

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

# **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

## **FORM 10-K**

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

**For the fiscal year ended December 31, 2005 or**



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

**Commission File No. 0-19974**

**ICU MEDICAL, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**92673**  
(Zip Code)

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

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

**None**

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

**Common Stock, \$.10 par value**

**Preferred Stock Purchase Rights**

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

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

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

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

Yes  No

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

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

### DOCUMENTS INCORPORATED BY REFERENCE

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

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



**PART I**



**Item 1. Business.**

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous ( I.V. ) therapy applications. Our devices are designed to protect patients from Catheter Related Bloodstream Infections and healthcare workers from exposure to infectious diseases through accidental needlesticks. We are also a leader in the production of custom I.V. systems and low cost generic I.V. systems and we incorporate our proprietary products on many of those custom I.V. systems. With the acquisition of Hospira, Inc. s ( Hospira ) Salt Lake City plant on May 1, 2005 and commencement of production under a twenty-year Manufacturing, Commercialization and Distribution Agreement with Hospira ( MCDA ), we are now also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems

In 1993, we launched the CLAVE<sup>®</sup>, an innovative one-piece, needleless I.V. connection device that accounted for approximately 40% of our revenue in 2005 exclusive of CLAVEs incorporated into custom I.V. systems. We believe that the CLAVE offers healthcare providers a combination of safety, ease of use, reliability and cost effectiveness that is superior to any other protective I.V. connection system on the market. It allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE is a successor to our protected needle products first introduced in 1984. We designed the CLAVE to eliminate needles from certain applications in acute care hospitals, home healthcare, ambulatory surgical centers, nursing homes, convalescent facilities, physicians offices, medical clinics, and emergency centers. Reduction in the use of needles not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal.

We are taking steps to reduce our dependence on our current proprietary products. The initiative involves a planned transition from being primarily a manufacturer of I.V. system components to producing and distributing complete I.V. systems, both custom and low-cost, generic systems, blood collection devices and other products. Many of the I.V. systems include our I.V. proprietary component products. In 2002, we acquired the Punctur-Guard line of blood collection needles. In 2004, we invested in a company developing a new medical device. In 2005, we acquired Hospira s Salt Lake City manufacturing facility (see below). There is no assurance that any of these initiatives will succeed or continue to succeed.

We have been manufacturing and distributing custom and generic I.V. systems since late 1995. In 1999, we decided to substantially increase our emphasis on marketing and selling custom I.V. systems. A key element of our strategy to expand our custom I.V. system business has been the development and implementation of our proprietary software, known as SetMaker , for custom product design, customer orders and order tracking, combined with an innovative system to coordinate the manufacture of components in the U.S., assembly of components into sets in Mexico and Italy and distribution of finished products. We believe that we offer customers substantially shorter delivery times and lower costs than other manufacturers of custom I.V. systems can currently offer.

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

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



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

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We currently sell substantially all of our products to I.V. product manufacturers and independent distributors. Our largest customer is Hospira, Inc., which accounted for 73% of our revenues in 2005.

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

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

### **I.V. Usage and Infection Control**



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

Prior to the introduction of needle-safe connectors, conventional practice was to make, primary I.V. system connections by inserting an exposed steel hollow-bore needle attached to the primary I.V. line into an injection port connected to the catheter. Conventional secondary I.V. connections, so called piggyback connections, were made by inserting an exposed steel hollow-bore needle attached to a secondary I.V. line into an injection port or other I.V. connector. In those I.V. connections, the needles, which typically were secured only with tape, could detach from the catheter or injection port resulting in disconnection and a serious and sometimes fatal interruption of the flow of the I.V. solution to the patient. The exposed needles could easily be contaminated by contact with unsterile objects or through contact with fluid in the I.V. lines. Accidental needlesticks from contaminated needles can result in infection to healthcare workers and, less frequently, patients. Increasing awareness of the risk of infection from needlesticks and the substantial and increasing expense to healthcare providers of complying with regulatory protocols when needlesticks occur have led to a growing demand for safe medical devices such as our protective I.V. connectors.

