SRI SURGICAL EXPRESS INC Form 10-K March 07, 2011 **Table of Contents**

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2010

or

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

For the transition period from

Commission file number: 001-34953

SRI/SURGICAL EXPRESS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: SRI SURGICAL EXPRESS INC - Form 10-K

Florida (State or other jurisdiction of incorporation or organization)

12425 Race Track Road Tampa, Florida (Address of principal executive offices) 59-3252632 (I.R.S. Employer Identification No.)

> **33626** (Zip Code)

Name of each exchange on which registered

The NASDAQ Stock Market LLC

The NASDAQ Stock Market LLC

Registrant s telephone number, including area code:

(813) 891-9550

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

Title of each class Common Stock, par value \$.001

Rights to Purchase Series A

Junior Participating Preferred

Stock

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 "No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 shorter period that the registrant was required to submit and post such files). Yes "No"

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 definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Edgar Filing: SRI SURGICAL EXPRESS INC - Form 10-K

Large accelerated filer " Accelerated filer " Non-accelerated filer " Small reporting company x

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 common stock held by non-affiliates of the registrant, based on the closing sale price of the common stock on June 30, 2010, as reported on the NASDAQ Global Market, was approximately \$16,334,000. For purposes of this determination, the registrant excluded shares of common stock known to be held by officers, directors, and 10% shareholders, because those persons might be deemed affiliates. This determination of affiliate status is not necessarily conclusive for other purposes.

The registrant had 6,485,978 shares of common stock outstanding as of February 25, 2011.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated.

Portions of the Proxy Statement for the registrant s 2011 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

SRI/SURGICAL EXPRESS, INC.

FORM 10-K

YEAR ENDED DECEMBER 31, 2010

Section		Page
PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	8
Item 1B.	Unresolved Staff Comments	10
Item 2.	Properties	10
Item 3.	Legal Proceedings	11
PART II		
Item 5.	Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity	
	Securities	12
Item 6.	Selected Financial Data	13
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	23
Item 8.	Financial Statements and Supplementary Data	24
Item 9.	Changes in and Disagreements With Accountants On Accounting and Financial Disclosure	48
Item 9A.	Controls and Procedures	48
Item 9B.	Other Information	48
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	50
Item 11.	Executive Compensation	50
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	50
Item 13.	Certain Relationships and Related Transactions, and Director Independence	50
Item 14.	Principal Accountant Fees and Services	50
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	51
SIGNATURES		55

PART I

Item 1. Business

This Annual Report on Form 10-K, other documents that we publicly disseminate, and oral statements that are made on our behalf might contain both statements of historical fact and forward-looking statements. These forward-looking statements do not guarantee future performance, and our actual results could differ materially from those indicated by the forward-looking statements. Examples of forward-looking statements include: (i) projections of our revenue, earnings, capital structure, and other financial items, (ii) statements of our plans and objectives, (iii) statements of our expected future economic performance, and (iv) assumptions underlying our statements regarding SRI/Surgical Express, Inc. and our business. Among the factors that could cause or contribute to differences are those discussed below under the section entitled Risk Factors . We do not undertake to update our forward-looking statements.

The Company

SRI Surgical Express, Inc. (SRI Surgical, the Company, we, us or our) is a supplier and reprocessor of reusable surgical linen and instrumentation. Our tagline, Environmental Solutions, Delivered Daily[®] reflects SRI Surgical s commitment to provide our healthcare clients with high quality reusable products, and the opportunity to reduce waste in the Operating Room (OR). Reducing waste in the OR begins with purchasing the appropriate reusable products that meet the needs of the clinical user and minimize the use of disposable products in the surgical environment. We believe our reusable surgical gowns, drapes, table covers, towels, and instruments provide the opportunity for waste avoidance and environmental sustainability in the surgical arena. We start with products that have been manufactured specifically to be reusable and to be reprocessed. Our products are not single use products that are reprocessed for economic benefit.

We have ten reprocessing facilities that are regionally located across the United States. These facilities adhere to the standards of the United States Food and Drug Administration (FDA) regulated medical device manufacturing environment. We guarantee that our surgical linens will always be 100% inspected, repaired when necessary, and sterilized properly. No other company in the industry provides this service for their reusable surgical products.

SRI Surgical has a history of commitment to the environment. In addition to providing our healthcare clients with environmentally friendly surgical linens and instruments, we have a demonstrated commitment to waste reduction in the communities that we serve, both as a healthcare service provider and a corporate citizen. SRI Surgical is a Charter Member of Practice Greenhealth, a networking organization for institutions in the healthcare community that are committed to sustainable, eco-friendly practices. In 2010, we were awarded Practice Greenhealth s Champion for Change Award for the second year in a row. This award recognizes organizations that demonstrate successful accomplishments in greening their organization as well as assisting healthcare clients in improving their environmental performance. SRI Surgical is also an EPA WasteWise Partner. The EPA WasteWise program targets the reduction of waste in the business environment. In 2009, we received the EPA s Design for the EPA s Climate Leaders, a consortium of small business leaders that are measuring their greenhouse gas emissions and setting and achieving goals to reduce them, and the EPA s SmartWay Transport Partnership program, which identifies products and services that reduce transportation-related emissions. In 2009, we received the EPA s Transport Award, which recognizes organizations that have made outstanding contributions to reducing climate change emissions and other air pollutants.

We also offer expert daily instrument reprocessing at both our facilities (off-site) and our customers facilities (on-site). This innovative offering provides customized, high quality surgical instrument sets on a per-procedure fee basis. Sets processed at our FDA-regulated facilities have a consistently high level of quality built into every set. After each use, our highly trained instrument-processing technicians follow a thorough cleaning and inspection process to help ensure that the instruments are in proper working order. We ensure

instrument availability and functionality, which offers our customers an opportunity to achieve high efficiency levels. In addition, we manage the instrumentation and supply chain of hospitals, surgery centers and operating rooms and their central sterilization facilities. In this setting, by using our expertise in implementing and managing FDA-regulated instrument processing facilities, we can deliver desired quality and performance levels that our customers seek.

Our integrated closed-loop process starts with daily delivery of reusable and disposable surgical supplies and instruments to healthcare providers. After use, we pick up the reusable surgical linens, basins, and instruments used in surgery and return them to our processing facilities. Used products arriving at our processing facilities are sorted, cleaned, inspected, packaged, sterilized, and shipped back to the healthcare providers. This closed-loop system eliminates the need for healthcare providers to stock on-hand inventory and greatly simplifies our customers surgical supply chain process. This process also allows healthcare providers to reduce medical waste disposal costs and increase the quality of products used by their staff and physicians. Additionally, with our daily just-in-time delivery model, our customers working capital requirements are favorably affected by their ability to carry less on-hand inventory of disposable products to support their surgical procedures.

We are well positioned to help healthcare providers reduce operating costs while improving the quality of care, so that they can respond to pressures created by the continued growth of managed care and reductions in procedure reimbursement. To reduce operating costs, we offer comprehensive procedure bundling solutions and outsourcing of surgical instrument processing. By providing surgical instruments of superior functionality and bundling solutions that allow surgical staff to shift focus from supply management to patient management, we help our customers significantly reduce operating and capital costs, increase revenue, and improve the quality of patient care.

