

ATRION CORP
Form 10-K/A
March 14, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K/A
(Amendment No.1)

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

For the Fiscal Year Ended December 31, 2016

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

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 No

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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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 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, June 30, 2016, the last business day of the Registrant's most recently completed second fiscal quarter was approximately \$604,830,170 based on the \$427.86 closing price reported for such date on the NASDAQ Global Select Market. Number of shares of Common Stock outstanding at February 15, 2017: 1,833,880

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 2017 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, 2016

EXPLANATORY NOTE

On March 13, 2017, the filing agent engaged by Atrion Corporation (the "Company") inadvertently filed our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 with the Securities and Exchange Commission (the "Original Filing"). Such filing was made prior to the issuance of the Report of the Independent Registered Public Accounting Firm, prior to the recommendation of the Audit Committee the Company's audited financial statements as of and for the year ended December 31, 2016 be included in the Annual Report on Form 10-K and prior to the approval of the Board of Directors of such filing.

This Amendment No. 1 (the "Amendment") to the Original Filing has been approved by the Company's Board of Directors and is being filed to report that the Independent Registered Public Accounting Firm has issued its Report on the Company's financial statements included in Item 8 of this Amendment and that the Audit Committee has recommended the inclusion of such financial statements in this Amendment and to set forth the correct dates for the Report of the Independent Registered Public Accounting Firm and its Consent. In addition, new certifications by the Company's principal executive officer and principal financial officer are filed as exhibits to this Amendment and two typographical errors in the Original Filing have been corrected. Other than the foregoing changes and this Explanatory Note, no information in the Original Filing has been supplemented, updated or amended. This amendment replaces the Original Filing in its entirety.

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ATRION CORPORATION

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ANNUAL REPORT TO
THE SECURITIES AND EXCHANGE COMMISSION
FOR THE YEAR ENDED DECEMBER 31, 2016

PART I

ITEM 1. BUSINESS.

General

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

Our fluid delivery products accounted for 42 percent of net revenues for both 2016 and 2015 and 41 percent of net revenues for 2014. These products include proprietary valves that promote infection control and needle safety. We have developed a wide variety of valves designed to fill, hold and release controlled amounts of fluids or gasses on demand for use in various intubation, intravenous, catheter and other applications in fields such as anesthesia and oncology.

Our cardiovascular products accounted for 33 percent, 32 percent and 30 percent of net revenues for 2016, 2015 and 2014, respectively. At the core of our cardiovascular products is the MPS2® Myocardial Protection System, or MPS2, a proprietary technology that is the only system used in open-heart surgery that delivers essential fluids and medications, mixes critical drugs and controls temperature, pressure and other variables. This system indicates improved outcomes offering an integrated, flexible set of choices during surgery without diluting the blood. 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 11 percent, 12 percent and 14 percent of our net revenues for 2016, 2015 and 2014, respectively. We are a leading manufacturer of specialized medical devices that disinfect contact lenses. 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 14 percent of our net revenues for both 2016 and 2015, and 15 percent of our net revenues for 2014. 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 components used in survival products such as life vests, life rafts, escape slides, inflatable boats, and other inflatable structures. We also produce one-way and two-way pressure relief valves that protect sensitive electronics and munitions during transport as well as pressure relief valves used in 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 37 percent, 35 percent and 42 percent of our net revenues for 2016, 2015 and 2014, respectively. In 2015, we saw a reduction in the percentage of our international sales that was driven in large part by a customer's decision to build a new facility in the United States. Our international sales are made to various manufacturers and through distributors in over 60 countries. 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 also have 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 EN ISO13485:2012 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, or R&D, program is an essential part of our activities, and we are currently engaged in a number of R&D 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 R&D in 2017 in all these fields.

Our consolidated R&D expenditures for 2016, 2015 and 2014 were \$6,574,000, \$6,346,000 and \$5,286,000, 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 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. Substantially 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 substantially 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 515 active patents and patent applications pending on products that are either being sold or are in development. We pay royalties to outside parties for three 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 20 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, R&D 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, health maintenance organizations, 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 our customers 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 customers' success in the marketing of the ultimate products 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 comprehensive regulation by numerous United States and foreign regulatory agencies, principally the FDA. The R&D, 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.

The FDA promulgates 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 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. This excise tax applied to approximately 28 percent of our product revenue generated in the United States in 2015. During 2015, we remitted \$600,000 related to this excise tax. In December 2015, as part of the Omnibus Appropriations Act, collection of the medical device excise tax was suspended for 2016 and 2017. We do not know whether postponement will be continued beyond 2017. The Affordable Care Act, also established a payment transparency program, sometimes referred to as the Physician Payments Sunshine Act, that requires medical device and drug manufacturers, including the Company, to report to the Centers for Medicare & Medicaid Services payments or other transfers of value made to physicians and teaching hospitals. The program is intended to provide patients with enhanced transparency as to the financial relationships that physicians and teaching hospitals have with medical device and drug manufacturers. Additionally, various healthcare reform proposals have also emerged at the state level. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, President Trump and the Republican leadership in Congress have announced that they intend to repeal the Affordable Care Act and replace it with other legislation. This legislation and state healthcare reform measures could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or create additional pricing pressures.

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, directly or indirectly, subject to various federal and state laws governing our relationship with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal

healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, has issued a series of regulations, known as the “safe harbors.” These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

The Federal False Claims Act, or FCA, imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the United States government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice, on behalf of the government, has previously alleged that the marketing and promotional practices of medical device and drug manufacturers that included the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

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, 2017, we had 520 employees. We are proud that many of our employees have tenures with us ranging from 10 to 40 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.

Our sales could decline materially if we lose 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.

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 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 depends, in part, 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.

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.

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 to us as the supply arrangements that we currently have or that such replacement could be timely completed.

Issues with product quality could have an adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving our products and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. While we have one quality system that covers the lifecycle of our products, quality and safety issues may occur with respect to any of our products. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity or a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. Additionally, we have made and continue to make significant investments in assets, including inventory and property, plant and equipment, which relate to potential new products or modifications to existing products. Product quality or safety issues may restrict us from being able to realize the expected returns from these investments, potentially resulting in asset impairments in the future.

Unaffiliated third party suppliers provide a number of goods and services to our manufacturing and R&D organizations. Third party suppliers are required to comply with our quality standards. Failure of a third party supplier to provide compliant raw materials or supplies could result in delays, service interruptions or other quality related issues that may negatively impact our business results.

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.

