

ATRION CORP  
Form 10-K  
March 12, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-K

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

For the Fiscal Year Ended December 31, 2009  
Commission File Number 0-10763

Atrion Corporation

(Exact name of Registrant as specified in its charter)

Delaware

63-0821819

(State of incorporation or organization)

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

One Allentown Parkway,

Allen, Texas

75002

(Address of principal executive offices)

(ZIP code)

Registrant's telephone number, including area code: (972) 390-9800

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT:

Title of Class

Name of Each Exchange on Which  
Registered

Common Stock, \$.10 Par  
Value

NASDAQ

SECURITIES REGISTERED UNDER SECTION 12(g) OF THE EXCHANGE ACT: None

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

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

Indicate by check mark whether the 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 the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Indicate by check whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a

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smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  
 Smaller reporting company

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

Yes  No

The aggregate market value of the voting Common Stock held by nonaffiliates of the Registrant as of the last business day of the Registrant’s most recently completed second fiscal quarter, June 30, 2009, was \$206,789,575 based on the last reported sales price of the common stock on the NASDAQ Global Select Market on such date. Shares of voting stock held by executive officers, directors and holders of more than 10% of the outstanding voting shares have been excluded from this calculation because such persons may be deemed to be affiliates. Exclusion of such shares should not be construed to indicate that any of such persons possesses the power, direct or indirect, to control the Registrant, or that such person is controlled by or under common control of the Registrant

Number of shares of Common Stock outstanding at February 24, 2010: 2,021,452

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference information from the Company's definitive proxy statement relating to the 2010 annual meeting of stockholders, to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this report.

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ATRION CORPORATION  
 FORM 10-K  
 ANNUAL REPORT TO  
 THE SECURITIES AND EXCHANGE COMMISSION  
 FOR THE YEAR ENDED DECEMBER 31, 2009

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ATRION CORPORATION

FORM 10-K

ANNUAL REPORT TO  
THE SECURITIES AND EXCHANGE COMMISSION  
FOR THE YEAR ENDED DECEMBER 31, 2009

PART I

ITEM 1. BUSINESS

General

Atrion Corporation (“we,” “our,” “us,” “Atrion,” or the “Company”) develops and manufactures products, primarily for medical applications. Our products range from ophthalmology and cardiovascular products to fluid delivery devices. We also have a line of non-medical components that is sold for use in aviation and marine safety products. Additionally, we own and maintain a small gaseous oxygen pipeline that is incidental to our overall operations.

Our fluid delivery products accounted for 35 percent, 34 percent and 32 percent of net revenues for 2009, 2008 and 2007, respectively. We develop and manufacture several specialized intravenous fluid delivery tubing sets and accessories. Our intravenous fluid delivery line includes more than 80 distinct models used for complex therapy procedures employed in anesthesia administration, intravenous fluid therapy, critical care and oncology therapy. We are an industry leader in the manufacturing of medical tubing clamps. These products include clamps offering such features as six match-to-fit sizes with compatibility to all grades of medical tubing, molding in a variety of materials, and compatibility with different sterilization processes. Our swabbable luer valve allows needleless luer connections to luer access devices in IV applications. These valves provide an economical replacement for needle access ports in drug delivery and IV applications and maintain a sterile, closed IV system without the need for replacement caps. We have developed a wide variety of luer syringe check valves and one-way valves designed to fill, hold and release controlled amounts of fluids or gasses on demand for use in various intubation, catheter and other applications.

Our cardiovascular products accounted for 29 percent, 30 percent and 27 percent of our net revenues for 2009, 2008 and 2007, respectively. At the heart of our cardiovascular products is the MPS2® Myocardial Protection System, or MPS2, a proprietary technology that delivers essential fluids and medications to the heart during open-heart surgery. The MPS2 integrates key functions relating to the delivery of solutions to the heart, such as varying the rate and ratio of oxygenated blood, crystalloid, potassium and other additives, and controlling temperature, pressure and other variables to allow simpler, more flexible management of this process, indicating improved patient outcomes. New features include an expanded flow range, low volume mode and cyclic flow mode. The MPS2 is the only device used in open-heart surgery that allows for the mixing of drugs into the bloodstream without diluting the blood. The MPS2 employs advanced pump, temperature control and microprocessor technologies and includes a line of disposable products. We also develop and manufacture other cardiovascular products that consist principally of the following: cardiac surgery vacuum relief valves; Retract-O-Tape® silicone vessel loops for retracting and occluding vessels in minimally invasive surgical procedures; inflation devices for balloon catheter dilation, stent deployment and fluid dispensing; and Clean-Cut® rotating aortic punch and PerfectCut® Aortotomy System, both of which are used in heart bypass surgery to make a precision opening in the heart for attachment of the bypass vessels.