During 2010 we entered into a three-year reusable surgical products agreement with KP Select, Inc. the purchasing agent for the Kaiser Permanente Healthcare System (Kaiser Permanente). This agreement was effective March 1, 2010 and gives us the ability to contract with any Kaiser Permanente hospital that designates KP Select as its purchasing agent. Kaiser Permanente is a 48-hospital system located in the states of California, Ohio, Maryland, Oregon, Washington, and other states. This agreement allows us to assist Kaiser Permanente with its environmental awareness initiative, but does not commit Kaiser Permanente or its member hospitals to purchase any minimum quantity of products or services from us. As of December 31, 2010, a total of 13 Kaiser Permanente hospitals were under contract under this agreement.

We recently entered into a three-year reusable surgical products agreement with Catholic Healthcare West. This agreement, which is effective January 1, 2011, gives us the ability to contract with any Catholic Healthcare West hospital that chooses to use our products. Catholic Healthcare West is a 40-hospital system located in the states of California, Arizona, and Nevada. This agreement allows us to assist Catholic Healthcare West with its environmental awareness initiative, but does not commit Catholic Healthcare West or its member hospitals to purchase any minimum quantity of products or services from us.

On November 26, 2008, we entered into a five-year Supply and Co-Marketing Agreement (the Co-Marketing Agreement) with Cardinal Health 200, Inc. (Cardinal or Cardinal Health), an affiliate of Cardinal Health, Inc. Under the terms of the Co-Marketing Agreement, Cardinal is our exclusive supplier of disposable surgical packs, and provides for a new product offering, the Hybrid Preference Pack , in which we combine our reusable surgical packs with Cardinal Health s disposable surgical packs. We share profits from sales of the Hybrid Preference Pack based on an agreed-upon margin split. This new product couples the convenience of disposables with the waste-wise benefits of our reusable products. This environmentally friendly solution reduces packaging and medical waste, saves water and energy consumption, reduces chemical usage and provides just-in-time delivery and retrieval. In addition, the Co-Marketing Agreement appoints Cardinal the exclusive provider of our complete line of more than 400 disposable surgical kits.

The Co-Marketing Agreement allows us to focus on our strengths: reusable surgical products, instrumentation and management of central sterilization and supply chain activities. The Co-Marketing

Agreement gives our environmentally friendly solution greater reach and visibility throughout the healthcare market. It brings together the strengths of two organizations that are market leaders in their segments for a more efficient and effective delivery of healthcare solutions.

On February 3, 2010, SRI Surgical and Cardinal entered into an Amended and Restated Supply and Co-Marketing Agreement (the Amended and Restated Supply Agreement). We previously received disposable component products included in the Hybrid Preference Packs from Cardinal Health on a consignment basis and shared profits with Cardinal based on an agreed margin split from revenue actually received from sales of Hybrid Preference Packs. The Amended and Restated Supply Agreement provides, among other things, that we purchase from Cardinal Health the disposable component products included in the Hybrid Preference Packs instead of receiving them on a consignment basis. In addition, under the Amended and Restated Supply Agreement, we pay Cardinal Health for such components a fixed percentage of the price we charge our customers for such components. This amount payable to Cardinal Health under the Amended and Restated Supply Agreement is reconciled quarterly to an agreed margin split based on revenue actually billed to Hybrid Preference Pack customers. The term of the Co-Marketing Agreement remains unchanged.

Effective June 2009, we entered into a four-year national brand distribution agreement with Cardinal Health s medical and surgical supply chain business. This agreement appoints Cardinal a non-exclusive, authorized distributor of our products. Cardinal Health includes our products on its master merchandise file and categorizes our products as a national brand. This agreement expands upon our current supply and co-marketing relationship with Cardinal Health s Presource surgical kitting business and gives us access to a national distribution network that currently serves the Federal government as well as other healthcare providers not currently using our reusable product offering.

We maintain an internet website located at <u>www.srisurgical.com</u>, which makes available, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports filed or furnished to the Securities and Exchange Commission (SEC). This information is made available as soon as reasonably practicable after we electronically file it with or furnish it to the SEC. Our Code of Ethics and Corporate Compliance Policies are also posted on our website. Information contained on our website, whether currently posted or posted in the future, is not part of this document or any documents incorporated by reference in this document.

Market

Since our introduction in the early 1990 s of reusable surgical gowns and drapes of exceptional quality for healthcare providers use, we have added custom disposable surgical packs to our product offering. Since the early 2000 s, we have supplied and reprocessed high quality surgical instruments for our customers. Our ability to offer reusable surgical gowns and drapes, custom disposable surgical packs and reusable surgical instruments enables us to supply most everything our customers require for surgical procedures.

According to the American Hospital Association and Verispan, a healthcare consulting organization, the United States healthcare market includes approximately 5,800 acute care hospitals and 6,000 surgery centers.

The following market conditions and strategies provide continuing opportunities for us:

Continued Pressure on Providers to Contain Costs and Improve Profitability. With the growth of managed care and a decrease in surgical service reimbursements, economic constraints require providers to continually increase their efficiency. To assist them in reducing their costs of operation, we offer products and services that help our customers eliminate inventory, reduce staff, capital expenditures and medical waste, and improve their overall supply chain efficiency.

Increased Outsourcing of Provider Functions That Do Not Involve Patient Care. Providers with significant staff, capital and space dedicated to in-house processing of reusable surgical products and surgical instruments are outsourcing these functions to qualified outsourcing providers. By enabling our customers to outsource non-core functions, we allow them to increasingly focus on patient care.

Concern Regarding the Transmission of Infectious Diseases. The healthcare industry must manage the risk of infectious disease. These concerns increase the need for surgical barrier fabrics that protect surgeons and surgical staff from blood borne pathogens. Industry response to these concerns led to the promulgation of the Association for the Advancement of Medical Instrumentation (AAMI) PB70 standard, which establishes levels I, II, III and IV indicating increasing barrier protection. Using this standard as a guideline, the FDA mandates that any company marketing its products according to the AAMI PB70 standard submit a 510(k) prior to marketing the various levels. Our line of *GreenGown* gowns helps to prevent liquid and viral strike-through in critical areas during surgical procedures and is cleared by the FDA for appropriate barrier labeling. Additionally, our FDA-regulated processes for decontamination and reprocessing of surgical instrumentation enable healthcare providers to better manage the risk of transmission of infectious diseases.

Concern Regarding the Handling and Disposal of Biohazardous Waste. The disposal of large volumes of infectious and hazardous waste generated by the healthcare industry continues to attract increased public awareness. Healthcare providers are under pressure to reduce their generation of biohazardous waste because of restrictions on incineration and limited access to dump sites. This market dynamic offers an advantage to companies that provide outsourced reusable alternatives to disposable surgical products.

Leverage Infrastructure with Increased Penetration in Markets. Our existing facilities combined currently have significant available capacity to access more of the national market. Distribution expansion, if prudently executed, could provide opportunity for business growth with incremental capital investment.