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

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

### Products



*CLAVE Products*

Prior to the introduction of needlesafe connectors, a conventional I.V. line terminated with a male luer connector to which a hollow-bore needle would be attached to penetrate a latex or non-latex rubber covered injection port to make a primary

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

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

The Y-CLAVE is designed to be integrated directly into primary and secondary I.V. sets, thus eliminating the need for special adapters, pre-slit injection ports, or metal needles when making piggyback I.V. connections. Currently, many popular I.V. connection systems that compete with our systems require a metal needle, a pre-slit injection port or a special adapter to make piggyback connections. The original CLAVE can be used to make a piggyback connection, but it also requires a special adapter when used in piggyback applications. We believe the Y-CLAVE offers a lower cost alternative to existing systems by eliminating the need for multiple parts. The healthcare professional simply inserts the male luer of any secondary I.V. set, without a needle, into the CLAVE Y site and twists to make the connection. The Y-CLAVE will not replace CLAVE products used in non-piggyback connections. Unlike the original CLAVE site, the Y-CLAVE is marketed exclusively to I.V. set manufacturers, such as Hospira, to build directly into their I.V. sets or used by us in our custom I.V. sets.

The CLAVE is our largest selling product line, and accounted for \$62.5 million or 40% of our revenue in 2005, \$35.4 million or 47% of our revenue in 2004 and \$62.9 million or 59% of our revenue in 2003. CLAVE products and Custom I.V. systems including one or more CLAVES accounted for \$85.9 million, \$53.8 million and \$78.7 million of our revenue in 2005, 2004 and 2003, respectively.

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

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

During late 1995, we entered the low end of the safe medical connector market by manufacturing and distributing I.V. sets which incorporated lower priced safe medical connectors, and also commenced manufacturing and distributing custom I.V. sets incorporating the CLAVE. In 1999, we substantially increased our emphasis on marketing and selling custom I.V. systems. To promote the growth of the business, we have developed innovative software systems and manufacturing processes known as SetMaker that permit us to design a custom I.V. set to a hospital's or clinician's exact specifications, commence production within less than a day after we receive the customer order and ship smaller orders of the custom I.V. sets to the customer within three days of receipt for smaller orders. While we are capable of meeting customer demand on this accelerated three-day schedule, in normal circumstances we ship within twenty-one to thirty days of receipt of the customer's order. This is a fraction of the time required by other custom set manufacturers. The use of sophisticated design, ordering and order tracking systems and streamlined assembly and distribution processes allows us to sell custom I.V. sets at prices substantially lower than those charged by other producers of custom I.V. sets.

In February, 2001, we signed an agreement with Hospira under which we manufacture all new custom I.V. sets for sale by Hospira, and the two companies jointly promote the products under the name SetSource. This agreement is effective to



2014. Sales of custom I.V. systems continue to increase as a result of the agreement and we expect further significant increases in sales of custom I.V. systems, although there is no assurance that such increases will be achieved.

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

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

#### *Critical Care Products*

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

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

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

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

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

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

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

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

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

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

*Punctur-Guard*



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Punctur-Guard products are based on a patented technology that internally blunts a needle while still in the patient's vein, and are the only products which allow the procedure to continue while the needle is rendered safe. We currently use the technology to make Blood Collection Needles (BCN) and Winged Sets, primarily for use by phlebotomists and other medical personnel in hospitals and independent clinical laboratories. Our Sales of Punctur-Guard products for 2005, 2004 and 2003 were \$4.2 million, \$3.9 million and \$7.3 million, respectively.

We are currently concentrating our sales and marketing efforts for the Winged Sets on outpatient provider contracts and the diagnostic laboratory market. We are not currently making any significant efforts to sell and market the BCN. There is no assurance as to future sales of Punctur-Guard products.