Our ophthalmic products accounted for 19 percent, 16 percent and 20 percent of our net revenues for 2009, 2008 and 2007, respectively. We are a leading manufacturer of soft contact lens storage and disinfection cases. We produce a complete line of products which is compatible with all solutions for use with soft or rigid gas permeable lenses. We

also work with customers to provide customized distribution of products. As a registered pharmaceutical reseller, we provide custom packaging, including component purchasing as well as labeling. Warehousing as well as inventory management is included in our complete kitting services. We also manufacture and sell the LacriCATH® product line, a line of balloon catheters that is used in the treatment of nasolacrimal duct obstruction in children and adults. Nasolacrimal duct obstruction can cause a condition called epiphora, or chronic tearing. People affected by this condition experience excessive and uncontrollable tearing and often encounter infection as a result of nasolacrimal blockage. LacriCATH balloon catheters are the only balloon catheters with United States Food and Drug Administration, or FDA approval for use in the treatment of nasolacrimal duct obstruction.

Our other medical and non-medical products accounted for 17 percent, 20 percent and 21 percent of our net revenues for 2009, 2008 and 2007, respectively. We are the leading manufacturer of inflation systems and valves used in marine and aviation safety products. We manufacture inflation devices, oral inflation tubes, right angle connectors, valves, and closures for life vests, life rafts, inflatable boats, survival equipment, and other inflatable structures. We also produce many one-way and two-way "Breather" valves for use on electronics cases, munitions cases, pressure vessels, transportation container cases, escape slides, and many other medical and non-medical applications requiring pressure relief. Also, we provide contract manufacturing services for other major original equipment manufacturers of medical devices. We have the ability to take a product from concept through design, development and prototype all the way to full-scale production manufacturing. Core competencies include engineering product design and development, prototyping, assembly, insert and injection molding, automation, RF-welding, ultrasonic and heat sealing, and sterile packaging. Our ACTester product line consists of instrumentation and associated disposables used to measure the activated clotting time of blood. We manufacture and sell a line of products designed for safe needle and scalpel blade containment. In addition, we own and maintain a 22-mile high-pressure steel pipeline in north Alabama that is leased to an industrial gas producer which transports gaseous oxygen to one of its customers.

#### Marketing and Major Customers

We market components to other equipment manufacturers for incorporation in their products and sell finished devices to physicians, hospitals, clinics and other treatment centers. We sell our products in the United States through a sales force of approximately 65 people as of December 31, 2009. This sales force, which works with our sales managers, consists of direct sales personnel, independent sales representatives and distributors. Our sales managers also work closely with major customers in designing and developing products to meet customer requirements.

Our revenues from sales to customers outside the United States totaled approximately 39 percent, 35 percent and 36 percent of our net revenues in 2009, 2008 and 2007, respectively. Our international sales are made to various manufacturers and through distributors in over 60 countries. Revenues from sales to customers in Canada totaled approximately 15 percent, 13 percent and 17 percent of our net revenues in 2009, 2008 and 2007, respectively.

We offer customer service, training and education, and technical support such as field service, spare parts, maintenance and repair for certain of our products. We periodically advertise our products in trade journals, routinely attend and participate in industry trade shows throughout the United States and internationally, and sponsor scientific symposia as a means of disseminating product information. We also provide supportive literature on the benefits of our products.

During 2009, Novartis International AG was our only customer accounting for more than 10 percent of our revenues, with various products sold to several divisions of Novartis accounting for approximately 15 percent of our net revenues.

#### Manufacturing

Our medical products and other components are produced at facilities in Arab, Alabama, St. Petersburg, Florida and Allen, Texas. The facilities in Arab and St. Petersburg both utilize plastic injection molding and specialized assembly as their primary manufacturing processes. Our other manufacturing processes consist of the assembly of standard and custom component parts and the testing of completed products.

We devote significant attention to quality assurance. Our quality assurance measures begin with the suppliers which participate in our supplier quality assurance program. These measures continue at the manufacturing level where many components are assembled in a “clean room” environment designed and maintained to reduce product exposure to particulate matter. Products are tested throughout the manufacturing process for adherence to specifications. Most finished products are then shipped to outside processors for sterilization by radiation or ethylene oxide gas. After sterilization, the products are quarantined and tested before they are shipped to customers.