Activities by Hospitals, Hospital Groups and the Federal Government to Become Better Stewards of the Environment and to Create Facilities that Practice Environmental Sustainability. Increasing governmental pressure and public awareness are driving healthcare institutions, including government run institutions, to develop plans and implement policies to control their impact upon the communities in which they reside. The realization that the healthcare industry ranks second only to the food industry in waste generation is fueling increased interest in methods to control and eliminate waste through more aggressive efforts to reduce, reuse, and recycle. Through its Green Procurement Strategy (DoD GPP), the U.S. Department of Defense is implementing an agency-wide green procurement program designed to reduce resource consumption and solid waste generation. Green procurement includes, among other things, the acquisition of environmentally preferable products and services. Our reusable products are ideally suited to enable these institutions to respond aggressively by reducing waste through reuse of their surgical linens and basin sets. Additionally, our agreement with Cardinal s distribution group allows us to reach more healthcare facilities that currently do not utilize our reusable product offering, including healthcare facilities operated by the U.S. Government. As part of that agreement, our products are listed on the Department of Defense s distribution and pricing agreement (more commonly known as the DAPA list). Having our products included on the DAPA list, through the agreement with Cardinal, allows government operated hospitals the ability to purchase our products.

Customers

As of December 31, 2010, we served a customer base of approximately 450 hospitals and surgery centers located throughout the United States. Our strategy is to further expand on the supply chain management needs of our current customer base, and grow our customer base by focusing on hospitals and surgery centers that are surgical procedure intensive.

We maintain short-term agreements to supply several group purchasing organizations (GPOs), including Novation, LLC, HealthTrust Purchasing Group, L.P., MedAssets, Inc. (including the acquisition of The Broadlane Group, effective November 16, 2010), Intermountain Health Services, Inc., Premier Purchasing

Partners, L.P., and Hospital Corporation of America. Novation is the supply company for 25,000 Voluntary Hospitals of America, Inc. and University Health System Consortium organizations. HealthTrust Purchasing is a GPO representing over 1,400 not for profit hospitals and for profit acute care facilities. MedAssets is the largest independent healthcare purchasing group in the United States. Intermountain Health Services, Inc. is a healthcare purchasing group that services 23 hospitals. Premier has more than 2,400 member hospitals and 72,000 other healthcare sites. Hospital Corporation of America represents 164 hospitals and over 100 freestanding surgery centers in 20 states. Through these relationships our products and services are potentially available to the vast majority of providers and surgery centers in our service areas. We continue to pursue additional GPO contracts that would allow us opportunities to further penetrate the healthcare market.

Products

Our principal reusable surgical products are *GreenGown*[®] surgical gowns. We also offer reusable towels, surgical drapes, and stainless steel basin sets as part of our reusable surgical product line. We provide these products in a variety of configurations for a provider s specific needs. A major benefit of our reusable system is reduced medical waste because of the elimination of disposable, single-use products.

Our *GreenGown*[®] liquid resistant Level III and liquid proof Level IV gowns are made of some of the most technologically advanced materials available, providing users with a highly breathable gown and excellent protection. This added protection is critical to healthcare providers given the continuing concerns of doctors, staff, and regulatory authorities regarding transmission of blood borne pathogens, including HIV and hepatitis viruses. The Level III and Level IV gowns are ideal for procedures with high bodily fluid volume and of longer duration. Our Standard Level II gown is made from an advanced micro-fiber polyester liquid resistant fabric, ensuring a high degree of comfort to the user, and is a cost-effective alternative to higher priced gowns. We believe this gown is ideal for procedures with minimal fluid exposure and of shorter duration. In November 2008, we obtained FDA 510(k) clearance to market our surgical gowns as Level III and Level IV, and our surgical drape as Level IV, which is intended for use in healthcare facilities, and they are in compliance with AAMI PB70 standard. In May 2009, we obtained FDA 510(k) clearance to market our surgical for use in healthcare facilities, as they are in compliance with AAMI PB70 standard.

W.L. Gore and Associates (Gore), the supplier of the barrier fabric used in our Level III and Level IV surgical gowns and our Level IV drapes, recently notified us that it intends to exit the medical fabrics market in a timed, phased manner. Gore gave its customers the option to make advance purchases of fabric to bridge their process of transitioning to another supplier, and we expect to make substantial purchases of fabric pursuant to this program. See *Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.* As a result of Gore s exit from the medical fabrics market, we will need to identify, evaluate, and engage a new supplier of barrier fabric to replace Gore. We believe alternate suppliers exist that could manufacture comparable medical fabrics for us. We are exploring arrangements with potential alternate suppliers. See *Item 1A. Risk Factors We Rely on Key Suppliers*

We utilize RFID technology in our ten processing facilities. RFID technology is a method for identifying and tracking objects based on the use of a small tag that stores a unique code. We utilize multi-read RFID tags in our reusable surgical gowns and drapes, which allow us to replace the use of labor-intensive bar code scanning to track product usage. This technology offers us improved inventory control and monitoring of product quality. SRI Surgical holds a patent covering this process.

We contract with third-party vendors for cutting and sewing of gowns and drapes. We had a procurement agreement with Standard Textile Co., Inc. (Standard Textile) as our supply source for reusable surgical products, the term of which expired in August 2008. We continue to work with Standard Textile on a month-to-month basis. We are also utilizing a secondary supplier.

To complement our reusable surgical products, we offer disposable packs containing single-use disposable products, such as gauze, needles, syringes, and tubing. These packs are developed to a customer s specifications,

and in combination with our reusable line of surgical products, offer a cost-effective, high-quality alternative to custom procedure packs containing all disposable products. As mentioned above, in November 2008, we entered into the Co-Marketing Agreement with Cardinal (see *Item 1. Business the Company*). Under this agreement, Cardinal is appointed our sole vendor of disposable surgical packs for our existing customer base on the date the agreement was signed. In addition, this agreement provides for a new product offering known as the Hybrid Preference Pack. The Hybrid Preference Pack combines our reusable products with Cardinal s disposable surgical packs. This combined product responds to hospital and surgery center green initiatives by providing environmentally preferred purchasing options that maximize value and minimize waste.

Our instrument-processing program, called AccuSetSM, offers our customers the benefit of consistently available surgical instruments processed at an FDA-regulated facility. Our thorough cleaning and inspection process assures that surgical instruments are functional and meet rigorous quality standards. We offer general, laparoscopic, orthopedic, arthroscopic, ophthalmic, neurological, ENT (ear, nose and throat) and L&D (labor and delivery) instrument processing at our facilities. We have also introduced an overnight instrument processing program, ReadyCaseSM OnDemand. The program makes available to hospitals and surgery centers additional processing capabilities at our FDA-regulated facilities should they find themselves in sudden need. As of December 31, 2010, we serviced instrument programs at 72 hospitals.

We offer instruments as part of the AccuSetSM program pursuant to a Joint Marketing Agreement with Aesculap, Inc. (Aesculap), one of the oldest and largest worldwide suppliers of surgical instruments. In March 2003, we signed a 10-year Joint Marketing Agreement under which Aesculap provides most of the surgical instruments that we supply to our customers and are used in their surgical procedures. Aesculap receives an agreed upon fee from us for each procedure based on the number and kinds of procedures performed with its instruments and the number and combination of instruments used for each procedure. We have also developed vendor relationships with many leading manufacturers of surgical instruments to procure instrumentation preferred by our customers that Aesculap does not manufacture. These vendor relationships expand the range of solutions that we offer our customers. We expect our instrument-processing program will continue to grow.