The success of certain of our products depends upon relationships with healthcare professionals. The research, development, marketing, and sales of many of our new and improved products are dependent upon our maintaining working relationships with healthcare professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding our products. If we are unable to maintain our relationships with these professionals and do not continue to receive their advice and input, the development and commercialization of our products could suffer, which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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 20 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 device 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 R&D 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. In addition, the trend of consolidation in the medical device industry and among our customers could result in greater competition and pricing pressure.

Some of the markets in which we compete are dominated by established manufacturers that have broader product lines, greater distribution capabilities, substantially larger marketing, R&D 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 healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future.

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States. These laws and regulations are wide ranging and subject to changing interpretations and applications, which could restrict our sales or marketing practices. A violation of these laws could have a material adverse effect on our business, results of operations, financial condition and cash flow.

We will be unable to sell our products if we fail to comply with governmental 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 Original Equipment Manufacturer, or 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 products. 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 technology systems to conduct our business, enhance customer service and increase employee productivity. Some of these systems are vulnerable to breakdown or other interruption by fire, power loss, system malfunction, computer viruses, cyber-attacks, unauthorized access and other events. 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 technology 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. In addition, security breaches of our information technology systems could result in the misappropriation or unauthorized disclosure of confidential information belonging to us, our customers, our suppliers or our employees, which may result in significant costs and other adverse consequences.

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 or 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 try 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. Additionally, uncertainty about whether and how changes may be implemented could also have a negative impact on the demand for our products.

The outcome of the 2016 Presidential and Congressional elections that were recently held in the United States might result in material changes to governmental regulation of various aspects of our business and operations or cause disruptions to our business.

The outcome of the 2016 Presidential and Congressional elections that were recently held in the United States might result in material changes to governmental regulation of various aspects of our business and operations. We devote significant operational and managerial resources to comply with existing laws and regulations. Different interpretations and enforcement policies of existing laws and regulations, the possible repeal of existing laws and regulations, as well as the enactment of new laws and regulations, could require additional operational and managerial resources and could subject our current practices to allegations of impropriety or illegality or could require us to make significant changes to our products and operations.

Healthcare policy changes, including the proposed repeal and replacement of the Affordable Care Act, may have a material adverse effect on our business, financial condition and results of operations. One of the principal aims of the Affordable Care Act was to expand health insurance coverage to millions of Americans who were uninsured. The consequences of the proposed repeal and replacement of the Affordable Care Act on the sales of our products are unknown and speculative at this point.

The Affordable Care Act, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to develop or market our products successfully. Also, changes in the government's role in the United States healthcare industry may result in a further decrease in profits to us, lower reimbursement by payors for our products, and reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Our existing credit agreement contains restrictions that may limit our flexibility in operating our business. Our existing credit agreement contains, and any future agreements may contain, covenants that could impose significant operating and financial restrictions on us. Although we currently do not have any borrowings under our existing credit agreement, the covenants in those agreements may limit in the manner in which we conduct our business, and we may be unable to engage in favorable business activities or finance future operations or capital needs.

We have pledged certain of our assets as collateral under our existing credit agreement. If we borrow funds under that credit agreement and default on the terms of such credit agreement and the holders of our indebtedness accelerate the repayment of such indebtedness, there can be no assurance that we will have sufficient assets to repay our indebtedness.

Under our existing credit agreement, we are required to satisfy and maintain specified financial ratios. Our ability to meet those financial ratios can be affected by events beyond our control, and there can be no assurance that we will meet those ratios. A failure to comply with the covenants contained in the agreement could result in an event of default under such agreement, which, if not cured or waived, could have a material adverse effect on our business, financial condition, and profitability. In the event of any default under our existing credit agreement, the holders of our indebtedness thereunder:

- Will not be required to lend any additional amounts to us;

- Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable; or

- Could require us to apply all of our available cash to repay such indebtedness.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against the collateral granted to them to secure that indebtedness. If the indebtedness under our existing credit agreement were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

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.

A portion of our business relies on distribution agreements and relationships with various third parties and any adverse change in those relationships could result in a loss of revenue and harm that business.

We sell many of our products through distributors. Some of our distributors also sell our competitors' products, and, if they favor our competitors' products for any reason, they may fail to market our products as effectively or to devote resources necessary to provide effective sales, which would cause our results to suffer. The success of the arrangements with these third parties depends, in part, on the continued adherence to the terms of our agreements with them. Any disruption in these arrangements may adversely affect our financial condition and results of operations.

We utilize distributors for a portion of our sales, which subjects us to risks that could harm our business.

We have strategic relationships with a number of distributors for sales of our products. To the extent that we rely on distributors, our success will depend on the efforts of others over whom we may have little or no control. If these strategic relationships are terminated and not replaced, our revenues could be adversely affected. Also, we may be named as a defendant in litigation against our distributors related to sales of our products by them.

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 the production of 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 sales and operations are subject to the risks of doing business internationally.

A substantial portion of our sales occur outside the United States, and we are increasing our presence in international markets. Sales outside the United States subject us to many risks, such as:

- economic or political problems that disrupt foreign healthcare payment systems;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- protectionist laws and business practices that favor local competitors;
- the inability to obtain any necessary foreign regulatory or pricing approvals of products in a timely manner;
- changes in tax laws and tariffs;
- receivables may be more difficult to collect; and
- longer payment cycles.

Our operations and marketing practices are also subject to regulation and scrutiny by the governments of the other countries in which we operate. In addition, the Foreign Corrupt Practices Act, or FCPA, prohibits United States companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In certain countries, the healthcare professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. Additionally, we are

subject to other United States laws in our international operations. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and the imposition of civil or criminal sanctions.

We may lose revenues, market share and profits due to exchange rate fluctuations related to our international business.

Fluctuations in exchange rates may affect the prices that our international customers are willing to pay and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial condition and operations. Because payments from our international customers are received primarily in United States dollars, increases in the value of the United States dollar relative to foreign currencies could make our products less competitive or less affordable, and therefore adversely affect our sales in international markets.

We may experience fluctuations in our quarterly operating results.