Skills of assembly workers required for the manufacture of medical products are similar to those required in typical assembly operations. We currently employ workers with the skills necessary for our assembly operations and believe that additional workers with these skills are readily available in the areas where our plants are located.

Our medical device operations are ISO13485:2003 certified and are subject to FDA jurisdiction. Our non-medical device operations are ISO9001-2000 certified.

#### Research and Development

We believe that a well-targeted research and development program should be an essential part of our activities, and we are currently engaged in a number of research and development projects. The objective of this program is to develop new products in our current product lines, improve current products and develop new product lines. Recent major development projects include, but are not limited to, inflation devices for balloon catheter dilation, stent deployment, tissue displacement and fluid dispensing; inflation devices for orthopedic procedures; advanced contact lens disinfection systems; surgical devices used in open heart surgery; product-line expansion in ophthalmology; product-line expansion for MPS2 products; and the further integration of needle-free technology with fluid delivery products. The Company expects to incur additional research and development expenses in 2010 for various projects.

Our consolidated research and development expenditures for 2009, 2008 and 2007 were \$3,054,000, \$2,969,000, and \$2,778,000, respectively.

#### Sources and Availability of Raw Materials

The principal raw materials that we use in our products are polyethylene, polypropylene and polyvinyl chloride resins. Our ability to operate profitably is dependent, in large part, on the availability and pricing of these resins. The resins we use are derived from petroleum and natural gas, and the prices fluctuate substantially as a result of changes in petroleum and natural gas prices, demand and the capacity of the companies that produce these resins to meet market needs. Instability in the world markets for petroleum and natural gas could adversely affect the availability and pricing of these resins.

We contract with various suppliers to provide the component parts necessary to assemble our products. Almost all of these components are available from a number of different suppliers, although certain components are purchased from single sources that manufacture these components using our toolings. We believe that there are satisfactory alternative sources for single-sourced components, although a sudden disruption in supply from one or more of these suppliers could adversely affect our ability to deliver finished products on time. We own the molds used for production of a majority of our components. Consequently, in the event of supply disruption, we would be able to fabricate our own components or contract with another supplier, albeit after a possible delay in the production process.

#### Patents and License Agreements

Our commercial success is dependent, in part, on our ability to continue to develop patentable products, to preserve our trade secrets and to operate without infringing or violating the proprietary rights of third parties. We currently



have 428 active patents and patent applications pending on products that are either being sold or are in development. We pay royalties to outside parties for six patents. All of these patents and patents pending relate to products currently being sold by us or to products in evaluation stages. Our patents generally expire between 2010 and 2027.

We have developed technical knowledge which, although non-patentable, is considered to be significant in enabling us to compete. However, the proprietary nature of such knowledge may be difficult to protect. We have entered into agreements with key employees prohibiting them from disclosing any of our confidential information or trade secrets. In addition, these agreements also provide that any inventions or discoveries relating to our business by these individuals will be assigned to us and become our sole property.

The medical device industry is characterized by extensive intellectual property litigation, and companies in that industry sometimes use intellectual property litigation to gain a competitive advantage. Intellectual property litigation, regardless of outcome, is often complex and expensive, and the outcome of this litigation is generally difficult to predict.

### Competition

Depending on the product and the nature of the project, we compete on the basis of our ability to provide engineering and design expertise, quality, service, product and price. As such, successful competitors must have technical strength, responsiveness and scale. We believe that our expertise and reputation for quality medical products have allowed us to compete favorably with respect to each such factor and to maintain long-term relationships with our customers.

In many of our markets, we compete with numerous other companies in the sale of healthcare products. These markets are dominated by established manufacturers that have broader product lines, greater distribution capabilities, substantially greater capital resources and larger marketing, research and development staffs and facilities than ours. Many of these competitors offer broader product lines within the specific product market and in the general field of medical devices and supplies. Broad product lines give many of our cardiovascular and fluid delivery competitors the ability to negotiate exclusive, long-term medical device supply contracts and, consequently, the ability to offer comprehensive pricing of their competing products. By offering a broader product line in the general field of medical devices and supplies, competitors may also have a significant advantage in marketing competing products to group purchasing organizations, HMOs and other managed care organizations that are increasingly seeking to reduce costs through centralization of purchasing functions. Furthermore, innovations in surgical techniques or medical practices could have the effect of reducing or eliminating market demand for one or more of our products. In addition, our competitors may use price reductions to preserve market share in their product markets.