ReadyCaseSM, our surgical supply and instrument delivery system, combines reusable products, disposable packs, surgical instruments, and physician preference items to provide most of the products required for a surgical procedure. The system allows our healthcare customers to develop and implement best practice protocols. We believe that ReadyCaseSM is the most complete case cart system available in the market. By delivering a high percentage of surgical products and instruments used in a procedure, ReadyCaseSM offers our customers the potential to reduce their supply chain management costs, improve their operational efficiency, and increase their revenue by improving throughput in their surgical area.

We also provide an outsource solution for our customers instrument processing and sterilization needs. Utilizing our expertise in managing FDA-regulated instrument processing facilities, we offer cost-effective management of hospital and surgery center instrumentation supply chain and central sterilization facilities.

Employees

As of December 31, 2010, we employed 839 people. Our employees are not covered by a collective bargaining agreement. We consider our employee relations to be good.

Competition

We compete primarily with sellers of disposable gowns, drapes, basins and custom packs. Our principal competitors are Cardinal Converters (a subsidiary of Cardinal Health, Inc.), Medline Industries, Inc., DeRoyal Industries, Inc., and Kimberly Clark Corporation. We also compete with third party instrument processors and the in-house processing capabilities of hospitals and surgery centers to provide surgical instruments and reusable products.

The challenging healthcare environment in recent years has led to increasingly intense competition among suppliers and manufacturers of surgical products. As providers seek to reduce operating costs in response to pressure from governments, insurance companies, and health maintenance organizations, suppliers and manufacturers are being forced to compete on price, service, quality and delivery of innovative solutions that improve the healthcare supply chain. Because we believe competitive pressure will continue to intensify for the foreseeable future, we must position SRI Surgical to effectively compete based on our high quality service and innovative outsourcing solutions.

Regulation

Substantially all of our products and services are subject to extensive government regulation in the United States by federal, state, and local governmental agencies, including the FDA, the Department of Transportation (DOT), and the Occupational Safety and Health Administration (OSHA).

Our reusable products are regulated as medical devices by the FDA, which regulates the development, production, distribution, and promotion of medical devices in the United States. Various states in which we do business also regulate medical devices. Pursuant to the Federal Food, Drug and Cosmetics Act (the FDA Act), our medical devices are subject to general controls regarding FDA inspections of our facilities, current Good Manufacturing Practices (cGMP s), the Quality System Regulations (QSR), labeling, maintenance of records, and medical device reporting with the FDA. To the extent required, we have obtained FDA pre-market approval of our devices under Section 510(k) of regulations issued under the Code of Federal Regulations (CFR), which provides for FDA approval on an expedited basis for products shown to be substantially equivalent to devices already cleared by the FDA and currently legally marketable in the United States. Products must be produced in establishments registered with the FDA, and our labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The Medical Device Reporting regulation obligates us to provide information to the FDA on serious injuries or deaths alleged to have been associated with the use of a product or in connection with certain product failures that could have caused serious injury or death. If we fail to comply with the applicable provisions of the FDA Act, the FDA may institute proceedings to detain or seize products, impose fines, enjoin future company activities, impose product labeling restrictions, or enforce product recalls or withdrawals from the market.

We and our hospital customers also must comply with regulations of OSHA, including the blood borne pathogen standards requiring standard (universal) precautions which must be observed to minimize exposure to blood and other bodily fluids. To comply with these requirements, our employees wear appropriate personal protective equipment when handling soiled linens and materials in the facility s decontamination area. Properly used, our products allow our hospital customers to protect their employees in compliance with the OSHA regulations. Additionally, we must comply with local regulations governing the discharge of water used in our operations. We use locally licensed contractors to dispose of any biohazardous waste generated by our customers and received by us and therefore do not need to obtain permits for biohazardous waste disposal. We must comply with DOT and OSHA regulations governing the transportation of biohazardous materials, which include containing and labeling waste as well as reporting various discharges. We comply with these regulations by confining soiled products inside marked liquid proof bags for transport within secured and appropriately labeled transfer carts.

In addition, other federal, state and local regulatory authorities, including those enforcing laws which relate to the environment, fire hazard control, and working conditions, have jurisdiction to take actions that could have a material adverse effect on us. We make expenditures from time to time to comply with environmental regulations, but do not expect to make any material capital expenditures for environmental compliance during 2011. However, current environmental estimates could be modified as a result of changes in our plans, legal requirements or other factors.

Item 1A. Risk Factors

The cautionary statements set forth below, as well as factors described elsewhere in this Annual Report on Form 10-K and in other SEC filings, discuss important factors that could cause actual results to differ materially from any forward-looking statements that we make. We assume no obligation to update these forward-looking statements.

We may need additional capital in the future, which might not be available. Our business is capital intensive and requires annual expenditures for additional surgical products. Should we need or otherwise decide to raise additional funds, we may not be able to obtain financing on favorable terms, if at all. If we cannot raise funds, if needed, on acceptable terms, we may not be able to develop or enhance our products, take advantage of future opportunities, respond to competitive pressures or unanticipated requirements, or otherwise support our operations.

Our Credit Facility expires on August 7, 2011, and we might not be able to renew the facility with our current lender or secure another credit facility before this one matures. The absence of a credit facility would materially adversely affect us.

Our Credit Facility requires us to maintain minimum tangible net worth and fixed charge coverage ratio covenants. As of December 31, 2010, we are in compliance with all the financial and non-financial covenants under the amended credit facility. In certain past quarters, we were unable to comply with these covenants and we might not comply with those covenants in future periods. Based on our current projections, we likely will not be in compliance with the tangible net worth requirement in the first quarter of 2011. There is no assurance that our lender will waive compliance, and a breach of those covenants would adversely affect us. See *Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations* Liquidity and Capital Resources.

We cannot predict the effect that health care reform and other changes in government programs may have on our business, financial condition, results of operations or cash flows. In March 2010, the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (Health Care Reform Legislation) was signed into law. In general, the Health Care Reform Legislation seeks to reduce health care costs and decrease over time the number of uninsured legal U.S. residents, by among other things, requiring employers to offer, and individuals to carry, health insurance or be subject to penalties. At this time, we cannot predict the full impact of the Health Care Reform Legislation due to its complexity and lack of implementing regulations or interpretive guidance, as well as our inability to foresee the law s impact on our customers. Implementation of the Health Care Reform Legislation could ultimately have a material adverse affect on us.

Our future growth is dependent on the sales process and market acceptance of our products and services. Our future performance depends on our ability to maintain and increase revenues from new and existing customers. Our sales process to acquire new customers is typically extended in duration, because of industry factors such as the approval process in hospitals for purchases from new suppliers, the duration of existing supply contracts, and implementation delays pending termination of a hospital s previous supply relationships. Our future performance also depends on the market accepting our product and service offerings, which emphasize the supply of reusable surgical products to a market that predominantly uses disposable products. We are also regularly developing new instrument processing programs. We are subject to a risk that the market will not broadly accept these product offerings, which would adversely affect our revenues and operating results.

