increased costs may depend upon our ability to raise prices on our products. In the past, we have rarely raised prices and it is uncertain that we would be able to raise them to recover higher prices from our suppliers. Our inability to raise prices in those circumstances , or to otherwise recover these costs, could have an adverse effect on our profitability.

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

We depend on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer for new product concepts and manufacturing innovation. Dr. Lopez has conceived substantially all of our current and proposed new products and the systems and procedures to be used in the custom I.V. products and their manufacturing. We believe that the loss of his services could have a material adverse effect on our business.

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

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

We are substantially dependent upon the patents on our proprietary products, such as the CLAVE, to prevent others from manufacturing and selling products similar to ours. We have pending litigation against Alaris Medical Systems, Inc., a part of Cardinal, for alleged infringement of our patents. We believe the alleged infringement had and continues to have an adverse effect on our sales. Failure to prevail in this or in other litigation we bring against third parties for violating our patents could adversely affect our sales.

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

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

In the past, we have faced patent infringement claims related to the CLAVE, the CLC2000 and TEGO. We believe these claims had no merit, and all have been settled or dismissed, although a case involving the CLC2000 is pending on appeal. We may also face claims in the future. Any adverse determination on these claims related to the CLAVE or other products, if any, could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

products may require a longer time for clearance than we have experienced in the past and there can be no assurance that a PMA application will not be required. Further, there is no assurance that other new products developed by us or any manufacturers that we might acquire will qualify for expedited clearance rather than a more time consuming pre-market approval procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. In addition, we must manufacture our products in compliance with the FDA s Quality System Regulations.

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

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To market our products in the European Community (EC), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of ISO 13485 (2003). Those quality standards are similar to the FDA s Quality System Regulations. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC (Medical Device Directive) and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the CE Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. There is no assurance that we will continue to meet the requirements for distribution of our products in Europe.

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

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

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

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

On July 15, 1997, our Board of Directors adopted a Stockholder Rights Plan (the Plan) and, pursuant to the Plan, declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on July 28, 1997. The Plan expired in 2007 and our Board of Directors adopted an Amended and Restated Rights Agreement in July 2007. Under its current provisions, each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior participating Preferred Stock, no par value, at a purchase price of $225 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board of Directors a great deal of flexibility in dealing with any takeover attempts and is designed to cause persons interested in acquiring us to deal directly with the Board of Directors, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire us.

Investors should refer to the description of the Plan in our 2007 10-K filed with the Securities and Exchange Commission.

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

provisions of Delaware law may discourage, delay or prevent someone from acquiring or merging with us.

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

The market for small-market capitalization companies can be highly volatile, and we have experienced significant volatility in the price of our common stock in the past. From January 2007 through December 2008, our trading price ranged from a high of $45.02 per share to a low of $22.14 per share We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts expectations and actual quarterly and annual results, new product introductions by us or our competitors, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders and substantial product orders could contribute to the volatility in the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles and changing interest rates may also adversely affect the market price of our common stock; the recent macroeconomic downturn could depress our stock price for some time.

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Most of our common stock is held by, or included in accounts managed by, institutional investors or managers. Several of those institutions own or manage a significant percentage of our outstanding shares, with the ten largest interests accounting for 45% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate its position in our common stock, it could cause a decrease in the price of the common stock that could be significant.

For the past several years there has been a significant short position in our common stock, consisting of borrowed shares sold, or shares sold for future delivery which may not have been borrowed. We do not know whether any of these short positions are covered by long positions owned by the short seller. The short position, as reported by the Nasdaq Stock Market on December 31, 2008 was 1,317,651 shares, or approximately nine percent of our outstanding shares. Any attempt by the short sellers to liquidate their position over a short period of time could cause very significant volatility in the price of our common stock.

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

At December 31, 2008, we had outstanding stock options to purchase 2.7 million shares, 70% of which had an exercise price below the market price of our stock. Exercise of those options would dilute the ownership interest of existing shareholders.

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We own a 39,000 square foot building and a 28,000 square foot building in San Clemente, California, a 450,000 square foot building in Salt Lake City, Utah, a 37,500 square foot building in Vernon, Connecticut, a 241,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico, a 17,000 square foot and a 21,000 square foot building in Roncanova, Italy.

Item 3. Legal Proceedings

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

In an action filed June 16, 2004 entitled ICU Medical, Inc. v. Alaris Medical Systems, Inc. in the United States District Court for the Central District of California, we alleged that Alaris infringes ICU s patent through the manufacture and sale of the SmartSite and SmartSite Plus Needle-Free Valves and Systems. On August 2, 2004, the Court denied our request for a preliminary injunction. On December 27, 2004, we amended our complaint to allege that Alaris infringes three additional patents. On July 17, 2006, the Court issued an order interpreting certain claims in the asserted patents in a manner that, if upheld, could significantly impair our ability to enforce those patents against Alaris and potentially others. The Court also issued partial summary judgment in favor of Alaris based on one of those interpretations. On January 22, 2007, the Court granted Alaris summary judgment motion of invalidity as to the remaining claims asserted against Alaris and on February 22, 2007, the Court entered judgment dismissing those remaining claims. The Court s order adjudicated only the asserted claims of the patents in suit, not other claims in the patents. Following entry of the judgment dismissing our case, the Court heard Alaris motion to recover its fees, costs and expenses, and on April 16, 2007, the Court granted in part Alaris motion. On June 28, 2007, the Court awarded Alaris $4.8 million in fees and costs, which were later increased to $5.0 million, plus post-judgment interest. We have appealed the Court s decisions, and oral argument has been heard by the Federal Circuit Court of Appeal on January 5, 2009. Because the award of fees and costs is a judgment against us and the outcome of the appeal is uncertain, we recorded a charge of $5.0 million in our financial statements for the year ended December 31, 2007. We have not paid the judgment, pending outcome of the appeal.

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

In an action filed July 27, 2007 entitled ICU Medical, Inc. v. RyMed Technologies, Inc. (RyMed), in the United States District Court for the District of Delaware, we alleged that RyMed infringes certain of ICU s patents through the manufacture and sale of certain products, including its InVision-Plus valves. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. RyMed has denied our allegations and sued ICU in the United States District Court for the Central District of California seeking a declaratory judgment of non-infringement and invalidity of our patents and alleging that we have infringed RyMed s trademark and engaged in unfair competition and other improper conduct. RyMed seeks monetary damages and injunctive relief. The Central District Court has transferred the patent claims to Delaware. RyMed s trademark and unfair competition claims remain pending in the Central District of California. ICU will continue to defend itself in the California action, and vigorously pursue its patent infringement claims against RyMed in the Delaware action.

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

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

Not Applicable.

Executive Officers of Registrant

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

	Age	Office Held
George A. Lopez, M.D.	61	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	36	Vice President of Marketing
Richard A. Costello	45	Vice President of Sales
Scott E. Lamb	46	Chief Financial Officer

Steven C. Riggs	49	Vice President of Operations

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

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Part II

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

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

2008	High	Low
First quarter	$ 38.08	$ 24.19
Second quarter	30.00	22.14
Third quarter	33.65	22.69
Fourth quarter	35.11	24.32

2007	High	Low
First quarter	$ 41.32	$ 38.01
Second q		