Depending on the product and the nature of the project, we compete in contract manufacturing on the basis of our ability to provide engineering and design expertise as well as on the basis of product and price. We frequently design products for a customer or potential customer prior to entering into long-term development and manufacturing agreements with that customer. Because these products are somewhat limited in number and normally are only a component of the ultimate product sold by our customers, we are dependent on our ability to meet the requirements of those major healthcare companies and must continually be attentive to the need to manufacture such products at competitive prices and in compliance with strict manufacturing standards. We compete with a number of contract manufacturers of medical products. Most of these competitors are small companies that do not offer the breadth of services we offer to our customers.

We also compete in the market for inflation devices used in marine and aviation equipment. We are the dominant provider in this market area.

## Government Regulation

### Products

The manufacture and sale of medical products are subject to regulation by numerous United States governmental authorities, principally the FDA, and corresponding foreign agencies. The research and development, manufacturing, promotion, marketing and distribution of medical products in the United States are governed by the Federal Food, Drug and Cosmetic Act, or FDCA, and the regulations promulgated thereunder. All manufacturers of medical devices must register with the FDA and list all medical devices manufactured by them. The list must be updated annually. Our medical products subsidiaries and certain of our customers are subject to inspection by the FDA for compliance with such regulations and procedures and our medical products manufacturing facilities are subject to regulation by the FDA.

The FDA has traditionally pursued a rigorous enforcement program to ensure that regulated entities comply with the FDCA. A company not in compliance may face a variety of regulatory actions, including warning letters, product detentions, device alerts, mandatory recalls or field corrections, product seizures, total or partial suspension of production, injunctive actions or civil penalties and criminal prosecutions of the company or responsible employees, officers and directors. We and certain of our customers are subject to these inspections. We believe that we have met all applicable FDA requirements.

Under the FDA's requirements, if a manufacturer can establish that a newly-developed device is "substantially equivalent" to a legally marketed device, the manufacturer may seek marketing clearance from the FDA to market the device by filing a 510(k) premarket notification with the FDA. The 510(k) premarket notification must be supported by data establishing the claim of substantial equivalence to the satisfaction of the FDA. The process of obtaining a 510(k) clearance typically can take several months to a year or longer. If substantial equivalence cannot be established or if the FDA determines that the device requires a more rigorous review, the FDA will require that the manufacturer submit a premarket approval, or PMA, that must be reviewed and approved by the FDA prior to marketing and sale of the device in the United States. The process of obtaining a PMA can be expensive, uncertain and lengthy, frequently requiring anywhere from one to several years from the date of FDA submission. Both a 510(k) and a PMA, if granted, may include significant limitations on the indicated uses for which a product may be marketed. FDA enforcement policy strictly prohibits the promotion of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing. We believe that we are in compliance with the requirements mentioned above.

Certain aviation and marine safety products are also subject to regulation by the United States Coast Guard and the Federal Aviation Administration and similar organizations in foreign countries which regulate the safety of marine and aviation equipment. We believe that we are in compliance with the requirements mentioned above.

### Third-Party Reimbursement and Cost Containment

In the United States, healthcare providers, including hospitals and physicians, that purchase medical products for treatment of their patients generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or a part of the costs and fees associated with the procedures performed using these products.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. Many international markets have government-managed healthcare systems that control reimbursement for new products and procedures. In most markets, there are private insurance systems as well as government-managed systems. Market acceptance of our

products in international markets depends, in part, on the availability and level of reimbursement.

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Medicare and Medicaid reimbursement for hospitals is generally based on a fixed amount for admitting a patient with a specific diagnosis. Because of this fixed reimbursement method, hospitals may seek to use less costly methods in treating Medicare and Medicaid patients. Frequently, reimbursement is reduced to reflect the availability of a new procedure or technique, and as a result hospitals are generally willing to implement new cost saving technologies before these downward adjustments take effect. Likewise, because the rate of reimbursement for physicians who perform certain procedures has been and may in the future be reduced, physicians may seek greater cost efficiency in treatment to minimize any negative impact of reduced reimbursement. Third-party payors may challenge the prices charged for medical products and services and may deny reimbursement if they determine that a device was not used in accordance with cost-effective treatment methods as determined by the payor, was experimental or was used for an unapproved application.