### *CLC2000*

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

The CLC2000 is typically used on central venous catheters where catheter occlusion is most prevalent. Generally, when an I.V. line is disconnected, there is a back-flow of blood into the catheter that is in the patient's vein. That blood in time coagulates and occludes the catheter. Occlusion ( clotting off ) of catheters requires expensive drugs and procedures to flush the catheter, or if those procedures are not effective, replacement of the catheter.

The CLC2000 was developed to reduce clotting of catheters because of back-flow when the I.V. line is disconnected. The CLC2000 consists of a T shaped cylindrical housing, which contains a poppet that is depressed as the luer tip enters the CLC2000. Fluid flows around the poppet and through the housing and into the catheter. When the luer is removed from the CLC2000, a portion of the fluid remaining in the housing is expelled out through the tip of the catheter while a constant positive pressure is maintained to prevent any back-flow into the catheter.

We began marketing the CLC2000 in November 1997. We concentrate the marketing of the CLC2000 where its no back-flow features are of maximum benefit in patient care. These are generally therapies that use long-term indwelling central venous catheters such as oncology and long-term infusion of medication. CLC2000 accounted for \$5.2 million, \$3.1 million and \$3.9 million our revenue in 2005, 2004 and 2003, respectively.

### *1o2 Valve*

The 1o2 Valve is the first one-way or two-way drug delivery system. It functions as a single unit or in multiple ganged units as a manifold, for use primarily in anesthesia and critical care. It provides the safety features of an automatic one-way valve, yet allows aspiration, or two-way function by simply pushing a button. The 1o2 Valve can be used in place of products such as stopcocks and check valve manifolds. We actively commenced sales in April 2000. Our initial manufacturing focus has been on anesthesia and critical care usage and we are selling the 1o2 Valve only as part of I.V. sets that we manufacture. Sales of I.V. sets containing 1o2 Valves were approximately \$5.2 million, \$4.4 million and \$3.6 million in 2005, 2004 and 2003, respectively.

### *Other Products and Revenues*

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

We have developed a family of inexpensive single-use needleless connectors for use in piggyback and non-piggyback applications. The RF100 is designed for use in piggyback applications. We developed the RF150, called the Rhino, specifically for Hospira for use with pre-slit injection ports in piggyback and non-piggyback applications. Although we believe

that the CLAVE has significant functional advantages over the RF100 and RF150, these products are alternative and less expensive needless I.V. connectors.

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

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

*New Products*





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We are developing several new products that we intend to introduce in 2006 and later. We believe innovative products continue to be important to maintaining and increasing our sales levels.

In September 2004, we invested approximately \$2.5 million cash for 57% of a company developing a new medical device for screening for heart disease. In October 2005, we invested an additional \$1.5 million, increasing our ownership to 68%. The device is in the early stage of design, uses new technology, and completion of a marketable device is expected to take at least several years at a cost somewhat in excess of our current funding commitment. There is no assurance as to the timing of or cost of completing a marketable device or whether it will be completed.

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

### **Marketing and Distribution**



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

As of January 31, 2006, we employed 73 product specialists worldwide to support our medical product manufacturing customers and our independent domestic distributors. Our product specialists call on prospective customers, demonstrate products and support programs to train the salespeople and customers' staffs in the use of our products.

### *Medical Products Manufacturers*

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

Hospira purchases CLAVE products packaged separately for distribution to healthcare providers and in bulk for assembly into Hospira's full range of I.V. products. The MicroCLAVE, 1o2 Valve, CLC2000, Punctur-Guard, Lopez Valve and Rhino products are purchased and packaged separately.

Under another agreement with Hospira that extends to December 2014, we have the exclusive right to manufacture all new custom I.V. sets for sale by Hospira, and Hospira and we jointly promote the products under the name SetSource. Hospira is the exclusive and non-exclusive distributor and co-promoter of SetSource products to certain categories of customers, including SetSource products containing both companies' proprietary products.

