STERIS CORP
Form 10-K
May 28, 2010
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United States Securities and Exchange Commission

Washington, D. C. 20549

FORM 10-K

x Annual Report Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

For the fiscal year ended March 31, 2010

OR

¨ 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 1-14643

STERIS Corporation

(Exact name of registrant as specified in its charter)

Ohio		34-1482024
(State or other jurisdiction of incorporation or organization)		(IRS Employer Identification No.)
5960 Heisley Road, Mentor, Ohio	44060-1834 (Zip Code)	440-354-2600 (Registrant s telephone number including area code)
(Address of principal executive offices)		

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

Title of each class	Name of Exchange on Which Registered
Common Shares, without par value	New York Stock Exchange

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE 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 x No ¨

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

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

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 (§ 229.405 of this chapter) 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 the Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark 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.

Large Accelerated Filer x	Accelerated Filer ¨
Non-Accelerated Filer ¨	Smaller Reporting Company ¨

(Do not check if a smaller reporting company)
Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the voting stock held by non-affiliates of the Registrant, computed by reference to the closing price of such stock as of September 30, 2009: $1,624,956,942

The number of Common Shares outstanding as of May 14, 2010: 59,260,580

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2010 Annual Meeting Part III

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PART I

Throughout this Annual Report, STERIS Corporation and its subsidiaries together are called STERIS, the Company, we, us, or our, unless otherwise noted. References in this Annual Report to a particular year or year-end mean our fiscal year, which ends on March 31. For example, fiscal year 2010 ended on March 31, 2010.

ITEM 1. BUSINESS

INTRODUCTION

STERIS Corporation is a leading provider of infection prevention and surgical products and services, focused primarily on the critical markets of healthcare, pharmaceutical and research. Our mission is to provide a healthier today and a safer tomorrow through knowledgeable people and innovative infection prevention, decontamination and health science technologies, products and services. We offer our Customers a unique mix of capital products, such as sterilizers and surgical tables; consumable products, such as detergents and skin care products; and services, including equipment installation and maintenance; and the bulk sterilization of single-use medical devices.

We were founded as Innovative Medical Technologies in Ohio in 1985, and renamed STERIS Corporation in 1987. However, some of our businesses that have been acquired and integrated into STERIS, notably American Sterilizer Company, have much longer operating histories. With global headquarters in Mentor, Ohio, we have approximately 5,000 employees worldwide and operate in more than 60 countries. We have a direct sales force of approximately 475 and a service organization of approximately 1,050 who work diligently to ensure that we are meeting the increasingly complex needs of our Customers.

We operate in three reportable business segments: Healthcare, Life Sciences, and STERIS Isomedix Services. Corporate and other, which is presented separately, contains the Defense and Industrial business unit plus costs that are associated with being a publicly traded company and certain other corporate costs. These costs include executive office costs, Board of Directors compensation, shareholder services and investor relations, external audit fees, and legacy pension and post-retirement benefit costs from our former Erie, Pennsylvania manufacturing operation.

Healthcare is our largest segment, contributing 71.0% of fiscal 2010 revenues and 74.4% of our fiscal 2010 operating income. In this segment, we serve Customers anywhere surgical procedures take place by providing support directly to the operating room, as well as to the sterile processing department where instruments are reprocessed between surgeries. Our products and services enable Customers to reduce costs and improve outcomes in these critical environments.

Our second largest segment, Life Sciences, contributed 17.3% of fiscal 2010 revenues and 15.2% of our fiscal 2010 operating income. In this segment, we primarily serve pharmaceutical manufacturers and research organizations by providing decontamination and sterilization technologies, products and services that help ensure the safety of the products they produce.

STERIS Isomedix Services (Isomedix) performs sterilization services on a contract basis through 20 facilities in North America, where we sterilize single-use medical devices and other products in bulk prior to their delivery to the end user. This segment contributed 11.2% of fiscal 2010 revenues and 15.3% of our fiscal 2010 operating income.

Corporate and other contributed 0.5% of fiscal 2010 revenues and an operating loss of $9.9 million to our fiscal 2010 operating income.

Many factors are driving an increased awareness of the importance of infection control throughout the world. In the United States, hospitals in more than 25 states are now required to report infection rates, providing patients with information that can help shape their decisions about where to receive care. On a more global basis, emerging threats such as H1N1 virus, Avian Bird Flu, and the rise in drug-resistant strains of bacterial diseases have gained prominence in the news, raising awareness of the need for enhanced safety on a worldwide basis. We are uniquely positioned to help address these concerns in traditional and non-traditional settings with our combination of capital equipment, consumables and services.

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INFORMATION RELATED TO BUSINESS SEGMENTS

Our chief operating decision maker is our President and Chief Executive Officer (CEO). The CEO is responsible for performance assessment and resource allocation. The CEO regularly receives discrete financial information about each reportable segment. The CEO uses this information to assess performance and allocate resources. The accounting policies of the reportable segments are the same as those described in note 1 to the Consolidated Financial Statements titled, Nature of Operations and Summary of Significant Accounting Policies, of this Annual Report. Segment performance information for fiscal years 2010, 2009, and 2008 is presented in note 12 to our Consolidated Financial Statements titled, Business Segment Information and in Item 7 titled, Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A), of this Annual Report.