We anticipate that Congress, state legislatures and the private sector will continue to review and assess healthcare reform, including alternative healthcare delivery and payment systems. Potential approaches that have been considered include mandated basic healthcare coverage and benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. We cannot predict what impact the adoption of any federal or state healthcare reform measures, future private sector reform or market forces may have on our business.

#### Product Liability and Insurance

The design, manufacture and marketing of products of the types we produce entail an inherent risk of product liability claims. A problem with one of our products could result in product liability claims or a recall of, or safety alert or advisory notice relating to, the product. We have product liability insurance in amounts that we believe are adequate.

#### Advisory Board

Several physicians and perfusionists with substantial expertise in the field of myocardial protection serve as our clinical advisors. These clinical advisors have assisted in the identification of the market need for myocardial protection systems and the subsequent design and development of the MPS2 and its predecessor. Members of our management and scientific and technical staff from time to time consult with these clinical advisors to better understand the technical and clinical requirements of the cardiovascular surgical team and product functionality needed to meet those requirements. We anticipate that these clinical advisors will play a similar role with respect to other products and may assist us in educating other physicians in the use of the MPS2 and related products.

Certain of the clinical advisors are employed by academic institutions and may have commitments to, or consulting or advisory agreements with, other entities that may limit their availability to advise us. The clinical advisors may also serve as consultants to other medical device companies. Our clinical advisors are not expected to devote more than a small portion of their time in providing services to us.

#### People

At January 31, 2010, we had 465 full-time employees. Employee relations are good and there has been no work stoppage due to labor disagreements. None of our employees is represented by any labor union.

#### Available Information

Our website address is [www.atrioncorp.com](http://www.atrioncorp.com). We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these

reports, as soon as reasonably practicable after they are filed with or furnished to the Securities and Exchange Commission. These filings are also available at [www.sec.gov](http://www.sec.gov).

## ITEM 1A. RISK FACTORS

In addition to the other information contained in this Form 10-K, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Additional risks and uncertainties that we do not currently know about or that we currently believe are immaterial, or that we have not predicted, may also harm our business operations or adversely affect us.

- The loss of a key supplier of raw materials could lead to increased costs and lower profit margins.

The loss of a key supplier would force us to purchase raw materials in the open market, which may be at higher prices, until we could secure another source and such higher prices may not allow us to remain competitive. If we are unable to obtain raw materials in sufficient quantities, we may not be able to manufacture our products. Even if we were able to replace one of our raw material suppliers through another supply arrangement, there is no assurance that the terms that we enter into with such alternate supplier will be as favorable as the supply arrangements that we currently have.

- Our sales could decline materially if we lost business from one or more of our larger customers or a significant number of our smaller customers.

Our sales are generally made under open short-term purchase orders or, purchase contracts. Customers with purchase orders could reduce their volumes, or cease purchasing our products, with minimal notice. Customers having purchase contracts may elect not to renew those contracts at expiration or the contracts may be renewed on terms less favorable to us. The loss of, or material reduction in orders by, one or more of our larger customers or a significant number of our smaller customers could have a material adverse effect on our business, financial condition and results of operations.

- Product liability claims could adversely affect our financial condition and results of operations.

We may be subject to product liability claims involving claims of personal injury or property damage. Our product liability insurance coverage may not be adequate to cover the cost of defense and the potential award in the event of a claim. Also, a well-publicized actual or perceived problem with one or more of our products could adversely affect our reputation and reduce the demand for our products.

- Our business is dependent on the price and availability of resins and our ability to pass on resin price increases to our customers.

The principal raw materials that we use in our products are polyethylene, polypropylene and polyvinyl chloride resins. Our ability to operate profitably is dependent, in large part, on the availability and pricing of these resins. The resins we use are derived from petroleum and natural gas; therefore, prices fluctuate substantially as a result of changes in petroleum and natural gas prices, demand and the capacity of the companies that produce these products to meet market needs. Instability in the world markets for petroleum and natural gas could adversely affect the prices of these raw materials and their availability.

Our ability to maintain profitability is heavily dependent upon our ability to pass through to our customers the full amount of any increase in raw material costs. If resin prices increase and we are not able to fully pass on the increases to our customers, our results of operations and our financial condition will be adversely affected.

- Any losses we incur as a result of our exposure to the credit risk of our customers could harm our results of operations.

