ATRION CORP
Form 10-K
March 11, 2013
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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Form 10-K

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

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

For the Fiscal Year Ended December 31, 2012
For the Transition Period from __to __

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 o No x

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 o No x

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 x No o

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. x

Indicate by check whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act (check one):
Large accelerated filer o Accelerated filer x Non-accelerated filer o Smaller reporting company o

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

The aggregate market value of the voting Common Stock held by nonaffiliates of the Registrant as of, June 30, 2012, the last business day of the Registrant’s most recently completed second fiscal quarter was approximately $322,289,234 based on the $204.98 closing price reported for such date on the NASDAQ Global Select Market.

Number of shares of Common Stock outstanding at February 12, 2013: 2,020,707

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates by reference information from the Company's definitive proxy statement relating to the 2013 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.

ATRION CORPORATION

FORM 10-K

ANNUAL REPORT TO
THE SECURITIES AND EXCHANGE COMMISSION
FOR THE YEAR ENDED DECEMBER 31, 2012

TABLE OF CONTENTS

ATRION CORPORATION

FORM 10-K

ANNUAL REPORT TO
THE SECURITIES AND EXCHANGE COMMISSION
FOR THE YEAR ENDED DECEMBER 31, 2012

PART I

ITEM 1. BUSINESS.

General

Atrion Corporation and its subsidiaries (”we,” “our,” “us,” “Atrion,” or the “Company”) develop and manufacture produc
primarily for medical applications. Our medical products range from fluid delivery devices to ophthalmic and cardiovascular products.

Our fluid delivery products accounted for 41 percent, 38 percent and 36 percent of net revenues for 2012, 2011 and 2010, respectively. These products include proprietary valves that promote infection control and needle safety. 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. We also make tubing clamps in a variety of materials and colors that are compatible with various grades of tubing and sterilization processes and produce specialized intravenous sets for use in numerous applications including anesthesia and oncology.

Our cardiovascular products accounted for 30 percent, 29 percent and 29 percent of our net revenues for each of 2012, 2011 and 2010, 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. 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 such as cardiac surgery vacuum relief valves; silicone vessel loops for retracting and occluding vessels in minimally invasive surgical procedures; inflation devices for balloon catheter dilation, stent deployment and fluid dispensing; as well as products used in heart bypass surgery to make a precision opening in the heart for attachment of the bypass vessels.

Our ophthalmic products accounted for 13 percent, 17 percent and 18 percent of our net revenues for 2012, 2011 and 2010, respectively. We are a leading manufacturer of contact lens disinfection cases. We also manufacture a proprietary line of balloon catheters 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.

Our other medical and non-medical products accounted for 16 percent, 16 percent and 17 percent of our net revenues for 2012, 2011 and 2010, respectively. One of these product lines consists of instrumentation and associated disposables used to measure the activated clotting time of blood. In addition, we manufacture and sell a line of

products designed for safe needle and scalpel blade containment. We are also the leading manufacturer of inflation systems and valves used in marine and aviation safety products. We manufacture inflation systems and valves for products such as life vests, life rafts, inflatable boats, survival equipment, and other inflatable structures. We also produce one-way and two-way pressure relief valves for use on electronics cases, munitions cases, pressure vessels, transportation container cases, escape slides, and many other medical and non-medical applications.

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 through a sales force which 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 net revenues from sales to customers outside the United States totaled approximately 42 percent, 42 percent and 40 percent of our net revenues for 2012, 2011 and 2010, 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 11 percent, 15 percent and 16 percent of our net revenues for 2012, 2011 and 2010, respectively. Additional information about our revenues from customers in and outside of the United States over the past three years is set forth in Part II, Item 8 of this Form 10-K.

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 may provide supportive literature on the benefits of our products.

Manufacturing

Our medical products and other components are produced at facilities in Florida, Alabama and Texas. The facilities in Alabama and Florida 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, including the assembly of electronic components, and the testing of completed products.

We are subject to the Quality System Regulation, or QSR, of the United States Food and Drug Administration, or FDA, which requires manufacturers of medical devices to adhere to certain design testing, quality control, documentation and other quality assurance procedures during the manufacturing process. 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.

Skilled workers are required for the manufacturing of our products, and we 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 ISO9001-2008 certified.