We have historically experienced, and may continue to experience, fluctuations in our quarterly operating results. These fluctuations are due to a number of factors, many of which are outside our control, and may result in volatility of our stock price. Future operating results will depend on many factors, including:

- demand for our products;
- pricing decisions, and those of our competitors, including decisions to increase or decrease prices;
- regulatory approvals for our products;
- timing and levels of spending for R&D, sales and marketing;
- timing and market acceptance of new product introductions by us or our competitors;
- development or expansion of business infrastructure in new clinical and geographic markets;
- tax rates in the jurisdictions in which we operate;
- shipping delays or interruptions;
- customer credit holds;
- timing and recognition of certain R&D milestones and license fees; and
- ability to control our costs;

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;
- operating and stock price performance of other companies that investors deem comparable to the Company;
- perceptions in the marketplace regarding the Company and our competitors;
- new technology used, or services offered, by competitors;
- trading by funds with high-turnover practices or strategies;
- significant acquisitions or business combinations, strategic partnerships, joint ventures or capital commitments by or involving the Company or our competitors;

failure to integrate acquisitions or realize anticipated benefits from acquisitions;
changes in government regulations; and
geopolitical conditions such as acts or threats of terrorism or military conflicts.

Additionally, our public float is small which can result in large fluctuations in stock price during periods with increased selling or buying activity. General market fluctuations, industry factors and general economic and political conditions and events, such as economic slowdowns or recessions, interest rate changes or credit loss trends, could also cause our stock price to decrease regardless of operating results.

We continue to evaluate expansion through acquisitions of, and investments in, other companies or technologies, which may carry significant risks.

If we pursue acquisitions of, or investments in, other companies or technologies, we may:

- Use cash that we may need in the future to operate our business;

- Incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay;

- Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;

- Be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales;

- Be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target;

- Be unable to secure or retain the services of key employees related to the acquisition;

- Be unable to succeed in the marketplace with the acquisition; or

- Assume material unknown liabilities associated with the acquired business.

Any of the above risks, should they occur, could materially, adversely affect our revenues, financial condition, profitability, and cash flows, including the inability to recover our investment or cause a write down or write off of such investment, associated goodwill, or assets.

If we make divestitures, we could encounter difficulties that harm our business.

We may sell a business or product line. Any divestiture may result in significant write-offs, which could have a material adverse effect on our business, financial condition or results of operations. Divestitures could also involve additional risks, including difficulties in separation of operations, services and personnel, the diversion of management's attention from other operations and the potential loss of key personnel.

Political and economic conditions could materially and adversely affect our revenue and results of operations. Our business may be affected by a number of factors that are beyond our control such as general geopolitical economic and business conditions, conditions in the financial markets, and changes in the overall demand for our products. A severe or prolonged economic downturn could adversely affect our customers' financial condition and the levels of business activity of our customers. Uncertainty about current global political or economic conditions could cause businesses to postpone spending in response to tighter credit, negative financial news or declines in income or asset values, which could have a material negative effect on the demand for our products. There could be additional effects on our business from these economic developments including the insolvency of key suppliers or their inability to obtain credit, the inability of our customers to pay for or obtain credit to finance purchases of our products and increased pressure to reduce the prices of our products.

Turbulence in the United States and international markets and economies could have a material adverse impact on our business, operating results and financial condition. In addition, if we are unable to successfully anticipate changing economic and political conditions, we may be unable to effectively plan for and respond to those changes, which could materially adversely affect our business and results of operations.

Conflict minerals regulations may cause us to incur additional expenses and could limit the supply and increase the cost of metals used in manufacturing our products.

The SEC has adopted rules establishing disclosure and reporting requirements regarding the use of specified minerals, or conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. These rules require us to determine, disclose and report whether or not such conflict minerals originate from the Democratic Republic of the Congo or an adjoining country. These rules could affect our ability to source certain materials used in our products at competitive prices and could impact the availability of certain minerals used in the manufacture of our products. As there may be only a limited number of suppliers of “conflict free” minerals, we cannot be sure that we will be able to obtain necessary conflict free minerals in sufficient quantities or at competitive prices. Our customers may require that our products be free of conflict minerals, and our revenues and margins may be harmed if we are unable to procure conflict free minerals at a reasonable price, or at all, or are unable to pass through any increased costs associated with meeting these demands. Additionally, we may face reputational challenges with our customers if we are unable to verify sufficiently the origins of all minerals used in our products through our due diligence procedures. We may also face challenges with government regulators and our customers and suppliers if we are unable to verify sufficiently that the metals used in our products are conflict free. There may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as cost related to possible changes to products, processes, or sources of supply as a consequence of such verification and disclosure requirements.

If we fail to manage our exposure to market risk and credit risk successfully, our financial condition could be adversely impacted.

We have exposure to market risk and credit risk in our investment activities. The fair values of our investments vary from time to time depending on economic and market conditions. Fixed income securities expose us to interest rate risk as well as credit risk. Equity securities expose us to equity price risk. Interest rates are highly sensitive to many factors, including governmental monetary policies and domestic and international economic and political conditions. These and other factors also affect the equity securities owned by us. The outlook of our investment portfolio depends on the future direction of interest rates, fluctuations in the equity securities market and the amount of cash flows available for investment. Our investments may decline in value in future periods, which could have a material adverse effect on our financial condition.

Provisions in our governing documents and Delaware law may discourage or prevent a change of control, which could cause our stock price to decline and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a change in the ownership of the Company or a change in our management. We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15 percent or more of our outstanding common stock. Although a delay or prevention of a change of control transaction or of changes in our Board of Directors could be effective in improving stockholder value, they also carry a risk of causing the market price of our common stock to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We own three facilities comprising approximately 398,000 square feet, and the 97 acres on which they are situated, in Texas, Alabama and Florida. Administrative, engineering, manufacturing and warehouse operations are conducted at each facility, and our corporate headquarters are located at our Texas facility.

ITEM 3. LEGAL PROCEEDINGS.

We have no pending legal proceedings of the type described in Item 103 of Regulation S-K.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

Executive Officers of the Company

Name	Age	Title
Emile A Battat	78	Chairman of the Board of the Company and Chairman of the Board of Halkey-Roberts Corporation, or Halkey-Roberts, one of our subsidiaries
David A. Battat	47	President and Chief Executive Officer of the Company, President of Halkey-Roberts and Chairman of the Board of all other subsidiaries
Jeffery Strickland	58	Vice President and Chief Financial Officer, Secretary and Treasurer of the Company and Vice President or Secretary-Treasurer of all subsidiaries

Messrs. David Battat and Strickland currently serve as officers of the Company and all subsidiaries. Mr. Emile Battat currently serves as an officer of the Company and Halkey-Roberts. The officers of the Company and our subsidiaries are elected annually by the respective Boards of Directors of the Company and our subsidiaries at the first meeting of such Boards of Directors held after the annual meetings of stockholders of such entities. The next meetings of the stockholders of the Company and our subsidiaries are expected to be held in May 2017 and the Boards of Directors of the Company and our subsidiaries are expected to meet promptly thereafter. Accordingly, the terms of office of the current officers of the Company and our subsidiaries are anticipated to expire in May 2017.