We monitor individual customer payment capability in granting credit arrangements, seek to limit credit to amounts we believe the customers can pay, and maintain reserves we believe are adequate to cover exposure for doubtful accounts. As we have grown our revenue and customer base, our exposure to credit risk has increased. Any material losses as a result of customer defaults could harm and have an adverse effect on our business, operating results and financial condition.

- Our success is measured in part by our ability to develop patentable products, to preserve our trade secrets and operate without infringing or violating the proprietary rights of third parties.

Others may challenge the validity of any patents issued to us, and we could encounter legal and financial difficulties in enforcing our patent rights against infringers. In addition, there can be no assurance that other technologies cannot or will not be developed or that patents will not be obtained by others which would render our patents less valuable or obsolete. Once patents expire, some customers may not continue to purchase from us, opting for competitive copies instead.

We have developed technical knowledge which, although non-patentable, we consider to be significant in enabling us to compete. However, the proprietary nature of such knowledge may be difficult to protect.

The medical device industry is characterized by extensive intellectual property litigation, and companies in the medical products industry sometimes use intellectual property litigation to gain a competitive advantage. Intellectual property litigation, regardless of outcome, is often complex and expensive, and the outcome of this litigation is generally difficult to predict. An adverse determination in any such proceeding could subject us to significant liabilities to third parties or require us to seek licenses from third parties or pay royalties that may be substantial. Furthermore, there can be no assurance that necessary licenses would be available to us on satisfactory terms or at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing or selling certain of our products, which could have a material adverse effect on our business, financial condition and results of operations.

- International patent protection is uncertain.

Patent law outside the United States is uncertain and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. We may participate in opposition proceedings to determine the validity of our or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

- New lines of business or new products and services may subject us to additional risks.

From time to time, we may implement new lines of business or offer new products and services within existing lines of business. There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. In developing and marketing new lines of business or new products and services, we may invest significant time and resources. Initial timetables for the introduction and development of new lines of business and new products or services may not be achieved and price and profitability targets may not prove feasible. External factors, such as compliance with regulations, competitive alternatives, and shifting market preferences, may also impact the successful implementation of a new line of business or a new product or service. Furthermore, any new line of business or new product or service could have a significant impact on the effectiveness of our system of internal control. Failure to successfully manage these risks in the development and implementation of new lines of business or new products or services could have a material adverse effect on our business, results of operations and financial condition.





- Some of our competitors have significantly greater resources than we do, and it may be difficult for us to compete against them.

In many of our markets, we compete with numerous other companies that have substantially greater financial resources and engage in substantially more research and development activities than we do. Furthermore, innovations in surgical techniques or medical practices could have the effect of reducing or eliminating market demand for one or more of our products.

Some of the markets in which we compete are dominated by established manufacturers that have broader product lines, greater distribution capabilities, substantially larger marketing, research and development staffs and facilities than we do. Many of these competitors offer broader product lines within the specific product market and in the general field of medical devices and supplies. Broad product lines give many of our cardiovascular and fluid delivery competitors the ability to negotiate exclusive, long-term medical device supply contracts and, consequently, the ability to offer comprehensive pricing of their competing products. By offering a broader product line in the general field of medical devices and supplies, competitors may also have a significant advantage in marketing competing products to group purchasing organizations. In addition, our competitors may use price reductions to preserve market share in their product markets.

- We are subject to substantial governmental regulation and our failure to comply with applicable governmental regulations could subject us to numerous penalties, any of which could adversely affect our business.

We are subject to numerous governmental regulations relating to, among other things, our ability to sell our products, third-party reimbursement and Medicare and Medicaid fraud and abuse. If we do not comply with applicable governmental regulations, governmental authorities could do one or more of the following:

- impose fines and penalties on us;
- prevent us from manufacturing our products;
- bring civil or criminal charges against us;
- delay the introduction of our new products into the market;
- recall or seize our products;
- disrupt the manufacture or distribution of our products; or
- withdraw or deny approvals for our products.

Any one of these actions could materially adversely affect our revenues and profitability and harm our reputation.

- We will be unable to sell our products if we fail to comply with manufacturing regulations.

To manufacture our products commercially, we must comply with governmental manufacturing regulations that govern design controls, quality systems and documentation policies and procedures. The FDA and equivalent foreign governmental authorities periodically inspect our manufacturing facilities and the manufacturing facilities of our OEM medical device customers. If we or our OEM medical device customers fail to comply with these manufacturing regulations or fail any FDA inspections, marketing or distribution of our products may be prevented or delayed, which would negatively impact our business.