We rely on key suppliers. We rely on Aesculap as our major source of supply of instruments for our instrument processing programs. Any failure of Aesculap to furnish instruments for any reason could materially and adversely affect our ability to service these programs until we secured one or more alternative suppliers. We had a procurement agreement with Standard Textile as our supply source for our reusable surgical products through August 2008. We are currently working with Standard Textile on a month-to-month basis until a new

agreement can be reached. We are also utilizing a secondary supplier. If Standard Textile were unable to perform or if we are unable to reach an agreement with Standard Textile or another supplier on favorable terms, we would be materially and adversely affected.

As disclosed under *Item 1. Business Products*, Gore, our supplier of the barrier fabric that we use in our Level III and Level IV surgical gowns and our Level IV drapes, notified us that it intends to exit the medical fabrics market in a timed, phased manner. We expect to make significant advance purchases of fabric to bridge the process of transitioning to another supplier and also initiating the process of identifying, evaluating, and engaging that new supplier. Any failure by us to make adequate advance purchases of barrier fabric from Gore or to engage a new supplier of barrier fabric that meets our requirements in a timely manner could materially adversely affect us. There is no assurance that Gore will make a sufficient amount of product available to us or that we will be able to finance the purchase price of the advance purchases on acceptable terms, if at all.

In November 2008, we entered into a Co-Marketing Agreement with Cardinal. The Co-Marketing Agreement appoints Cardinal the exclusive supplier of disposable products for our customers. If this arrangement does not provide the results that we expect we could be materially and adversely affected.

We are subject to fluctuations in the availability and cost of commodity items used in our products and distribution network. We depend on various component raw materials supplied by others for our operations and certain products we offer our customers. Our supplier relationships could be interrupted due to natural disasters or other events or could be terminated. A sustained interruption in the flow of adequate supplies, or a shortage of a particular item, could have an adverse effect on our business as we may not be able to manage price fluctuations in commodity type items.

Additionally, our distribution network uses diesel fuel. Oil and gas prices remain volatile and have fluctuated significantly in recent years, causing our costs to distribute our products to fluctuate. The healthcare industry is highly competitive and many of our customers have cost-containment initiatives, so we might not be able to pass along cost increases through higher prices or fuel surcharges. If we cannot fully offset cost increases through other cost reductions, or recover these costs through price increases or fuel surcharges, our results of operations could be adversely affected. We might also be adversely affected by increases in the cost of cotton, which is a component of our towels.

The loss of a significant customer or purchasing organization could adversely affect our operating results. During the year ended December 31, 2010, hospitals belonging to three group purchasing organizations (GPOs), Novation, LLC, HealthTrust Purchasing Group, L.P. and MedAssets, Inc. accounted for approximately 55% of our sales. No single healthcare provider accounted for more than 10% of our revenues in 2010. Our business with these GPOs is pursuant to short-term agreements, which are subject to renewal from time to time through competitive processes. Although each GPO member hospital makes its purchasing decisions on an individual basis, the loss of a substantial portion of a GPO hospitals business would adversely affect our revenues and results of operations.

Intense competition in the markets in which we operate could adversely affect us. Our business is highly competitive. Competitors include a number of distributors and manufacturers, as well as the in-house reprocessing operations of hospitals. Certain of our existing and potential competitors possess substantially greater resources than we possess. Some of our competitors, including Cardinal Converters (a subsidiary of Cardinal Health, Inc.) and Medline Industries, Inc., serve as the sole supplier of a wide assortment of products to a significant number of hospitals. While we have a substantial array of surgical products, many of our competitors have a greater number of products for the entire hospital, which in some instances is a competitive disadvantage for us. There is no assurance that we will be able to compete effectively with existing or potential competitors. See *Item 1. Business-Competition*.

The loss of key executives and employees could adversely affect us. Our success depends upon the contributions of executives and key employees. The loss of executives and certain key employees in sales, operations and marketing could have a significant adverse effect on our ability to penetrate our markets, operate efficiently, and develop and sell new products and services. We also believe our success will depend in large part upon our ability to attract and retain additional highly skilled personnel.

Our ability to effectively grow depends on our ability to improve our operational systems. We have expanded our operations since inception and may continue to expand to pursue existing and potential market opportunities. This growth places a significant demand on management, financial and operational resources. To manage growth effectively, we must implement and improve our operational systems, procedures and controls on a timely basis and continue to invest in the operational infrastructure of our business.

Our product liability insurance may not be sufficient to cover all claims. The use of medical devices such as surgical instruments entails an inherent risk of product liability or other claims initiated by patients or hospitals. Any of those claims in excess of our insurance coverage or not covered by insurance could adversely affect our results of operations.

Changes in federal or state regulations could materially adversely affect us. Significant aspects of our business are subject to federal, state and local statutes and regulations governing, among other things, medical waste-disposal and workplace health and safety. In addition, most of the products furnished or sold by us are subject to regulation as medical devices by the FDA, as well as by other federal, state and local agencies. Our facilities are subject to quality systems inspections by FDA officials. The FDA has the power to enjoin future violations, seize adulterated or misbranded devices, and require the manufacturer to remove products from the market, and publicize relevant facts. Federal, state or local governments might impose additional restrictions or adopt interpretations of existing laws that could materially adversely affect us. See *Item 1. Business-Regulation.*

Failure to maintain adequate internal systems and effective internal controls over financial reporting and information systems could adversely affect us. Adequate internal systems and an effective system of internal controls are necessary to ensure proper financial reporting and disclosure. If a significant deficiency or material weakness, as defined under the Public Company Accounting Oversight Board guidelines, exists in our business, it could adversely affect our ability to report our financial condition, results of operations or cash flows, and related disclosures.

We adopted a rights plan that could make it more difficult for a third party to acquire us. On November 10, 2010, our Board of Directors adopted a shareholder rights plan to better assure that we can evaluate and respond to a disclosed indication of interest. The plan could discourage, delay, or prevent a hostile third party from acquiring a large portion of our securities, initiating a tender offer or proxy contest, or acquiring us, even if our shareholders might receive a premium for their shares over then-current market prices.

Our stock price has fluctuated and might continue to be volatile. During the 12-month period ended December 31, 2010, the sale price of our common stock on the NASDAQ Stock Market System ranged from \$2.05 to \$5.38. The closing price of our common stock on February 28, 2011 was \$5.75. Our common stock price might continue to be volatile in the future.

Item 1B. Unresolved Staff Comments Not applicable

Item 2. Properties

We operate ten reusable processing facilities that range in size between 30,000 and 63,500 square feet in Baltimore, Chattanooga, Cincinnati, Dallas, Houston, Los Angeles, Raleigh, Salt Lake City, Stockton, and Tampa. Each facility has standardized processes and equipment, including computerized and fully automated

heavy-duty washers, dryers, and sterilizers to achieve consistent decontamination and sterilization of reusable surgical products and instruments. We follow the Quality System Regulations at each facility, and regularly implement at all facilities efficiencies that have been developed and tested at another location.

We maintain service centers in Atlanta, Detroit, Louisville, Miami and Oklahoma City to facilitate distribution of our products to our customers.

We own our Chattanooga, Cincinnati, Houston, and Stockton processing facilities and our corporate headquarters. We lease the remaining processing facilities and service centers.