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

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

*Independent Domestic Distributors*



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As of January 31, 2006, we had approximately 35 independent distributors in the United States and Canada who employ approximately 600 salespeople in the aggregate and which accounted for approximately 16% of our revenues in 2005. We include Canada as domestic for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

No single independent distributor accounts for more than 2% of revenue in 2005. Although the loss of one or more of our larger distributors could have an adverse affect on our business, we believe we could readily locate other distributors in the same territories who could continue to distribute our products to the same customers.

### *International*



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We distribute products principally in Europe, Asia Pacific, Southeast Asia, Latin America, South Africa and the Middle East. Foreign sales (excluding Canada) accounted for approximately \$13.0 million, \$9.0 million and \$5.8 million of our revenues in each of the years 2005, 2004, and 2003, respectively. The International Division currently has approximately 37 distributors. Customers in Europe are served by our distribution operation in Italy. We serve the rest of the world from our facilities in the U.S. and Mexico. We have four business development managers serving Europe and four serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add several more business development managers in 2006. Administrative operations are in Roncanova in northern Italy (at the site of our assembly plant) and San Clemente. Currently, all shipments from the United States are invoiced in U.S. dollars and sales from Italy are invoiced in Euros.

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

### **Manufacturing**





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

We own a fully integrated medical device manufacturing facility in two adjacent buildings totaling 78,000 square feet in San Clemente, California. A mold maintenance shop supports the repair and maintenance needs of our molding operation and manufactures some of our production molds. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment. This facility is currently equipped with 42 injection molding machines and ancillary equipment including robots designed to minimize human intervention, and sophisticated, highly automated assembly systems to assemble the CLAVE, Y-CLAVE, MicroCLAVE, CLAVE vial access spike, CLC2000, 1o2 Valve, RF150 and B. Braun Protected Needle products. The assembly systems are custom designed and manufactured for us.

We assemble our Punctur-Guard products in our 37,500 square foot manufacturing facility in Vernon, Connecticut. The assembly processes for both the BCN and the Winged Set use custom made automated assembly systems.

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

Excluding products currently assembled in our Salt Lake City facility under the MCDA, most of our manual assembly is done at our facilities in Ensenada, Baja California, Mexico. Those facilities include approximately 60,000 square feet of production and warehousing space and an electron beam sterilizer. Principal products assembled manually are I.V. therapy systems, the Lopez Valve, and CLAVE ancillary products and accessories. We also assemble I.V. therapy systems in our approximately 17,000 square foot facility in northern Italy that we acquired in June 2003.

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

Our state-of-the-art injection molding technology and highly automated assembly systems are designed to maintain a high level of product quality and achieve high volume production at low unit manufacturing costs. To achieve these advantages and to gain greater control over raw material and finished product delivery times, we mold our entire requirements of proprietary molded components. The raw materials for our molding operation are principally resins and silicones, and these materials are available from several sources. Generic, off-the-shelf items are purchased from outside vendors unless significant cost savings can be achieved by molding in-house. We are not dependent on any individual vendor for purchased parts and have no contracts with our suppliers beyond the terms of purchase orders issued.

The products we manufacture in California and Mexico are sterilized in processes which use electron beam ( e-beam ) radiation. The products we produce in Salt Lake City are currently sterilized in processes using gamma radiation or ethylene oxide gas ( EO ). The products we assemble in Italy are sterilized using gamma radiation. We prefer to use wherever possible e-beam sterilization because it is quicker and less expensive than gamma radiation or EO. In February 2004, we commenced operation of our own sterilization facility at our plant in Mexico and we sterilize all of our products that are assembled in Mexico. All other sterilization is done by independent contractors.