There are no arrangements or understandings between any officer and any other person pursuant to which the officer was elected. The only family relationship between any of our executive officers or directors is that Mr. David Battat is the son of Mr. Emile Battat.

There have been no events under any bankruptcy act, no criminal proceedings and no judgments or injunctions material to the evaluation of the ability and integrity of any executive officers during the past ten years.

Brief Account of Business Experience During the Past Five Years

Mr. Emile Battat has been a director of the Company since 1987 and has served as Chairman of the Board of the Company since January 1998. He has served as Chairman of the Board of Halkey-Roberts since October 1998. He served as Chief Executive Officer of the Company and Chairman of the Board or President of all subsidiaries from October 1998 until May 2011.

Mr. David Battat has been President and Chief Executive Officer of the Company and Chairman of the Board of all subsidiaries with the exception of Halkey-Roberts, Atrion Leasing Company, LLC and AlaTenn Pipeline Company, LLC, since May 2011. He has been President of Halkey-Roberts since January 2006. He also serves as President of Atrion Leasing Company, LLC and AlaTenn Pipeline Company, LLC. He served as the Company's President and Chief Operating Officer from May 2007 until May 2011 and from February 2005 until December 2005 he served as Vice President - Business Development and General Counsel at Halkey-Roberts.

Mr. Strickland has served as Vice President and Chief Financial Officer, Secretary and Treasurer of the Company since February 1, 1997 and has served as a Vice President, Secretary or Treasurer of all the Company's subsidiaries since January 1997. Mr. Strickland was employed by the Company or our subsidiaries in various other positions from September 1983 through January 1997.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the NASDAQ Global Select Market (Symbol ATRI). As of February 21, 2017, we had 262 record holders, and approximately 4,500 beneficial owners, of our common stock. The high and low sales prices as reported by NASDAQ for each quarter of 2015 and 2016 are shown below.

Year Ended	December 31, 2015:	High	Low
First Quarter		\$355.62	\$315.01
Second Quarter		\$396.00	\$316.25
Third Quarter		\$428.85	\$365.00
Fourth Quarter		\$423.00	\$343.50

Year Ended	December 31, 2016:	High	Low
First Quarter		\$415.00	\$350.00
Second Quarter		\$442.50	\$385.00
Third Quarter		\$490.45	\$393.96
Fourth Quarter		\$522.05	\$418.00

We pay regular quarterly cash dividends on our common stock. We have increased our quarterly cash dividend payments in September of each of the past thirteen years. The quarterly dividend was increased to \$.75 in September of 2014, \$.90 in September 2015 and to \$1.05 in September 2016. We paid cash dividends totaling \$7.1 million to our stockholders in 2016.

During the year ended December 31, 2016, we did not sell any equity securities that were not registered under the Securities Act of 1933 and during the fourth quarter of 2016 we did not purchase any of our common stock.

The stock performance graph set forth in our 2016 Annual Report to Stockholders is incorporated by reference herein and is included in Exhibit 13.1 to this Form 10-K. However, the stock performance graph is not to be deemed to be "soliciting material" or to be "filed" with the SEC or subject to the liabilities of Section 18 under the Securities Exchange Act of 1934. In addition, the stock performance graph shall not be deemed incorporated by reference by any statement that incorporates this Form 10-K by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that we specifically incorporate this information by reference.

ITEM 6. SELECTED FINANCIAL DATA.

Selected Financial Data

(In thousands, except per share amounts)

	2016	2015	2014	2013	2012
Operating Results for the Year ended December 31,					
Revenues	\$143,487	\$145,733	\$140,762	\$131,993	\$119,062
Operating income	39,126	42,510	40,817	37,944	33,626
Net income	27,581	28,925	27,808	26,582	23,629
Depreciation and amortization	8,953	8,823	8,723	8,592	7,610
Per Share Data:					
Net income per diluted share	\$14.85	\$15.47	\$14.08	\$13.18	\$11.66
Cash dividends per common share	\$3.90	\$3.30	\$2.78	\$2.40	\$12.10
Average diluted shares outstanding	1,857	1,870	1,975	2,017	2,027
Financial Position at December 31,					
Total assets	\$182,593	\$164,336	\$171,514	\$172,066	\$155,810
Long-term debt	-	-	-	-	-

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Overview

We develop and manufacture products primarily for medical applications. We market components to other equipment manufacturers for incorporation in their products and sell finished devices to physicians, hospitals, clinics and other treatment centers. Our medical products primarily serve the fluid delivery, cardiovascular, and ophthalmology markets. Our other medical and non-medical products include valves and inflation devices used in marine and aviation safety products. In 2016, approximately 37 percent of our sales were outside the United States.

Our products are used in a wide variety of applications by numerous customers. We encounter competition in all of our markets and compete primarily on the basis of product quality, price, engineering, customer service and delivery time.

Our strategy is to provide a broad selection of products in the areas of our expertise. R&D efforts are focused on improving current products and developing highly-engineered products that meet customer needs and serve niche markets with meaningful sales potential. Proposed new products may be subject to regulatory clearance or approval prior to commercialization and the time period for introducing a new product to the marketplace can be unpredictable. We also focus on controlling costs by investing in modern manufacturing technologies and controlling purchasing processes. We have been successful in consistently generating cash from operations and have used that cash to reduce or eliminate indebtedness, to fund capital expenditures, to make investments, to repurchase stock and to pay dividends.

Our strategic objective is to further enhance our position in our served markets by:

- Focusing on customer needs;
- Expanding existing product lines and developing new products;
- Maintaining a culture of controlling cost; and
- Preserving and fostering a collaborative, entrepreneurial management structure.

For the year ended December 31, 2016, we reported revenues of \$143.5 million, operating income of \$39.1 million and net income of \$27.6 million.

Results of Operations

Our net income was \$27.6 million, or \$15.12 per basic and \$14.85 per diluted share, in 2016 compared to \$28.9 million, or \$15.67 per basic and \$15.47 per diluted share, in 2015 and net income of \$27.8 million, or \$14.20 per basic and \$14.08 per diluted share, in 2014. Revenues were \$143.5 million in 2016 compared with \$145.7 million in 2015 and \$140.8 million in 2014. Our 2016 revenues were negatively impacted by the strong U. S. dollar in our international markets and lower sales prices in certain markets. The four percent revenue increase in 2015 over 2014 was generally attributable to higher sales volumes.