- Our products are subject to product recalls even after receiving regulatory clearance or approval, and any such recalls would negatively affect our financial performance and could harm our reputation.

Any of our products may be found to have significant deficiencies or defects in design or manufacture. The FDA and similar governmental authorities in other countries have the authority to require the recall of any such defective product. A government-mandated or voluntary recall could occur as a result of component failures, manufacturing errors or design defects. We do not maintain insurance to cover losses incurred as a result of product recalls. Any product recall would divert managerial and financial resources and negatively affect our financial performance, and

could harm our reputation with customers and end-users.

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- We may not receive regulatory approvals for new product candidates or for modifications of existing products or approvals may be delayed.

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our proposed products and in our ongoing research and product development activities. Any failure to receive the regulatory approvals necessary to commercialize our product candidates, or the subsequent withdrawal of any such approvals, would harm our business. Additionally, modification of our existing products may require regulatory approval. The process of obtaining these approvals and the subsequent compliance with federal and state statutes and regulations require spending substantial time and financial resources. If we fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any products we develop or modify, our ability to receive product revenues, and our liquidity and capital resources.

- We rely on technology to operate our business and any failure of these systems could harm our business.

We rely heavily on communications and information systems to conduct our business, enhance customer service and increase employee productivity. Any failure, interruption or breach in security of these systems could result in failures or disruptions in our customer relationship management, general ledger, inventory, manufacturing and other systems. There is no assurance that any such failures, interruptions or security breaches will not occur or, if they do occur, that they will be adequately addressed by our policies and procedures that are intended to safeguard our systems. The occurrence of any failures, interruptions or security breaches of our information systems could damage our reputation, result in a loss of customer business, subject us to additional regulatory scrutiny, and expose us to civil litigation and possible financial liability, any of which could have a material adverse effect on our financial condition and results of operations.

- We sell many of our products to healthcare providers that rely on Medicare, Medicaid and private health insurance plans to reimburse the costs associated with the procedures performed using our products and these third party payors may deny reimbursement for use of our products.

We are dependent, in part, upon the ability of healthcare providers to obtain satisfactory reimbursement from third-party payors for medical procedures in which our products are used. Third-party payors may deny reimbursement if they determine that a prescribed product has not received appropriate regulatory clearances or approvals, is not used in accordance with cost-effective treatment methods as determined by the payor, or is experimental, unnecessary or inappropriate. Failure by hospitals and other users of our products to obtain reimbursement from third-party payors, or adverse changes in government and private third-party payors' policies toward reimbursement for procedures utilizing our products, could have a material adverse effect on the Company's business, financial condition and results of operations. Major third-party payors for medical services in the United States and other countries continue to work to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to charges for services performed. Further implementation of legislative or administrative reforms to the United States or international reimbursement systems in a manner that significantly reduces reimbursement for procedures using our products or denies coverage for such procedures may result in hospitals or physicians substituting lower cost products or other therapies for our products which, in turn, would have an adverse effect on our business, financial condition and results of operations.

- We may not be able to attract and retain skilled people.

Our success depends, in large part, on our ability to attract and retain key people. Competition for the best people in most activities we engage in can be intense and we may not be able to hire qualified people or to retain them. The unexpected loss of services of one or more of our key personnel could have a material adverse impact on our business because of their skills, knowledge of our market, years of industry experience and the difficulty of promptly finding qualified replacement personnel.

- Severe weather, natural disasters, acts of war or terrorism or other external events could significantly impact our business.

We currently conduct all our development, manufacturing and management at three locations. Severe weather, natural disasters, acts of war or terrorism and other adverse external events at any one or more of these locations could have a significant impact on our ability to conduct business. We have the ability to transfer certain products from a facility affected by such events, but doing so would be expensive. Our disaster recovery policies and procedures may not be effective and the occurrence of any such event could have a material adverse effect on our business, which, in turn, could have a material adverse effect on our financial condition and results of operations. The insurance we maintain may not be adequate to cover our losses.

- Our stock price can be volatile.

Stock price volatility may make it more difficult for our stockholders to sell their common stock when they want and at prices they find attractive. Our stock price can fluctuate significantly in response to a variety of factors including, among other things:

- actual or anticipated variations in quarterly results of operations;
- recommendations by securities analysts;