We believe that our existing facilities adequately serve our current requirements. The table below summarizes our properties and the major markets they serve as of December 31, 2010:

	Square Footage		
	(Approx.)	Lease Expiration	Selected Markets Served
Processing Facilities:		•	
Baltimore, Maryland	58,700	May 31, 2012	Baltimore, Philadelphia, Richmond, New Jersey
		(Options to 2022)	
Chattanooga, Tennessee	50,000	Owned	Atlanta, Birmingham, Nashville, Mississippi
Cincinnati, Ohio	50,000	Owned	Columbus, Cincinnati, Louisville, Lexington, Detroit, Cleveland
Dallas, Texas	31,000	March 31, 2013	Dallas, Oklahoma City, Tulsa
Houston, Texas	30,000	Owned	Houston, San Antonio, Austin
Los Angeles, California	30,400	November 30, 2012	San Diego, Los Angeles
Raleigh, North Carolina	63,500	March 31, 2012 (Options to 2022)	South Carolina, North Carolina
Salt Lake City, Utah	31,800	July 6, 2012	Utah, Idaho
Stockton, California	57,000	Owned	Sacramento, San Francisco, Oakland
Tampa, Florida	63,000	January 23, 2012 (Options to 2032)	Florida, Georgia
Service Centers:			
Atlanta	3,150	March 31, 2013	
Detroit, Michigan	7,300	November 30, 2012	
Louisville, Kentucky	8,660	Month-to-Month	
Miami, Florida	4,000	January 31, 2011	
Oklahoma City, Oklahoma	3,600	February 28, 2012	
Corporate Office:			
Tampa, Florida	42,000	Owned	

We are currently negotiating amended lease agreements on the facilities that are set to expire in 2012. We believe new or amended leases will be completed prior to each lease expiration date.

Item 3. Legal Proceedings

From time to time, we are subject to legal proceedings that arise in the ordinary course of our business. We do not believe these proceedings, individually or in the aggregate, will have a material adverse effect on our financial position, results of operations, or cash flows.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Common Stock Information

Our common stock trades publicly on The NASDAQ Stock Market LLC (NASDAQ Global Market) (the NASDAQ) under the symbol STRC . On February 25, 2011, there were approximately 33 holders of record of our common stock. The table below sets forth the high and low sales prices for our common stock for fiscal years 2009 and 2010, as reported on the NASDAQ.

Common Stock Price Range

Year ended December 31, 2009	High	Low
First quarter	\$ 1.80	\$ 0.76
Second quarter	\$ 1.58	\$ 1.00
Third quarter	\$ 2.82	\$ 1.30
Fourth quarter	\$ 3.40	\$ 1.50
Year ended December 31, 2010		
First quarter	\$ 3.50	\$ 2.05
Second quarter	\$ 5.38	\$ 3.35
Third quarter	\$ 3.99	\$ 2.70
Fourth quarter	\$ 4.80	\$ 2.51

We have never declared or paid cash dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Additionally, financial covenants in our credit facility prohibit the payment of cash dividends. See *Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources* and *Notes to Financial Statements*.

Stock Performance Graph

The following graph shows a comparison of our cumulative total shareholder return, NASDAQ Global Market (U.S.), and the NASDAQ Health Care Index. This graph assumes that \$100 was invested on December 31, 2005 in our common stock and in the other indices and in each case, assumes reinvestment of all dividends. Historic stock price performance does not necessarily indicate future stock price performance.

Item 6. Selected Financial Data

The following table contains certain selected financial data that have been derived from our audited financial statements. The data should be read in conjunction with the Financial Statements and Notes thereto incorporated into Item 8 and *Management s Discussion and Analysis of Financial Condition and Results of Operations* incorporated into Item 7.

	2010	Years Ended December 2009 2008		2007	2006
Statement of anomations data.		(In thousan	ds, except per s	hare data)	
Statement of operations data: Revenues	\$ 100,864	\$ 98,453	\$ 97,028	\$ 94,201	\$ 93,831
Cost of revenues	78,096	78,355	75,599	73,947	71,534
Gross profit	22,768	20,098	21,429	20,254	22,297
Distribution expenses	7,525	6,933	7,227	6,394	6,327
Selling and administrative expenses	16,362	16,607	16,289	17,775	17,574
Loss from operations	(1,119)	(3,442)	(2,087)	(3,915)	(1,604)
Interest expense	702	619	1,077	1,385	1,206
Other income	(361)	(367)	(396)	(342)	
Loss before income taxes	(1,460)	(3,694)	(2,768)	(4,958)	(2,810)
Income tax expense (benefit)	100	82	(2,700)	(1,765)	(857)
r i contra di		-		()/	
Net Loss	\$ (1,560)	\$ (3,776)	\$ (2,556)	\$ (3,193)	\$ (1,953)
Basic loss per common share	\$ (0.24)	\$ (0.58)	\$ (0.40)	\$ (0.50)	\$ (0.31)
Diluted loss per common share	\$ (0.24)	\$ (0.58)	\$ (0.40)	\$ (0.50)	\$ (0.31)
Weighted average common shares outstanding:					
Basic	6,450	6,464	6,434	6,399	6,338
Diluted	6,450	6,464	6,434	6,399	6,338
Balance sheet data (at end of period):					
Reusable surgical products, net	\$ 17,369	\$ 18,151	\$ 20,577	\$ 19,416	\$ 20,954
Total assets	61,708	62,928	\$ 20,377 69,746	519,410 71,968	\$ 20,934 74,354
Notes payable	5,561	6,124	8,434	2,493	2,497
Mortgages payable	3,780	4,013	4,228	4,286	4,524
Bonds payable	520	520	520	7,060	7,720
Total liabilities	22,764	23,063	26,764	27,342	27,636
Shareholders equity	38,944	39,865	42,982	44,626	46,718
1 2	· · ·		,	, -	, -

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read with our financial statements and Notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains trend analysis and might contain forward-looking statements. These statements are based on current expectations and actual results might differ materially. Among the factors that could cause actual results to vary are those described in the Overview section below and in Item 1A. Risk Factors.

Overview

Edgar Filing: SRI SURGICAL EXPRESS INC - Form 10-K

We provide daily processing, assembly and delivery of reusable and disposable surgical products and instruments through our state-of-the-art, FDA-regulated service centers. Our integrated closed-loop process starts with daily delivery of reusable and disposable surgical supplies and instruments to healthcare providers.

After use, we pick up the reusable textiles, basins and instruments used in surgery and return them to our processing facilities. Used products arriving at our processing facilities are sorted, cleaned, inspected, packaged, sterilized and shipped back to the healthcare providers. We also manage the instrumentation and supply chain of hospitals, surgery centers and operating rooms and their central sterilization facilities.

We believe our facilities are strategically situated to capitalize on future market opportunities. These facilities have significant available capacity to access more of the national market.

We derive our revenue from the sale and servicing of reusable and disposable surgical products and instruments and the management of our customers supply chain and central sterilization functions. Reusable products include linens (gowns, towels and drapes) and basins (stainless steel cups, carafes, trays and basins). Disposable accessory packs supplement the reusable products with highly customizable components. We sell our products and services through a direct sales force located throughout most of the major markets in the United States. Our revenue growth is primarily determined by the number of customers, the number and type of surgical procedures that we service for each customer, and pricing for our various types of surgical packs and procedures. Revenues are recognized as the agreed upon products and services are delivered, generally daily. We incur most of our cost of revenues from processing the reusable surgical products and instruments at our processing facilities.