Annual revenues by product lines were as follows (in thousands):

	2016	2015	2014
Fluid Delivery	\$60,889	\$60,630	\$57,905
Cardiovascular	47,064	46,463	43,001
Ophthalmology	15,427	18,253	19,329
Other	20,107	20,387	20,527
Total	\$143,487	\$145,733	\$140,762

Our cost of goods sold was \$75.9 million in 2016, \$74.8 million in 2015 and \$72.2 million in 2014. Increased compensation costs, depreciation and repair costs partially offset by reduced utilities and reduced supplies were the primary contributors to the increase in cost of goods sold in 2016 over 2015. Higher sales volume along with increased compensation costs, supplies and utilities partially offset by improved manufacturing efficiencies were the primary contributors to the increase in cost of goods sold in 2015 over 2014.

Gross profit in 2016 was \$67.6 million compared with \$71.0 million in 2015 and \$68.5 million in 2014. Our gross profit was 47 percent of revenues in 2016 and 49 percent of revenues in both 2015 and 2014. The decrease in gross profit percentage in 2016 from 2015 was primarily related to reduced sales, lower sales prices and increased manufacturing costs.

Operating expenses were \$28.5 million in both 2016 and 2015 and \$27.7 million in 2014. R&D expenses increased \$228,000 in 2016 as compared to 2015 primarily as a result of increased costs for supplies and travel partially offset by reduced outside services. R&D expenses consist primarily of salaries and other related expenses of our R&D personnel as well as costs associated with regulatory matters. In 2016, selling expenses increased \$568,000 as compared with 2015 primarily as a result of increased travel, outside services, compensation and trade shows. Selling expenses consist primarily of salaries, commissions and other related expenses for sales and marketing personnel, marketing, advertising and promotional expenses. General and administrative, or G&A, expenses decreased \$763,000

in 2016 as compared to 2015 primarily as a result of reduced compensation and benefits. G&A expenses consist primarily of salaries and other related expenses of administrative, executive and financial personnel and outside professional fees.

R&D expenses increased \$1.1 million in 2015 as compared to 2014 primarily as a result of increased costs for outside services and supplies. In 2015, selling expenses decreased \$167,000 as compared with 2014 primarily as a result of decreased promotional costs partially offset by increased commissions. G&A expenses decreased \$123,000 in 2015 as compared to 2014 primarily as a result of reduced outside services partially offset by increased amortization.

Our operating income for 2016 was \$39.1 million compared with \$42.5 million in 2015 and \$40.8 million in 2014. Operating income was 27 percent of revenues for 2016 and 29 percent of revenues for both 2015 and 2014. Decreases in 2016 gross profit was the major contributor to the decrease in operating income for 2016 as compared to the previous year. Increases in gross profit partially offset by increases in operating expenses described above were the major contributors to the operating income increase in 2015 as compared to the previous year. We expect modest growth in our operating income during 2017 as compared to 2016, reflecting the volatility of our ophthalmic sales as well as the significant impact of the strong U. S. dollar on sales to our international markets.

Interest income for 2016 was \$448,000, compared with \$771,000 in 2015 and \$1.2 million in 2014. Lower interest rates were the primary reason for the reductions in 2016. Reduced levels of investments and lower interest rates were the primary reasons for the reductions in 2015.

Other income (expense) in 2015 is primarily related to an impairment loss on one of our long-term corporate bonds which experienced a significant decline in market value due to a changed outlook for the issuer resulting from a major economic decline in its industry. In the fourth quarter of 2015, we determined, based upon disclosures by the issuer, that more likely than not we would be required to sell or exchange the bond before recovery of its amortized cost. Therefore, we recorded an impairment loss on this bond of \$2.4 million reducing the carrying value of the bond to its market value at December 31, 2015. In 2016 after the issuer declared bankruptcy, we sold this bond that was previously intended to be held to maturity. We recorded an additional net loss of \$311,000 on this bond in 2016 prior to and including its sale.

Income tax expense in 2016 totaled \$11.7 million, compared with \$11.9 million in 2015 and \$14.2 million in 2014. The effective tax rates for 2016, 2015 and 2014 were 29.8 percent, 29.2 percent and 33.8 percent, respectively. The effective tax rate for 2016 benefitted by \$687,000 from the early adoption of ASU 2016-09 regarding the accounting for employee share-based compensation. The adoption was on a prospective basis and therefore had no impact on prior years. The effective tax rate for 2015 benefitted from tax credits totaling \$2.3 million for our R&D expenditures. These credits reflected amounts for the full year 2015 following the extension of the R&D tax credit in December 2015. This amount also included an adjustment for recalculation of these tax credits from prior years resulting from a new regulation issued by the Treasury Department which favorably impacted the benefits provided to the Company under these rules. Benefits from R&D tax credits totaled \$1.1 million in 2016, \$2.3 million in 2015 and \$393,000 in 2014. Benefits from tax incentives for domestic production totaled \$1.2 million in 2016, \$1.4 million in 2015 and \$1.3 million in 2014. Benefits from changes in uncertain tax positions totaled \$120,000 in 2016, \$9,000 in 2015 and \$217,000 in 2014. We expect our effective tax rate for 2017 to be approximately 33.0 percent. Accounting for stock based awards could create volatility in our effective tax rate depending upon the amount of exercise or vesting activity from these activities.

Liquidity and Capital Resources

At December 31, 2016, we had a \$40.0 million revolving credit facility with a money center bank that could be utilized for the funding of operations and for major capital projects or acquisitions, subject to certain limitations and restrictions. Interest under the credit facility was assessed at 30-day, 60-day or 90-day LIBOR, as selected by us, plus one percent and was payable monthly. We had no outstanding borrowings under our credit facility at December 31, 2016 or 2015. The credit facility contained various restrictive covenants, none of which was expected to impact our liquidity or capital resources. At December 31, 2016, we were in compliance with all financial covenants.

On February 28, 2017 we replaced the revolving credit facility with a new \$75.0 million revolving credit facility with the same bank. The new credit facility has similar operational, covenant and collateral characteristics as the prior facility. Interest under the new credit facility is assessed at one, two, three or six-month LIBOR, as selected by us, plus .875 percent. The new credit facility allows us to make advances until February 28, 2022. We believe the bank providing the credit facility is highly-rated and that the entire \$75.0 million under the credit facility is currently available to us.

At December 31, 2016, we had a total of \$54.0 million in cash and cash equivalents, short-term investments and long-term investments, an increase of \$15.8 million from December 31, 2015. The principal contributor to this increase was operational results.