HEALTHCARE SEGMENT

Description of Business. Our Healthcare segment manufactures and sells infrastructure capital equipment, accessory, consumable, and service solutions to healthcare providers, including acute care hospitals and surgery centers. These solutions aid our Customers in improving the safety, quality, productivity, and utility consumption of their surgical, sterile processing, gastrointestinal, and emergency environments.

Products Offered. These capital equipment, accessory and consumable solutions include:

- Sterilizers, including low temperature liquid, vaporized hydrogen peroxide, and Ethylene Oxide (EO) technologies, as well as steam sterilization, that allow Customers to meet rigorous sterility assurance standards and regulations and assist in the safe and effective re-use of medical equipment and devices.

- Automated washer/disinfector systems that clean and disinfect a wide range of items from rolling instrument carts and other large healthcare equipment to small surgical instruments.

- General and specialty surgical tables, surgical and examination lights, equipment management systems, operating room storage cabinets, warming cabinets, scrub sinks, and other complementary products and accessories for use in hospitals and other ambulatory surgery sites.

- Cleaning chemistries and sterility assurance products used in instrument cleaning and decontamination systems.

- Cleansing products, including hard surface disinfectants and skin care and hand hygiene solutions, for use by care-givers and patients.

- Connectivity solutions such as operating room (OR) integration and instrument management that allow for high quality transfer of information and images throughout the hospital and between hospitals throughout the world. These solutions aid in improving the productivity and quality of Customers inpatient and outpatient surgical departments and centralized sterile processing functions.

Significant brand names for these products include SYSTEM 1®, SYSTEM 1E , Amsco®, Hamo®, Reliance®, Cmax®, Harmony®, Kindest Kare®, Alcare®, Verify®, and Cal Stat®.

Services Offered. Our Healthcare segment provides various preventive maintenance programs and repair services to support the effective operation of capital equipment over its lifetime. We offer these corrective and preventive service solutions to both Customers who have internal clinical/biomedical engineering departments and Customers who rely on us to meet these needs. Field service personnel install, maintain, upgrade, repair, and troubleshoot equipment throughout the world. We also offer comprehensive sterilization management consulting services allowing healthcare facilities to achieve safety, quality, and productivity improvements in the end-to-end perioperative loop that flows between and among surgical suites and the central sterile department. We utilize remote equipment monitoring technology to improve Customers equipment uptime. Additionally, our Healthcare segment provides other support services such as construction and facility planning, engineering support, device testing, Customer education, hand hygiene process excellence, asset management/planning, and the sale of replacement parts.

Customer Concentration. Our Healthcare segment manufactures and sells capital equipment, consumables, and services to Customers in the United States and throughout the rest of the world. For the year ended March 31, 2010, the segment generated revenues in the United States and internationally of $666.7 million and $225.8 million, respectively. For the year ended March 31, 2010, no Customer represented more than 10% of the Healthcare segment s total revenues and the loss of any single Customer is not expected to have a material impact on the segment s results of operations or cash flows.

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Competition. We compete with a number of large companies that have significant product portfolios and global reach, as well as a number of small companies with very limited product offerings and operations in one or a limited number of countries. On a product basis, competitors include Getinge, Johnson & Johnson, 3M, Belimed, Berchtold, Cantel Medical, Cardinal, Ecolab, Hill-Rom, Kimberly-Clark, Skytron, and Stryker.

LIFE SCIENCES SEGMENT

Description of Business. Our Life Sciences segment manufactures and sells a broad range of capital equipment, formulated cleaning chemistries, and service solutions to pharmaceutical companies, and private and public research facilities around the globe.

Products Offered. These capital equipment and formulated cleaning chemistries include:

- Sterilizers used in the manufacture of pharmaceuticals and biopharmaceuticals as well as sterilizers for equipment and instruments used in research studies, mitigating the risk of contamination.

- Washer/disinfectors that decontaminate various large and small materials and components used in pharmaceutical and industrial manufacturing processes and in research labs, such as glassware, vessels, equipment parts, drums, hoses, and animal cages.

- High-purity water equipment, which generates water for injection and pure steam.

- Vaporized Hydrogen Peroxide (VHP®) generators used to decontaminate many high value spaces, from small isolators to large pharmaceutical processing and laboratory animal rooms.

- Consumables and supplies that are used to prevent the spread of infectious diseases and to monitor sterilization and decontamination processes, including products used to clean instruments, decontaminate systems, and disinfect hard surfaces. We also manufacture and sell skin care and hand hygiene solutions for use in high risk and routine applications.

Significant brand names for these products include Amsco®, Reliance®, Finn-Aqua®, Kindest Kare®, Alcare®, Verify®, and Cal Stat®.