In November 2008, we signed a five-year Supply and Co-Marketing Agreement (the Co-Marketing Agreement) with Cardinal Health 200, Inc. (Cardinal), an affiliate of Cardinal Health, Inc. We appointed Cardinal as our exclusive provider of disposable surgical products. We jointly market an environmentally friendly combined reusable pack (produced by us) and disposable surgical pack (produced by Cardinal) called the Hybrid Preference Pack. The Co-Marketing Agreement gives us an opportunity to focus on our core strengths: reusable surgical products, instrumentation and management of central sterilization and supply chain activities. The Co-Marketing Agreement gives our environmentally friendly solution greater reach and visibility throughout the healthcare market and combines the strengths of two organizations that are market leaders in their segments for a more efficient and effective delivery of healthcare solutions. We amended and restated the Co-Marketing Agreement in February 2010 to provide, among other things, that we purchase from Cardinal Health the disposable component products included in the Hybrid Preference Packs, instead of receiving them on a consignment basis. See *Item 1. Business The Company* for a further description. The change in the arrangement for disposable component products contributed approximately \$200,000 of the \$2.7 million increase in our gross margins in 2010.

Under the terms of the Co-Marketing Agreement with Cardinal Health, we received \$1.0 million and \$250,000 in January 2009 and 2010, respectively, which was initially recognized in other accrued expenses in our balance sheets. The amounts received from Cardinal Health reimbursed us for certain expenses incurred for marketing and sales, opening depots in territories not currently served by us, and to close our disposable products assembly plant located in Plant City, Florida, among other items. During the years ended December 31, 2010 and 2009, we incurred costs of \$37,000 and \$485,000, respectively, related to certain costs, including severance, asset disposal and other costs, associated with the closing of our disposable assembly facility in Plant City, Florida. The costs directly associated with the plant closing were applied against the payment received from Cardinal Health. Additionally, during the years ended December 31, 2010 and 2009, we incurred costs of \$329,000, respectively, related to the hiring of sales and marketing professionals to support the agreement, as well as software development, and training and management sessions in an effort to support the agreement. The direct costs incurred in support of the agreement with Cardinal Health were applied against the payment received from Cardinal Health. We accounted for cash incentive payments under the provisions of Accounting Standards Codification (ASC) 605-50-45-13b, *Revenue Recognition: Customer Payments and Incentives*, which requires that consideration received from a vendor that is a reimbursement for cost incurred to sell the vendor s product be characterized as a reduction of that cost when recognized in the income statement.

Most of our surgical instrument supply arrangements with customers use instruments owned by Aesculap, which receives an agreed upon fee for each procedure based on the number and kinds of procedures performed

with its instruments and the number and combination of instruments used for each procedure. This arrangement allows us to limit our cost of capital for instrument programs. In addition to the Aesculap-owned instruments, we purchase surgical instruments from other vendors to service customers who have requirements that Aesculap cannot fulfill. We expect instrument revenues will continue to grow and, as a result, we expect our instrument inventory will continue to grow.

Our profitability is primarily determined by our revenues, the efficiency with which we deliver products and services to our customers, and our ability to control our costs. We incurred operating and net losses for the year ended December 31, 2010, but our results trended positively to a net profit in the third and fourth quarters of 2010. We incurred a significant loss during the three months ended March 31, 2010, primarily as a result of lower procedure volumes at several of our largest customers, as well as an increase in insurance costs related to higher than normal claims volume, selling expenses, and distribution related costs. During the last nine months of 2010, our reusable surgical product revenues increased as the level of interest in our environmentally friendly products continued to grow, and we experienced higher margins driven by increased reusable surgical product revenue, improved operational efficiencies and lower levels of product loss.

Our principal strategic opportunity to improve our operating results is to capitalize on our service capabilities and considerable infrastructure by leveraging our current relationships with existing customers and adding new customers. We continue to focus on introducing our current and potential new customers to our physician-specific ReadyCaseSM case cart management system, which has been our principal source of new sales. In addition, the Co-Marketing Agreement with Cardinal Health allows our sales force to focus on our strengths: reusable surgical products, instrumentation, and management of central sterilization and supply chain activities. The agreement gives our environmentally friendly solution greater reach and visibility throughout the healthcare market. It combines the strengths of two organizations that are leaders in their segments for a more efficient and effective delivery of healthcare solutions. See *Item 1. Business The Company*.

Critical Accounting Policies and Estimates

The preparation of our financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make judgments, assumptions, and estimates that affect the amounts reported in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and assumptions based upon historical experience and various other factors and circumstances. We believe that these estimates and assumptions are reasonable under the circumstances; however, actual results may vary from these estimates and assumptions. Note B to our financial statements describes the significant accounting policies and methods that we use in preparing our financial statements. We identified the following critical accounting policies that affect the more significant judgments, assumptions and estimates used in preparing our financial statements.

Allowance for Doubtful Accounts. Our allowance for doubtful accounts is based on our assessment of the collectability of specific customer accounts, the overall aging of the balances and the financial stability of the customer. The use of different estimates or assumptions could produce different allowance balances. If a major customer s creditworthiness deteriorates or customer defaults run at a rate higher than historical experience, we would be required to increase this allowance, which could adversely affect our results of operations.

Reserves for Shrinkage, Obsolescence, and Scrap for Reusable Surgical Products and Instruments. We determine our reserves for shrinkage and obsolescence of our reusable surgical products and instruments based on historical experience. Any linen products not scanned by our RFID system for a 210-day period are considered lost and written off. We determine our reserve for scrap based upon quality assurance standards and historical evidence. We periodically verify the quantity of other reusable surgical products by counting and by applying observed turn rates. A third party, Aesculap, owns most of the surgical instruments that we use. We base our reserve for owned surgical instrument losses on our assessment of our historical loss experience, including periodic physical counts. Using different estimates or assumptions could produce different reserve

balances for our reusable products and instruments. We review this reserve quarterly. If actual shrinkage, obsolescence or scrap differs from our estimates, our reserve would increase or decrease accordingly, which could adversely affect our results of operations.

Reserves for Shrinkage and Obsolescence for Inventories. We determine our reserves for shrinkage and obsolescence of our inventories based on historical data, including the results of cycle counts performed during the year and the evaluation of the aging of our disposable surgical products. Using different estimates or assumptions could produce different reserve balances. We review this reserve quarterly. If actual losses differ from our estimates, our reserve would increase or decrease accordingly, which could adversely affect our results of operations.

Amortization of Reusable Surgical Products and Instruments. Our reusable surgical products are stated at cost. We amortize linens and basins on a basis similar to the units of production method. Estimated useful lives for each product are based on the estimated total number of available uses for each product. The expected total available usage for our linen products using the three principal fabrics (accounting for approximately 73% of the reusable surgical products) is 75, 100, and 125 uses, based on several factors, including our actual historical experience with these products. We believe our RFID technology enables us to evaluate the useful lives of linen products more often. Basins are amortized on a straight-line basis over their estimated useful life, up to 20 years. We amortize owned surgical instruments on the straight-line method based on a four-year useful life. If our actual use experience with these products is shorter than these assumptions, our amortization rates for reusable products and instruments would increase, which could adversely affect our results of operations.