Cash flows provided by operations of \$37.4 million in 2016 were primarily comprised of net income plus the net effect of non-cash expenses. At December 31, 2016, we had working capital of \$85.0 million, including \$20.0 million in cash and cash equivalents and \$24.1 million in short-term investments. The \$16.1 million increase in working capital during 2016 was primarily related to increases in short-term investments. This increase was partially offset by decreases in cash and cash equivalents. The increase in short-term investments was primarily a result of operational results partially offset by purchases of treasury stock under our stock repurchase program, purchases of property, plant and equipment and payment of dividends. Working capital items consisted primarily of cash, accounts receivable, short-term investments, inventories and other current assets minus accounts payable and other current liabilities.

Capital expenditures for property, plant and equipment totaled \$10.6 million in 2016, compared with \$9.3 million in 2015 and \$12.7 million in 2014. These expenditures were primarily for machinery and equipment. We expect 2017 capital expenditures, primarily machinery and equipment, to be greater than the average of the levels expended during each of the past three years.

We paid cash dividends totaling \$7.1 million, \$6.1 million and \$5.4 million during 2016, 2015 and 2014, respectively. We expect to fund future dividend payments with cash flows from operations. We purchased treasury stock totaling \$1.3 million, \$30.7 million and \$23.6 million during 2016, 2015 and 2014, respectively.

The table below summarizes debt, lease and other contractual obligations outstanding at December 31, 2016:

Payments due by period

Contractual Obligations	Total	2017	2018 - 2019	2020 and thereafter
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(In thousands)

Purchase Obligations	\$11,863	\$11,643	\$220	\$-
Total	\$11,863	\$11,643	\$220	\$-

We believe our cash, cash equivalents, short-term investments and long-term investments, cash flows from operations and available borrowings of up to \$75.0 million under our credit facility will be sufficient to fund our cash requirements for at least the foreseeable future. We believe our strong financial position would allow us to access equity or debt financing should that be necessary. Additionally, we expect our cash and cash equivalents and investments, as a whole, will continue to increase in 2017.

Off-Balance Sheet Arrangements

We have no off-balance sheet financing arrangements.

Impact of Inflation

We experience the effects of inflation primarily in the prices we pay for labor, materials and services. Over the last three years, we have experienced the effects of moderate inflation in these costs. At times, we have been able to offset a portion of these increased costs by increasing the sales prices of our products. However, competitive pressures have not allowed for full recovery of these cost increases.

New Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-09, Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). This amendment simplifies the accounting for some aspects of share-based payment transactions, including the income tax treatment of excess tax benefits and deficiencies, forfeitures, classification of share-based awards as either equity or liabilities, and classification in the statement of cash flows for certain share-based transactions related to tax benefits and payments. Under this guidance all excess tax benefits (“windfalls”) and deficiencies (“shortfalls”) related to employee stock compensation are recognized within income tax expense. Under prior guidance windfalls were recognized in paid-in capital and shortfalls were only recognized to the extent they exceeded the pool of windfall tax benefits. ASU 2016-09 also requires companies to classify cash flows resulting from excess tax benefits and deficiencies from employee share-based payments as cash flows from operating activities. These items were previously included as cash flows from financing activities. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. The Company early adopted this guidance in the second quarter of 2016 effective January 1, 2016. The Company elected to account for forfeitures as they occur and to use a prospective transition method for the presentation of excess tax benefits on the statement of cash flows. As a result of the adoption, a tax benefit of \$687,000 was recorded in 2016 reflecting the excess tax benefits resulting from the vesting of restricted stock and restricted stock units. Prior to adoption, this amount would have been recorded as additional paid-in capital. This change could create future volatility in our effective tax rate depending upon the amount of exercise or vesting activity from our stock based awards. This adoption also impacted the computation of diluted shares outstanding for all 2016 reporting periods as we excluded the excess tax benefits from the assumed proceeds available to repurchase shares in the computation of our diluted earnings per share. The effect of this change on our diluted earnings per share was not significant. The excess tax benefit recorded in 2016 was included in our consolidated statements of cash flows as an operating activity rather than as a financing activity as was done in prior years. There were no restatements of cash flows from operating activities or cash flows from financing activities for the years 2015 and 2014 because we elected to adopt this change on a prospective basis. ASU 2016-09 also requires the presentation of employee taxes paid by the Company through the withholding of shares as a financing activity on the statement of cash flows, which is how we had previously reflected these items.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The main objective of this update is to enhance the reporting model for financial instruments in order to provide users of financial statements with more decision-useful information. The new guidance addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. This ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are currently evaluating the new guidance to determine the impact it may have on our consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes (ASU 2015-17) which requires that deferred tax liabilities and assets be classified as noncurrent on the balance sheet. The current

requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this guidance. ASU 2015-17 is effective for annual and interim periods beginning after December 15, 2016 but early application is permitted and the guidance may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company does not anticipate a material impact on its consolidated financial statements at the time of adoption of this new standard.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASU 2014-09). ASU 2014-09 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in United States Generally Accepted Accounting Principles when it becomes effective. In July 2015, the FASB voted to delay the effective date of ASU 2014-09 by one year, making it effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, with early adoption permitted as of the original effective date. ASU 2014-09 permits the use of either the retrospective or cumulative effect transition method. We plan on adopting the ASU in the first quarter of the year ended December 31, 2018. The Company has not yet selected a transition method and is currently evaluating the effect that our pending adoption of this guidance will have on our consolidated financial statements and related disclosures. We anticipate our assessment to be completed by December 31, 2017. Based on our existing evaluation process, we have not identified any revenue stream that would be materially impacted.

From time to time, new accounting standards updates applicable to us are issued by the FASB which we will adopt as of the specified effective date. Unless otherwise discussed, we believe the impact of recently issued standards updates that are not yet effective will not have a material impact on our consolidated financial statements upon adoption.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. In the preparation of these financial statements, we make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. We believe the following discussion addresses our most critical accounting policies and estimates, which are those that are most important to the portrayal of our financial condition and results and require management's most difficult, subjective and complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could differ significantly from those estimates under different assumptions and conditions.

From time to time, we accrue legal costs associated with certain litigation. In making determinations of likely outcomes of litigation matters, we consider the evaluation of legal counsel knowledgeable about each matter, case law and other case-specific issues. We believe these accruals are adequate to cover the legal fees and expenses associated with litigating these matters. However, the time and cost required to litigate these matters as well as the outcomes of the proceedings may vary significantly from what we have projected.