Services Offered. Our Life Sciences segment offers various preventive maintenance programs and repair services to support the effective operation of capital equipment over its lifetime. Field service personnel install, maintain, upgrade, repair, and troubleshoot equipment throughout the world. We utilize remote equipment monitoring technology to improve Customers equipment uptime. We also offer consulting services and technical support to architecture and engineering firms and laboratory planners. Our services deliver expertise in decontamination and infection control technologies and processes to end users. Our service personnel also provide higher-end validation services in support of our pharmaceutical Customers.

Customer Concentration. Our Life Sciences segment manufactures and sells capital equipment, consumables, and services to Customers in the United States and throughout the rest of the world. For the year ended March 31, 2010, the segment generated revenues in the United States and internationally of $143.6 million and $74.6 million, respectively. For the year ended March 31, 2010, no Customer represented more than 10% of the Life Sciences segment s total revenues and the loss of any single Customer is not expected to have a material impact on the segment s results of operations or cash flows.

Competition. Our Life Sciences segment operates in highly regulated environments where the most intense competition results from technological innovations, product performance, convenience and ease of use, and overall cost-effectiveness. In recent years, our pharmaceutical Customer base has also undergone consolidation and reduced capital spending, resulting in more intense competition. We compete for pharmaceutical, research and industrial Customers with a number of large companies that have significant product portfolios and global reach, as well as a number of small companies with very limited product offerings and operations in one or a limited number of countries. Competitors include Belimed, Ecolab, Fedegari, Getinge, MECO, Stilmas, and Techniplast.

STERIS ISOMEDIX SERVICES SEGMENT

Description of Business. Our Isomedix segment operates through a network of 20 facilities located in North America. We sell a comprehensive array of contract sterilization services using Gamma Irradiation (Gamma) and Ethylene Oxide (EO) technologies. We provide sterilization and microbial reduction services to companies that supply products to the healthcare, industrial, and consumer product industries.

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Services Offered. We use Gamma and EO technologies to sterilize a wide range of products. Gamma, using radioisotope (cobalt-60), is an irradiation process. EO uses a gaseous process to sterilize medical products. Greater than 90 percent of the industrial contract sterilization market uses Gamma or EO. Our locations are in major population centers and core distribution corridors throughout North America, primarily in the Northeast, Midwest, Southwest, and southern California. We adapt to increasing imports and changes in manufacturing points-of-origin by monitoring trends in supply chain management. Demographics partially drive this segment s growth. The aging population and rising life expectancy increase the demand for medical procedures, which increases the consumption of single use medical devices and surgical kits. Our technical services group supports Customers in all phases of the sterilization design process, including product development, materials testing, and sterility validation.

Customer Concentration. Our Isomedix segment operates in North America. For the year ended March 31, 2010, the segment generated revenues in the United States and Canada of $133.9 million and $7.0 million, respectively. The segment s services are offered to Customers throughout the footprint of our network. For the year ended March 31, 2010, no Customer represented more than 10% of the segment s revenues. Because of a largely fixed cost structure, the loss of a single Customer could have a material impact on the segment s results of operations or cash flows but would not be expected to have a material impact on STERIS.

Competition. Isomedix operates in a highly regulated industry and competes in North America with Sterigenics International, Inc., other smaller contract sterilization companies and manufacturers that sterilize products in-house.

INFORMATION WITH RESPECT TO OUR BUSINESS IN GENERAL

Recent Events. During the third quarter of fiscal 2009, we announced a joint venture with VTS Medical Systems Inc. designed to bring the latest high-definition video, touch-screen integration, and communication technology into hospital operating rooms. We have invested $5.7 million in this joint venture.

Sources and Availability of Raw Materials. We purchase raw materials, sub-assemblies, components, and other supplies needed in our operations from numerous suppliers in the United States and internationally. The principal raw materials and supplies used in our operations include stainless steel, organic chemicals, fuel, and plastic components. These raw materials and supplies are available from several suppliers and in sufficient quantities that we do not expect any significant sourcing problems in fiscal 2011. We have longer-term supply contracts for certain materials, such as radioisotope (cobalt-60) used by the Isomedix segment, for which there are few suppliers.

We have recently experienced some volatility in prices for raw materials such as chemicals and various metals, which are important to our operations. While cost and availability are unpredictable, we have not experienced any difficulty, and do not expect significant difficulty in obtaining the raw materials, sub-assemblies, components, or other supplies we need for our operations.

Intellectual Property. We protect our technology and products by, among other means, obtaining United States and foreign patents. There can be no assurance, however, that any patent will provide adequate protection for the technology, system, product, service, or process it covers. In addition, the process of obtaining and protecting patents can be long and expensive. We also rely upon trade secrets, technical know-how, and continuing technological innovation to develop and maintain our competitive position.

As of March 31, 2010, we held 283 United States patents and 578 foreign patents and had 83 United States patents and 348 foreign patents pending. Patents for individual products extend for varying periods according to the date of filing or grant and legal term of patents in various countries where a patent is obtained. The actual protection a patent provides, which can vary from country to country, depends upon the type of patent, the scope of its coverage, and the availability of legal remedies in each country.

Our products are sold around the world under various brand names and trademarks. We consider our brand names and trademarks to be valuable in the marketing of our products. As of March 31, 2010, we had a total of 968 trademark registrations in the United States and in various foreign countries.