## **Government Regulation**

Government regulation is a significant factor in the development, marketing and manufacturing of our products. The Food and Drug Administration ( FDA ) regulates medical product manufacturers and their products under a number of statutes including the Food, Drug and Cosmetic ( FDC ) Act, and we and our products are subject to the regulations of the FDA. The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, under which the manufacturer gives the FDA a pre-market notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the Section 510(k) procedure, the manufacturer must file a pre-market approval ( PMA ) application. This requires substantially more extensive pre-filing testing than the Section 510(k) procedure and involves a significantly longer FDA review process. FDA approval of a PMA application occurs only after the applicant has established safety and efficacy to the satisfaction of the FDA. Each of our current products has qualified, and we anticipate that any new products that we are likely to market will qualify, for the expedited Section 510(k) clearance procedure. There is no assurance, however, that

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new products we develop or any manufacturers that we might acquire, or claims that we may make concerning those products, will qualify for expedited clearance rather than the more time consuming PMA procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. All of the regulated products that we currently manufacture are classified as Class II medical devices by the FDA. Class II medical devices are subject to performance standards relating to one or more aspects of the

design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

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

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

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

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

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

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

**Competition**



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

In addition to competing with conventional needle I.V. connection systems and protected needle connection systems marketed by companies such as Baxter Healthcare Corporation ( Baxter ) and Hospira, our present and future products compete with needleless I.V. connection systems like those marketed by Baxter, Becton-Dickinson and Company ( BD ), B. Braun



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Medical, Inc. ( B. Braun ), Alaris Medical Systems ( Alaris ) and others. Although we believe that our needleless CLAVE has distinct advantages over competing systems, there is no assurance that it will be able to compete successfully with these products.

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

The blood collection needle market is highly competitive, and a large segment of the market continues to use non-safety devices that are generally less expensive than safety devices such as the Punctur-Guard products. The largest share of the blood collection needle market is held by BD.

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

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

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

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

### Patents



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We have United States and certain foreign patents on the CLAVE, TEGO, CLC2000, Punctur-Guard technology, Click Lock, and Piggy Lock I.V. connectors and have United States patents on the Lopez Valve. We have applications pending for additional United States and foreign patents on the 1o2 Valve, TEGO, Y-CLAVE with integral check valve, Orbit 90, CLC2000, CLAVE and Punctur-Guard. The expiration dates of our patents range from 2006 to 2021. While we no longer manufacture and sell the Click Lock and Piggy Lock, the patents have considerable value for potential use in other devices.

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

products could adversely affect our ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on our financial results.

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

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

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

#### **ICU Finance**

In 2002 we established ICU Finance, Inc., a wholly-owned consolidated subsidiary, to provide financing to healthcare entities. As of December 31, 2005 we had finance loans receivable of approximately \$3.6 million that are fully secured by real and personal property. We plan to hold the loans to maturity or payoff and have discontinued new lending activities. Weighted average maturity (principal and interest) at December 31, 2005 was 1.5 years and the weighted average interest rate was 5.1%. There were no unfunded commitments at December 31, 2005.

#### **Employees**



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

### **Item 1A. Risk Factors.**

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

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

We have steadily increased our sales to Hospira in recent years, except for 2004 when sales to Hospira declined as Hospira reduced its inventories of our products. As a result, we depend on Hospira for a high percentage of our sales. Sales to Hospira increased by approximately \$75.2 million in 2005. Approximately \$46.7 million of the increase was attributable to the purchase of Hospira's Salt Lake City plant and commencement of production under a twenty-year MCDA as of May 1, 2005. The balance of the increase was attributable to the resumption of more normal levels of CLAVE sales to Hospira in 2005 after a sharp decline in 2004 described below. The table below shows our total revenue to various types of customers for 2005, 2004 and 2003 (dollars in millions):

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	2005		Years Ended December 31, 2004		2003				
Hospira (U.S.)	\$	115.0	73%	\$	39.8	53%	\$	71.3	67%
Other manufacturers		2.2	1%		1.5	2%		1.5	1%
Domestic distributors									