Research and Development

A well-targeted research and development program is 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. The Company expects to continue additional research and development in 2013 in all these areas.

Our consolidated research and development expenditures for 2012, 2011 and 2010 were $3,766,000, $2,868,000, and $2,669,000, respectively.

Sources and Availability of Raw Materials

The principal raw materials that we use in our products are 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 tooling. 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 nearly all our components. Consequently, in the event of supply disruption, we should 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 413 active patents and patent applications pending on products that are either being sold or are in development. We pay royalties to outside parties for four patents. All of these patents and patents pending relate to products currently being sold by us or to products in evaluation stages. Our patents expire at various times over the next 18 years.

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. 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, product design or functions, 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.

We 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 quality 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. Additionally, we are dependent on our customer's success in the marketing of the ultimate product sold. We also compete in the market for inflation devices used in marine and aviation equipment.

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. The FDA has recently been increasing its scrutiny of the medical device industry, and the government is expected to continue to scrutinize the industry closely. 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.

The FDA sets forth rules, which are available to the public, for the approval of medical devices. The process of obtaining FDA approval for new devices can take several months to several years depending on the type of application required for a particular device. Furthermore, the process of obtaining FDA approval can be expensive and uncertain. Even if granted, FDA approval may include significant limitations on the indicated uses for which a product may be marketed. FDA enforcement policy strictly regulates the promotion of approved medical devices. Product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing. We are also subject to regulation in certain foreign countries where we sell our products. Some of the regulations in these countries that are applicable to our products are similar to those of the FDA.

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.

Healthcare Regulations

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 Medicare, 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.

Medicare and Medicaid reimbursement for hospitals is generally based on a fixed amount for a patient based upon that patient’s specific diagnosis. Because of this fixed reimbursement method, hospitals may seek to reduce the costs they incur 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.

In March 2010, comprehensive healthcare reform legislation in the form of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively known as the “Affordable Care Act”) was enacted. Among other provisions, this legislation imposes a 2.3 percent excise tax on the sale in the United States of certain medical devices by the manufacturer, producer or importer after December 31, 2012. We believe that this excise tax will apply to less than 50 percent of our product revenue generated in the United States. The Affordable Care Act also includes numerous provisions to limit Medicare spending through reductions in various fee schedule payments and by instituting more sweeping payment reforms, such as bundled payments for episodes of care and the establishment of “accountable care organizations” under which hospitals and physicians will be able to share savings that result from cost control efforts and imposes new reporting and disclosure requirements for medical device manufacturers effective March 30, 2013. The Physician Payment Sunshine Act, which was included in the Affordable Care Act, imposes new reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. Manufacturers will be required to begin data collection on August 1, 2013 and report such data to the Centers for Medicare and Medicaid Services by March 31, 2014. Many of these provisions will be implemented through the regulatory process, and certain policy details have not yet been finalized. Various healthcare reform proposals have also emerged at the state level.

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. We cannot predict what impact the adoption or modification of any federal or state healthcare reform measures, including the Affordable Care Act, and state healthcare reform, future private sector reform or market forces may have on our business.

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. Violation of these laws can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Government officials have focused recent enforcement efforts on, among other things, sales and marketing activities of pharmaceutical, medical device and other healthcare companies.

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 other healthcare professionals serve as our clinical advisors. These clinical advisors have assisted in the identification of the market need for some of our products. 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 current and future products. We anticipate that these clinical advisors will continue to play a role in our development activities.

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, 2013, we had 459 full-time employees. We are proud that many of our employees have tenures with us ranging from 10 to 36 years.

Available Information

Our website address is www.atrioncorp.com. We make available free of charge through our website our Annual Reports 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, or SEC. These filings are also available at 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 and 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. A product liability claim, regardless of its merit or outcome, could result in significant legal defense costs. 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. Our patents expire at various times over the next 18 years. Once patents expire, some customers may not continue to purchase from us, opting for competitive copies instead. If we do not develop and launch new products prior to the expiration of patents for our existing products, our sales and profits could decline substantially.

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;
- exclusion from participation in Medicare and Medicaid and other federal healthcare programs;
- 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 regulations.

To manufacture our products commercially, we must comply with governmental regulations that govern design controls, quality systems and documentation policies and procedures, including continued compliance with QSR. 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, including meeting reporting obligations to the FDA, 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.

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.