Research and Development. Research and development is an important factor in our long-term strategy. For the years ended March 31, 2010, 2009, and 2008, research and development expenses were $34.0 million, $32.8 million, and $36.9 million, respectively. We incurred these expenses primarily for the research and development of commercial products.

New products were a key element of our success in a tough economic environment. In the operating room, the Harmony® LED Lighting and Visualization System brought surgical lighting, high definition images and surgeon comfort to a new level. Our V-PRO 1 low temperature sterilizer and the

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Reliance Vision Single-chamber Washer improve efficiencies in the sterile processing department by increasing the number and volume of instruments that can be reprocessed compared with older units. Another recent introduction is the 5085 SRT Surgical Table, the first sliding, rotating and transporting table to be released in the United States as a single-driver transport device for the operating suite. The table is designed to enhance both patient and staff safety by reducing the transfer risk before and after surgery. Finally, the recent introduction of the SYSTEM 1E , our next generation liquid chemical sterilant processing system, provides an alternative for existing SYSTEM 1® Customers.

Quality Assurance. We manufacture, assemble, and package products in the United States and throughout the world. Each of our production facilities are dedicated to particular processes and products. Our success depends upon Customer confidence in the quality of our production process and the integrity of the data that supports our product safety and effectiveness. We have implemented quality assurance procedures to support the quality and integrity of scientific information and production processes. All of our manufacturing and contract sterilization facilities throughout the world are ISO9001 or ISO13485 certified.

Government Regulation. Our business is subject to various degrees of governmental regulation in the countries in which we operate. In the United States, the United States Food and Drug Administration (FDA), the United States Environmental Protection Agency (EPA), the United States Nuclear Regulatory Commission (NRC), and other governmental authorities regulate the development, manufacture, sale, and distribution of our products and services. Our international operations also are subject to a significant amount of government regulation, including country-specific rules and regulations and U.S. regulations applicable to our international operations. Government regulations include detailed inspection of, and controls over, research and development, clinical investigations, product approvals and manufacturing, marketing and promotion, sampling, distribution, record-keeping, storage, and disposal practices.

Compliance with applicable regulations is a significant expense for us. Past, current or future regulations, their interpretation, or their application could have a material adverse impact on our operations. Also, additional governmental regulation may be passed that could prevent, delay, revoke, or result in the rejection of regulatory clearance of our products. We cannot predict the effect on our operations resulting from current or future governmental regulation or the interpretation or application of these regulations.

If we fail to comply with any applicable regulatory requirements, sanctions could be imposed on us. For more information about the risks we face regarding regulatory requirements, see Part I, Item 1A of this Annual Report titled, Risk Factors, We are subject to extensive regulatory requirements .

We have received warning letters, paid civil penalties, conducted product recalls, and been subject to other regulatory sanctions, and most recently agreed with the FDA to the terms of a consent decree approved by the Federal District Court for the Northern District of Ohio concerning our SYSTEM 1® processing system. See Part I, Item 1A of this Annual Report titled, Risk Factors, We may be adversely affected by product liability claims or other legal actions or regulatory or compliance matters, including the Warning Letter and Consent Decree, Risk Factors, Our business may be adversely affected as a result of the U.S. Food and Drug Administration notice to healthcare administrators and device manufacturers, and related matters, and Risk Factors, Compliance with the Consent Decree may be more costly and burdensome than anticipated. and see also Part I, Item 3, Legal Proceedings , for further information on SYSTEM 1® and other regulatory issues and their potential impact. We believe that we are currently compliant in all material respects with applicable regulatory requirements. However, we cannot assure you that future or current regulatory, governmental, or private action will not have a material adverse affect on us or on our performance, results, or financial condition.

Environmental Matters. We are subject to various laws and governmental regulations concerning environmental matters and employee safety and health in the United States and in other countries. We have made, and continue to make, significant investments to comply with these laws and regulations. We cannot predict the future capital expenditures or operating costs required to comply with environmental laws and regulations. We believe that we are currently compliant with applicable environmental, health, and safety requirements in all material respects. However, we cannot assure you that future or current regulatory, governmental, or private action will not have a material adverse affect on our performance, results, or financial condition. You should also read Part I, Item 3, Legal Proceedings for further information.

In the future, if a loss contingency related to environmental matters, employee safety, health or conditional asset retirement obligations is significantly greater than the current estimated amount, we would record a liability for the obligation and it may result in a material impact on net income for the annual or interim period during which the liability is recorded. The investigation and remediation of environmental obligations generally occur over an extended period of time, and therefore we do not know if these events would have a material adverse affect on our financial condition, liquidity, or cash flow, nor can we assure you that such liabilities would not have a material adverse affect on our performance, results, or financial condition.

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Competition. The markets in which we operate are highly competitive and generally highly regulated. Competition is intense in all of our business segments and includes many large and small competitors. Brand, design, quality, safety, ease of use, serviceability, price, product features, warranty, delivery, service, and technical support are important competitive factors to us. We expect to face increased competition in the future as new infection prevention, sterile processing, contamination control, and surgical support products and services enter the market. We believe many organizations are working with a variety of technologies and sterilizing agents. Also, a number of companies have developed disposable medical instruments and other devices designed to address the risk of contamination.