We maintain an allowance for doubtful accounts to reflect estimated losses resulting from the failure of customers to make required payments. On an ongoing basis, the collectability of accounts receivable is assessed based upon historical collection trends, current economic factors and the assessment of the collectability of specific accounts. We evaluate the collectability of specific accounts and determine when to grant credit to our customers using a combination of factors, including the age of the outstanding balances, evaluation of customers' current and past financial condition, recent payment history, current economic environment, and discussions with our personnel and with the customers directly. Accounts are written off when it is determined the receivable will not be collected. If circumstances change, our estimates of the collectability of amounts could be changed by a material amount.

We are required to estimate our provision for income taxes and uncertain tax positions in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure, including assessing the risks associated with tax audits, together with assessing temporary differences resulting from the different treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within the balance sheet. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is more likely than not, do not establish a valuation allowance. In the event that actual results differ from these estimates, the provision for income taxes could be materially impacted.

We assess the impairment of our long-lived identifiable assets, excluding goodwill which is tested for impairment as explained below, whenever events or changes in circumstances indicate that the carrying value may not be recoverable. This review is based upon projections of anticipated future cash flows. Although we believe that our estimates of future cash flows are reasonable, different assumptions regarding such cash flows or changes in our business plan could materially affect our evaluations. No such changes are anticipated at this time.

We assess goodwill for impairment pursuant to Accounting Standards Codification, or ASC, 350, Intangibles—Goodwill and Other, which requires that goodwill be assessed whenever events or changes in circumstances indicate that the carrying value may not be recoverable, or, at a minimum, on an annual basis by applying a qualitative assessment on goodwill impairment to determine whether it is necessary to perform the two-step goodwill impairment test.

We assess the total carrying value for each of our investments on a quarterly basis for changes in circumstance or the occurrence of events that suggest our investment may not be recoverable. If an investment is considered impaired, we must determine whether the impairment is other than temporary. If it is determined to be other than temporary, the impairment must be recognized in our financial statements.

During 2016, 2015 and 2014, none of our critical accounting policy estimates, with the exception of the previously mentioned impairment loss on one of our long-term corporate bonds, required significant adjustments. We did not note any material events or changes in circumstances indicating that the carrying value of long-lived assets were not recoverable.

Quantitative and Qualitative Disclosures About Market Risks

Foreign Exchange Risk

We are not exposed to material fluctuations in currency exchange rates because the payments from our international customers are received primarily in United States dollars.

However, fluctuations in exchange rates may affect the prices that our international customers are willing to pay and may put us at a price disadvantage compared to other customers. Increases in the value of the United States dollar relative to foreign currencies could make our products less competitive or less affordable and therefore adversely affect our sales in international markets.

Market Risk and Credit Risk

The Company's cash and cash equivalents are held in accounts with financial institutions that we believe are creditworthy. Certain of these accounts at times may exceed federally-insured limits. We have not experienced any credit losses in such accounts and do not believe we are exposed to any significant credit risk on these funds.

We have investments in taxable corporate bonds, certificates of deposit and equity securities. As a result, we are exposed to potential loss from market risks that may occur as a result of changes in interest rates, changes in credit

quality of the issuer and otherwise. These securities have a higher degree of credit or default risk and a greater exposure to credit risk and may be less liquid in times of economic weakness or market disruptions. We have also invested a portion of our available funds in common stock. The value of these securities fluctuates due to changes in the equity and credit markets along with other factors. In times of economic weakness, the market value and liquidity of these assets may decline and may negatively impact our financial condition.

Forward-looking Statements

Statements in this Management's Discussion and Analysis and elsewhere in this Form 10-K that are forward looking are based upon current expectations, and actual results or future events may differ materially. Therefore, the inclusion of such forward-looking information should not be regarded as a representation by us that our objectives or plans will be achieved. Such statements include, but are not limited to, our growth in operating income in 2017, our 2017 effective tax rate, the impact of the restrictive covenants in our credit facility on our liquidity and capital resources, our earnings in 2017, our 2017 capital expenditures, funding future dividend payments with cash flows from operations, availability of equity and debt financing, our ability to meet our cash requirements for the foreseeable future, the impact on our consolidated financial statement of recently issued accounting standards when we adopt those standards, and increases in 2017 in cash, cash equivalents and investments. Words such as "expects," "believes," "anticipates," "intends," "should," "plans," and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements contained herein involve numerous risks and uncertainties, and there are a number of factors that could cause actual results or future events to differ materially, including, but not limited to, the following: changing economic, market and business conditions; acts of war or terrorism; the effects of governmental regulation; the impact of competition and new technologies; slower-than-anticipated introduction of new products or implementation of marketing strategies; implementation of new manufacturing processes or implementation of new information systems; our ability to protect our intellectual property; changes in the prices of raw materials; changes in product mix; intellectual property and product liability claims and product recalls; the ability to attract and retain qualified personnel and the loss of any significant customers. In addition, assumptions relating to budgeting, marketing, product development and other management decisions are subjective in many respects and thus susceptible to interpretations and periodic review which may cause us to alter our marketing, capital expenditures or other budgets, which in turn may affect our results of operations and financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

See Management's Discussion and Analysis of Financial Condition and Results of Operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Atrion Corporation

We have audited the accompanying consolidated balance sheets of Atrion Corporation and subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of income, comprehensive income, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2016. Our audits of the basic consolidated financial statements included the financial statement schedule listed in the index appearing under Item 15, Exhibits and Financial Statement Schedules. These financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Atrion Corporation and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company’s internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 14, 2017 expressed an unqualified opinion.

/s/ Grant Thornton LLP

Dallas, Texas

March 14, 2017

ATRION CORPORATION
CONSOLIDATED STATEMENTS OF INCOME
For the year ended December 31, 2016, 2015 and 2014

	2016	2015	2014
	(In thousands, except per share amounts)		
Revenues	\$143,487	\$145,733	\$140,762
Cost of Goods Sold	75,857	74,752	72,244
Gross Profit	67,630	70,981	68,518
Operating Expenses:			
Selling	6,611	6,043	6,210
General and administrative	15,319	16,082	16,205
Research and development	6,574	6,346	5,286
	28,504	28,471	27,701
Operating Income	39,126	42,510	40,817
Interest Income	448	771	1,191
Other Income (Expense), net	(308)	(2,411)	13
Income before Provision for Income Taxes	39,266	40,870	42,021
Provision for Income Taxes	(11,685)	(11,945)	(14,213)
Net Income	\$27,581	\$28,925	\$27,808
Net Income Per Basic Share	\$15.12	\$15.67	\$14.20
Weighted Average Basic Shares Outstanding	1,824	1,846	1,958
Net Income Per Diluted Share	\$14.85	\$15.47	\$14.08
Weighted Average Diluted Shares Outstanding	1,857	1,870	1,975
Dividends Per Common Share	\$3.90	\$3.30	\$2.78

The accompanying notes are an integral part of these statements.