We believe that our long-term competitive position depends on our success in discovering, developing, and marketing innovative, cost-effective products and services. We devote significant resources to research and development efforts and we believe STERIS is positioned as a global competitor in the search for technological innovations. In addition to research and development, we invest in quality control, Customer programs, distribution systems, technical services, and other information services.

We cannot assure you that new products or services we provide or develop in the future will be more commercially successful than those provided or developed by our competitors. In addition, some of our existing or potential competitors may have greater resources than us. Therefore, a competitor may succeed in developing and commercializing products more rapidly than we do. Competition, as it relates to our business segments and product categories, is discussed in more detail in the section above titled, Information Related to Business Segments.

Employees. As of March 31, 2010, we had approximately 5,000 employees throughout the world. We believe we have good relations with our employees.

Methods of Distribution. As of March 31, 2010, we employed approximately 1,150 direct field sales and service representatives within the United States and approximately 375 in international locations. Sales and service activities are supported by a staff of regionally based clinical specialists, system planners, corporate account managers, and in-house Customer service and field support departments. We also contract with distributors in select markets.

Customer training is important to our business. We provide a variety of courses at Customer locations, at our training and education centers throughout the world, and over the internet. Our training programs help Customers understand the science, technology, and operation of our products. Many of our operator training programs are approved by professional certifying organizations and offer continuing education credits to eligible course participants.

Seasonality. Our financial results have been, from time to time, subject to seasonal patterns. We cannot assure you that these patterns will continue.

International Operations. We have a large opportunity to expand internationally, as we currently only serve a small portion of the world that could benefit from our products. Through our subsidiaries, we operate in various international locations within the same business segments as in the United States. For the year ended March 31, 2010, international revenues were $308.1 million, or 24.5%, of our total revenues and international cost of revenues was 29.9% of our total cost of revenues. Revenues from Europe, Canada, and other international locations were 51.2%, 23.1%, and 25.7%, respectively, of our total international revenues for the year ended March 31, 2010.

Also see note 12 to our Consolidated Financial Statements titled, Business Segment Information, and Item 7, MD&A , for a geographic presentation of our revenues for the three years ended March 31, 2010.

We conduct manufacturing in the United States, Canada, Mexico, and various European countries. There are, in varying degrees, a number of inherent risks to our international operations. We describe some of these risks in Part I, Item 1A of this Annual Report titled, Risk Factors, We conduct manufacturing, sales, and distribution operations on a worldwide basis .

Fluctuations in the exchange rate of the U.S. dollar relative to the currencies of foreign countries in which we operate can also increase or decrease our reported net assets and results of operations. During fiscal 2010, revenues were favorably impacted by $0.6 million, or 0.1%, and income before taxes was unfavorably impacted by $1.8 million, or 0.9%, as a result of foreign currency movements relative to the U.S. dollar. We cannot predict future changes in foreign currency exchange rates or the effect they will have on our operations.

Backlog. We define backlog as the amount of unfilled capital equipment purchase orders at a point in time. At March 31, 2010, we had a backlog of $169.6 million. Of this amount, $127.8 million and $41.8 million related to our Healthcare and Life Sciences segments, respectively. At March 31, 2009,

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we had backlog orders of $165.0 million. Of this amount $119.8 million and $45.2 million related to our Healthcare and Life Sciences segments, respectively. A significant portion of the backlog orders in both years were expected to ship in the next fiscal year.

Availability of Securities and Exchange Commission Filings. We make available free of charge on or 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 we electronically file such material with, or furnish such material to the Securities and Exchange Commission (SEC). You may access these documents on the Investor Relations page of our website at http://www.steris-ir.com. You may also obtain copies of these documents by visiting the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549 or by accessing the SEC s website at http://www.sec.gov. You may obtain information on the Public Reference Room by calling the SEC at 1-800-SEC-0330.

We also make available free of charge on our website our Corporate Governance Guidelines, our Director Code of Ethics, and our Code of Business Conduct, as well as the Charters of the Audit and Financial Policy Committee, the Compensation and Corporate Governance Committee, and the Compliance Committee of the Company s Board of Directors.

ITEM 1A. RISK FACTORS

This item describes certain risk factors that could affect our business, financial condition and results of operations. You should consider these risk factors when evaluating the forward-looking statements contained in this Annual Report on Form 10-K, because our actual results and financial condition might differ materially from those projected in the forward-looking statements should these risks occur. We face other risks besides those highlighted below. These other risks include additional uncertainties not presently known to us or that we currently believe are immaterial, but may ultimately have a significant impact. Should any of these risks, described below or otherwise, actually occur, our business, financial condition, performance, prospects, value, or results of operations could be negatively affected.

The current economic climate may adversely affect us.

Adverse economic cycles or conditions and Customer, regulatory or government response thereto, could affect our results of operations. There can be no assurance when these cycles or conditions will occur or when they will begin to improve after they occur. There also can be no assurance as to the strength or length of any recovery from a business downturn or recession. United States and worldwide financial and business conditions are uncertain, and the recent severe recession has had a significant adverse effect on U.S. and global economies, which also has negatively impacted access to capital markets and investment activity within key geographic and market segments served.

Credit and liquidity problems may continue to make it difficult for some businesses to access credit markets and obtain financing and may cause some businesses to continue to curtail spending to conserve cash in anticipation of persistent business slowdowns and liquidity needs. If our Customers have difficulty financing their purchases due to tight credit markets or related factors or because of other operational problems they may be experiencing or otherwise decide to curtail their purchases, our business could be adversely affected. Our exposure to bad debt losses could also increase if Customers are unable to pay for products previously ordered and delivered. Also, continuing tightness of credit in financial markets may limit the ability of our lenders to satisfy their obligations to us to provide funding and letters of credit or the ability of our insurers to respond to a claim under an insurance policy.

In addition, economic conditions and market volatility have impacted the investment portfolio of our defined benefit pension plans, including a significant decline in fair value since March 31, 2008. Because the values of these pension plan investments have and will fluctuate in response to changing market conditions, the amount of gains or losses that will be recognized in subsequent periods and the impact on the funded status of the plans and future minimum required contributions, if any, could have a material adverse effect on our liquidity, value, financial conditions or result of operations.

Our businesses are highly competitive, and if we fail to compete successfully, our revenues and results of operations may be hurt.

We operate in a highly competitive global environment. Our businesses compete with other broad line manufacturers, as well as many smaller businesses specializing in particular products or services, primarily on the basis of brand, design, quality, safety, ease of use, serviceability, price, product features, warranty, delivery, service, and technical support. We face increased competition from new infection prevention, sterile processing, contamination control, and surgical support, cleaning consumables, contract sterilization, and other products and services entering the market. Competitors and potential competitors also are attempting to develop alternate technologies and sterilizing agents, as well as disposable medical instruments and other devices

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designed to address the risk of contamination. If our products, services, support, distribution and/or cost structure do not enable us to compete successfully, our business, performance, prospects, value, financial condition, and results of operations may be adversely affected.

Our success depends, in part, on our ability to design, manufacture, distribute, and achieve market acceptance of new products with higher functionality and lower costs.

Many of our Customers operate businesses characterized by technological change, product innovation and evolving industry standards. Price is a key consideration in their purchasing decisions. To successfully compete, we must continue to design, develop, and improve innovative products. We also must achieve market acceptance of and effectively distribute those products, and reduce production costs. Our business, performance, prospects, value, financial condition, and results of operations might be adversely affected if our competitors product development capabilities become more effective, if they introduce new or improved products that displace our products or gain market acceptance, or if they begin to produce and sell products at lower prices.

If our cost reduction and restructuring efforts are ineffective, our profitability may be hurt or our business otherwise might be adversely affected.

We have undertaken various cost reduction and restructuring activities, including the restructuring activities announced in January 2006 and, in particular, the transfer of our Erie, Pennsylvania manufacturing operations to Mexico. In the fourth quarter of fiscal 2008, we announced cost reduction activities intended to generate annualized operating expense savings of approximately $30 million through direct and indirect overhead expense reductions and other savings, and, in the third quarter of fiscal 2009, we announced cost reduction activities primarily related to our international operations, which were intended to generate annualized cost savings of approximately $20 million to be realized over the next several years. Most recently we announced a restructuring plan primarily related to the consolidation of our European Healthcare manufacturing operations into two central locations within Europe and the transfer of the remaining operations in our Erie, Pennsylvania facility to our U.S. headquarters in Mentor, Ohio and recorded pre-tax expenses totaling $6.3 million related to these actions in the fourth quarter of fiscal 2010. These efforts may not produce the full efficiencies and cost reduction benefits we expect or efficiencies and benefits might be delayed or not realized. Implementation costs also might exceed expectations and further cost reduction measures might become necessary, resulting in additional future charges. If these cost reduction and restructuring efforts are not properly implemented or are unsuccessful, we might experience business disruptions or our business otherwise might be adversely affected.

Decreased availability or increased costs of raw materials or energy supplies or other supplies might increase our production costs or limit our production capabilities.

We purchase raw materials, fabricated and other components, and energy supplies from a variety of suppliers. Key materials include stainless steel, organic chemicals, fuel, cobalt, and plastic components. The availability and prices of raw materials and energy supplies are subject to volatility and are influenced by worldwide economic conditions, speculative action, world supply and demand balances, inventory levels, availability of substitute materials, currency exchange rates, anticipated or perceived shortages, and other factors. In some situations, we may be able to temporarily limit price increases or support availability through supply agreements. Otherwise, raw material prices and availability are subject to numerous factors outside of our control, including those described above. Increases in prices or decreases in availability of raw materials and oil and gas might impair our procurement of necessary materials or our product production, or might increase production costs. In addition, energy costs impact our transportation and distribution and other supply and sales costs. Also, a number of our key materials and components are single-sourced or have a limited number of suppliers, such as cobalt used in our Isomedix operations. Shortages in supply, regulatory requirements, or increases in the price of raw materials, components and energy supplies may adversely impact our business, performance, prospects, value, financial condition, or results of operations.