ATRION CORPORATION
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
 For the year ended December 31, 2016, 2015 and 2014

	2016	2015	2014
	(In thousands)		
Net Income	\$27,581	\$28,925	\$27,808
Other Comprehensive Income (Loss), net of tax:			
Unrealized Gain (Loss) on investments, net of tax benefit of \$408 in 2016, net of tax expense of \$283 in 2015 and net of tax benefit of \$131 in 2014	(757)	528	(245)
Comprehensive Income	\$26,824	\$29,453	\$27,563

The accompanying notes are an integral part of these statements.

ATRION CORPORATION
CONSOLIDATED BALANCE SHEETS
As of December 31, 2016 and 2015

Assets:	2016	2015
	(In thousands)	
Current Assets:		
Cash and cash equivalents	\$20,022	\$28,346
Short-term investments	24,080	44
Accounts receivable, net of allowance for doubtful accounts of \$71 and \$50 in 2016 and 2015, respectively	17,166	16,620
Inventories	29,015	29,771
Prepaid expenses and other current assets	3,181	2,934
Deferred income taxes	651	580
Total Current Assets	94,115	78,295
Long-term investments	9,945	9,866
Property, Plant and Equipment	160,413	150,807
Less accumulated depreciation and amortization	95,148	87,493
	65,265	63,314
Other Assets and Deferred Charges:		
Patents and licenses, net of accumulated amortization of \$11,911 and \$11,647 in 2016 and 2015, respectively	1,929	2,193
Goodwill	9,730	9,730
Other	1,609	938
	13,268	12,861
Total Assets	\$182,593	\$164,336

The accompanying notes are an integral part of these statements.

ATRION CORPORATION
CONSOLIDATED BALANCE SHEETS
As of December 31, 2016 and 2015

Liabilities and Stockholders' Equity:	2016	2015
	(In thousands)	
Current Liabilities:		
Accounts payable	\$4,028	\$3,926
Accrued liabilities	4,635	5,061
Accrued income and other taxes	410	329
Total Current Liabilities	9,073	9,316
Line of credit	--	--
Other Liabilities and Deferred Credits:		
Deferred income taxes	9,404	9,989
Other	1,128	933
	10,532	10,922
Total Liabilities	19,605	20,238
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, par value \$.10 per share, authorized 10,000 shares, issued 3,420 shares	342	342
Additional paid-in capital	37,448	35,945
Accumulated other comprehensive income (loss)	(474)	283
Retained earnings	239,946	219,516
Treasury shares, 1,596 shares in both 2016 and 2015, at cost	(114,274)	(111,988)
Total Stockholders' Equity	162,988	144,098
Total Liabilities and Stockholders' Equity	\$182,593	\$164,336

The accompanying notes are an integral part of these statements.

ATRION CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the year ended December 31, 2016, 2015 and 2014

	2016	2015	2014
	(In thousands)		
Cash Flows From Operating Activities:			
Net income	\$27,581	\$28,925	\$27,808
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	8,953	8,823	8,723
Deferred income taxes	(247)	(1,431)	2
Stock-based compensation	1,566	1,841	2,209
Impairment of investment	345	2,413	--
Net change in accrued interest, premiums, and discounts on investments	(37)	100	340
Other	--	17	29
	38,161	40,688	39,111
Changes in operating assets and liabilities:			
Accounts receivable	(546)	371	(2,798)
Inventories	756	(1,749)	(1,756)
Prepaid expenses and other current assets	(247)	1,786	(3,117)
Other non-current assets	(673)	(103)	(22)
Accounts payable and accrued liabilities	(324)	(492)	968
Accrued income and other taxes	81	(128)	(396)
Other non-current liabilities	195	54	(767)
	37,403	40,427	31,223
Cash Flows From Investing Activities:			
Property, plant and equipment additions	(10,639)	(9,323)	(12,671)
Purchase of investments	(30,799)	(168)	(33,115)
Proceeds from sale of investments	210	--	--
Proceeds from maturities of investments	5,000	13,400	35,975
	(36,228)	3,909	(9,811)
Cash Flows From Financing Activities:			
Shares tendered for employees' withholding taxes on stock-based compensation	(1,112)	(154)	(376)
Tax benefit related to stock-based compensation	--	156	168
Purchase of treasury stock	(1,276)	(30,698)	(23,556)
Dividends paid	(7,111)	(6,069)	(5,432)
	(9,499)	(36,765)	(29,196)
Net change in cash and cash equivalent	(8,324)	7,571	(7,784)
Cash and cash equivalents, beginning of year	28,346	20,775	28,559

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Cash and cash equivalents, end of year	\$20,022	\$28,346	\$20,775
Cash paid for:			
Income taxes, net of refunds	\$10,750	\$12,900	\$17,475

The accompanying notes are an integral part of these statements.

ATRION CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the year ended December 31, 2016, 2015 and 2014
(In thousands)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Other Retained Earnings	Total
	Shares Outstanding	Amount	Shares	Amount				
Balances, January 1, 2014	1,985	\$342	1,435	\$(57,302)	\$31,592	\$-	\$174,362	\$148,994
Net income							27,808	27,808
Other comprehensive income						(245)		(245)
Tax benefit from stock-based compensation					168			168
Stock-based compensation transactions	3		(3)	61	2,180			2,241
Shares surrendered in stock transactions	(1)		1	(376)				(376)
Purchase of treasury stock	(74)		74	(23,556)				(23,556)
Dividends							(5,464)	(5,464)
Balances, December 31, 2014	1,913	342	1,507	(81,173)	33,940	(245)	196,706	149,570
Net income							28,925	28,925
Other comprehensive income						528		528
Tax benefit from stock-based compensation					156			156
Stock-based compensation transactions	1		(1)	37	1,849			1,886
Shares surrendered in stock transactions	(1)		1	(154)				(154)

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Purchase of treasury stock	(89)		89	(30,698)				(30,698)
Dividends							(6,115)	(6,115)
Balances, December 31, 2015	1,824	342	1,596	(111,988)	35,945	283	219,516	144,098
Net income							27,581	27,581
Other comprehensive loss								