Our operations, and those of our suppliers, are subject to a variety of business continuity hazards and risks, any of which could interrupt production or operations or otherwise adversely affect our performance, results, or value.

Business continuity hazards and other risks include:

- explosions, fires, inclement weather, and other disasters;
- utility or other mechanical failures;

unscheduled downtime;

labor difficulties;

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inability to obtain or maintain any required licenses or permits;

disruption of communications;

data security, preservation and redundancy disruptions;

inability to hire or retain key management or employees; and

disruption of supply or distribution.

The occurrence of any of these or other events might disrupt or shut down operations, or otherwise adversely impact the production or profitability of a particular facility, or our operations as a whole. Certain casualties also might cause personal injury and loss of life, or severe damage to or destruction of property and equipment, and for casualties occurring at our facilities, result in liability claims against us. Although we maintain property and casualty insurance and liability and similar insurance of the types and in the amounts that we believe are customary for our industries, our insurance coverages have limits and we are not fully insured against all potential hazards and risks incident to our business. Should any of the hazards or risks occur, or should our insurance coverage be inadequate or unavailable, our business, performance, prospects, value, financial condition, and results of operations might be adversely affected, both during and after the event.

We conduct manufacturing, sales and distribution operations on a worldwide basis and are subject to a variety of risks associated with doing business outside the United States.

We maintain significant international operations, including operations in Canada, Europe, Asia and Latin America. As a result, we are subject to a number of risks and complications associated with international manufacturing, sales, services, and other operations. These include:

risks associated with foreign currency exchange rate fluctuations;

difficulties in enforcing agreements and collecting receivables through some foreign legal systems;

foreign Customers with longer payment cycles than Customers in the United States;

tax rates in certain foreign countries that exceed those in the United States, and foreign earnings subject to withholding requirements;

tax laws that restrict our ability to use tax credits, offset gains, or repatriate funds;

tariffs, exchange controls or other trade restrictions including transfer pricing restrictions when products produced in one country are sold to an affiliated entity in another country;

general economic and political conditions in countries where we operate or where end users of our products are situated;

- difficulties associated with managing a large organization spread throughout various countries;

- difficulties in enforcing intellectual property rights or weaker intellectual property right protections in some countries; and

- difficulties associated with compliance with a variety of laws and regulations governing international trade, including the Foreign Corrupt Practices Act.

Implementation and achievement of international growth objectives also may be impeded by political, social, and economic uncertainties or unrest in countries in which we conduct operations or market or distribute our products. In addition, compliance with multiple, and potentially conflicting, international laws and regulations, import and export limitations, anti-corruption laws, and exchange controls may be difficult, burdensome or expensive.

For example, we are subject to compliance with various laws and regulations, including the Foreign Corrupt Practices Act and similar anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. While our employees and agents are required to comply with these laws, we cannot assure you that our internal policies and procedures will always protect us from violations of these laws, despite our commitment to legal compliance and corporate ethics. The occurrence or allegation of these types of risks may adversely affect our business, performance, prospects, value, financial condition, and results of operations.

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Consolidations among our healthcare and pharmaceutical Customers may result in a loss of Customers or more significant pricing pressures.

A number of our Customers have consolidated. These consolidations are due in part to healthcare cost reduction measures initiated by competitive pressures as well as legislators, regulators and third-party payors. In an effort to attract Customers, some of our competitors have also reduced production costs and lowered prices. This has resulted in greater pricing pressures on us and in some cases loss of Customers. Additional consolidations could result in a loss of Customers or more significant pricing pressures. Additional consolidations and pricing pressures may occur as a result of recent healthcare legislation and economic conditions. A loss of Customers or more significant pricing pressure could have an adverse effect on our business, performance, prospects, value, financial conditions or results of operations.

Changes in healthcare laws or government and other third-party payor reimbursement levels to healthcare providers, or failure to meet healthcare reimbursement or other requirements might negatively impact our business.

We sell many of our products to hospitals and other healthcare providers and pharmaceutical manufacturers. Many of these Customers are subject to or supported by government programs or receive reimbursement for services from third-party payors, such as government programs, including Medicare and Medicaid, private insurance plans, and managed care programs. In the United States, many of these programs set maximum reimbursement levels for these healthcare services and can have complex reimbursement requirements. In addition, the recent healthcare legislation imposes additional taxes on device manufacturers, and the overall impact of the legislation is uncertain. Outside the United States, reimbursement systems vary significantly by country. However, government-managed healthcare systems control reimbursement for healthcare services in many foreign countries. In these countries, as well as in the United States, public budgetary constraints may significantly impact the ability of hospitals, pharmaceutical manufacturers, and other Customers supported by such systems to purchase our products. If government or other third-party payors deny or change coverage, reduce their current levels of reimbursement for healthcare services, or otherwise implement measures to regulate pricing or contain costs or if our costs increase more rapidly than reimbursement level or permissible pricing increases or we do not satisfy the standards or requirements for reimbursement, our revenues or profitability may suffer and our business, performance, value, prospects, financial condition or results of operations may be adversely affected.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, recently enacted in the U.S., contains provisions that could have a material impact on our business. Among other provisions, this legislation imposes an excise tax on medical devices manufactured or offered for sale in the United States beginning in 2013. Various health care reform proposals have also emerged at the state level, and we are unable to predict which, if any, of those proposals will be enacted. However, the ultimate effect of health care reform legislation or any future legislation or regulation could have a material adverse affect on our business, performance, value, prospects, financial condition, or results of operation.

We are subject to extensive regulatory requirements and must receive and maintain regulatory clearance or approval for many products and operations. Failure to receive or maintain, or delays in receiving, clearance or approvals may hurt our revenues, profitability, financial condition, or value.

Our operations are subject to extensive regulation in both the United States and in other countries where we do business. In the U.S, our products and services are regulated by the FDA and other regulatory authorities. In many foreign countries, sales of our products are subject to extensive regulations that may or may not be comparable to those of the FDA. In Europe, our products are regulated primarily by country and community regulations of those countries within the European Economic Area and must conform to the requirements of those authorities.

Government regulation applies to nearly all aspects of testing, manufacturing, safety, labeling, storing, recordkeeping, reporting, promoting, distributing, and importing or exporting of medical devices, products, and services. In general, unless an exemption applies, a sterilization, decontamination or medical device or product or service must receive regulatory approval or clearance before it can be marketed or sold. Modifications to existing products or the marketing of new uses for existing products also may require regulatory approvals, approval supplements or clearances. If we are unable to obtain any required approvals, approval supplements or clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and sale, or recall or restrict the use of such modified device, pay fines, or take other action until such time as appropriate clearance or approval is obtained.

Regulatory agencies may refuse to grant approval or clearance, or review and disagree with our interpretation of approvals or clearances, or with our decision that regulatory approval is not required or has been maintained. Regulatory submissions may require the provision of additional data and may be

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time consuming and costly, and their outcome is uncertain. Regulatory agencies may also change policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay approval or clearance of devices, or could impact our ability to market a previously cleared, approved, or unregulated device. Our failure to comply with the regulatory requirements of the FDA or other applicable regulatory requirements in the United States or elsewhere might subject us to administratively or judicially imposed sanctions. These sanctions include, among others, warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and/or promotion. The failure to receive or maintain, or delays in the receipt of, relevant United States or international qualifications could have a material adverse affect on our business, performance, prospects, value, financial condition or results of operations.

Refer also for further information to the Risk Factor below titled, We may be adversely affected by product liability claims or other legal actions or regulatory or compliance matters, including the Warning Letter and Consent Decree and the Risk Factor below titled Our business may be adversely affected as a result of the U.S. Food and Drug Administration notices to healthcare administrators, and related matters , and the Risk Factor below titled Compliance with the Consent Decree may be more costly and burdensome than anticipated. and to Part I, Item 3, Legal Proceedings .

Our products are subject to recalls and restrictions, even after receiving United States or foreign regulatory clearance or approval.

Ongoing medical device reporting regulations require that we report to appropriate governmental authorities in the United States and/or other countries when our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to a death or serious injury if the malfunction were to recur. Governmental authorities can require product recalls or impose restrictions for product design, manufacturing, labeling, clearance, or other issues. For the same reasons, we may voluntarily elect to recall or restrict the use of a product. Any recall or restriction could divert managerial and financial resources and might harm our reputation among our Customers and other healthcare professionals who use or recommend the products. Product recalls, restrictions, suspensions, re-labeling, or other change might have a material adverse affect on our business, performance, prospects, value, financial condition, or results of operations.

We may be adversely affected by product liability claims or other legal actions or regulatory or compliance matters, including the Warning Letter and Consent Decree.

We face an inherent business risk of exposure to product liability claims and other legal and regulatory actions. A significant increase in the number, severity, amount, or scope of these claims and actions may result in substantial costs and harm our reputation or otherwise adversely affect product sales and our business. Product liability claims and other legal and regulatory actions may also distract management from other business responsibilities.

We are also subject to a variety of other types of claims, proceedings, investigations, and litigation initiated by government agencies or third parties and other potential risks and liabilities. These include compliance matters, product regulation or safety, taxes, employee benefit plans, employment discrimination, health and safety, environmental, antitrust, customs, import/export, government contract compliance, financial controls or reporting, intellectual property, allegations of misrepresentation, false claims or false statements, commercial claims, claims regarding promotion of our products and services, or other similar or different matters. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs, restrictions on product use or sales, or otherwise injure our business.

Administratively or judicially imposed or agreed sanctions might include warning letters, fines, civil penalties, criminal penalties, loss of tax benefits, injunctions, product seizure, recalls, suspensions or restrictions, re-labeling, detention, and/or debarment. We also might be required to take actions such as payment of substantial amounts, or revision of financial statements, or to take the following types of actions with respect to our products, services, or business:

- redesign, re-label, restrict, or recall products;
- cease manufacturing and selling products;