Health Insurance Reserves. We offer employee benefit programs including health insurance to eligible employees. We retain a liability up to \$110,000 annually for each health insurance claim. Our policy has an estimated annual aggregate liability limit of \$3.9 million. We accrue health insurance costs using estimates to approximate the liability for reported claims and claims incurred but not reported. Using different estimates or assumptions could produce different reserve balances. If actual claim results exceed our estimates, our health insurance reserve would increase, which could adversely affect our results of operations.

Workers Compensation Insurance Reserve. Our workers compensation insurance program is a large dollar deductible, self-funded plan. We retain a liability of \$250,000 for each claim occurrence. Our policy has an annual aggregate liability limit of \$1.6 million. We base our reserve on historical claims experience and reported claims. We accrue workers compensation insurance costs using estimates to approximate the liability for reported claims and claims incurred but not reported. We review this reserve quarterly. If actual claims differ from our estimates, the reserve would increase or decrease accordingly, which could adversely affect our results of operations.

Income Taxes. Our effective tax rate is based on our income or losses and statutory tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our effective tax rate and evaluating our tax positions. Income taxes have been provided using the asset and liability method in accordance with ASC Topic 740, *Income Taxes*, (ASC 740). In accordance with ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in operations in the period that includes the enactment date of the rate change. The tax benefits must be reduced by a valuation allowance in certain circumstances. Realization of the deferred tax benefits is dependent on generating sufficient taxable income prior to the expiration of any net operating loss carry-forwards. We periodically review deferred tax assets for recoverability, and provide valuation allowances as necessary.

Stock-Based Compensation. In accordance with ASC Topic 718, *Share-Based Payments*, (ASC 718) and the Security and Exchange Commission Staff Accounting Bulletin No. 107 (SAB 107), we recognize

stock-based compensation expense in our statements of operations. We have elected to use the binomial model to determine the fair value of our issued options. Option pricing models require the input of subjective assumptions, including the expected life of the option, the price volatility of the underlying stock, expected interest rates and forfeitures. If actual results differ significantly from our assumptions, stock-based compensation could increase or decrease. For further discussion of our stock-based compensation, see *Note B-Summary of Significant Accounting Policies Stock-Based Compensation* and *Note J Stock-Based Compensation* to the financial statements.

Recently Issued Accounting Standards

In January 2010, the FASB issued ASU No. 2010-6, *Improving Disclosures About Fair Value Measurements*, that amends existing disclosure requirements under ASC 820 by adding required disclosures about items transferring into and out of levels 1 and 2 in the fair value hierarchy; adding separate disclosures about purchase, sales, issuances, and settlements relative to level 3 measurements; and clarifying, among other things, the existing fair value disclosures about the level of disaggregation. This ASU was effective for us for the first quarter of 2010, except for the requirement to provide level 3 activities of purchases, sales, issuances, and settlements on a gross basis, which is effective beginning the first quarter of 2011. Since this standard impacts disclosure requirements only and we do not have any items that meet the classification as Level 2 or Level 3 items, its adoption will not have a material impact on our results of operations or financial condition.

Results of Operations

We operate on a 52-53 week fiscal year ending the Sunday nearest December 31st. The financial statements are reflected as of December 31, 2010, 2009 and 2008 for presentation purposes only. The actual end of each period was January 2, 2011, January 3, 2010, and December 28, 2008, respectively. There are 52 weeks in 2010, 53 weeks in 2009 and 52 weeks in 2008.

The following table sets forth for the periods shown the percentage of revenues represented by certain items reflected in our statements of operations:

	Years l	Years Ended December 31,		
	2010	2009	2008	
Revenues	100.0%	100.0%	100.0%	
Cost of revenues	77.4	79.6	77.9	
Gross profit	22.6	20.4	22.1	
Distribution expenses	7.5	7.0	7.4	
Selling and administrative expenses	16.2	16.9	16.8	
Loss from operations	(1.1)	(3.5)	(2.1)	
Interest expense	0.7	0.6	1.1	
Other income	(.4)	(0.4)	(0.4)	
Loss before income taxes	(1.4)	(3.7)	(2.8)	
Income tax provision (benefit)	0.1	0.1	(0.2)	
Net loss	(1.5)%	(3.8)%	(2.6)%	

Year ended December 31, 2010 compared to year ended December 31, 2009

Revenues

Revenues increased \$2.4 million, or 2.4%, to \$100.9 million for the year ended December 31, 2010, compared to \$98.4 million for the year ended December 31, 2009. As noted above, we operate on a 52-53 week fiscal year. Those weeks break down into a number of operating days which varies after taking into account

company holidays. As a result, a key metric we utilize to run our business is our average daily revenue. There were 254 billing days in 2010 and 258 billing days in 2009. Our average daily revenue was \$397,000 and \$382,000 in 2010 and 2009, respectively. The increase in our average daily revenue in 2010 when compared to 2009 is primarily related to the increase in demand for our reusable surgical product offering and the amendment to the co-marketing agreement under which we now recognize all revenues for Hybrid Preference Pack customers. Partially offsetting these increases were lower procedure volumes and industry pricing pressures, as well as, customer losses.

Under the Supply and Co-Marketing Agreement with Cardinal Health, the Company accounted for disposable component products that were included in the Hybrid Preference Packs on a consignment basis and did not recognize any associated revenue. On February 3, 2010 the Company entered into the Amended and Restated Supply Agreement, at which time the Company began purchasing the disposable component products that were included in the Hybrid Preference Packs and recognizing the associated revenue upon sale. During 2010, the Company recognized \$2.7 million of revenue related to the disposable component products of the Hybrid Preference Packs, which accounted for approximately \$11,000 of the average daily revenue increase in 2010 compared to 2009.

Gross Profit

Gross profit increased \$2.7 million, or 13.3%, to \$22.8 million for the year ended December 31, 2010, compared to \$20.1 million for the prior year. As a percentage of revenues, gross profit increased by 2.2 percentage points to 22.6% for the year ended December 31, 2010 compared to 20.4% for the prior year. The increase in gross profit was primarily due to higher revenues of approximately \$2.4 million, lower reusable surgical product loss of \$1.8 million, lower instrument usage fees of \$844,000, lower repairs and maintenance of \$301,000 and lower sterilization expense of \$147,000 relating to the closure of our Plant City operations in 2009, as well as improved labor efficiency of \$472,000 and the change in the co-marketing agreement with Cardinal which accounted for less than \$200,000. Partially offsetting these items were higher disposable material costs of \$2.5 million, as well as, higher pack consumable costs of \$223,000, as result of the increase in our revenues.

The lower reusable surgical product loss was due to lower levels of product loss in 2010, as well as the prior year adjustment for additional product loss that was recorded in the three months ended September 30, 2009, see Note P *Third Quarter 2009 Adjustments*. The lower levels of product loss in 2010 are attributable to our focus on the management of linens at customer locations, as well as improved technology to track linens once they leave our facilities. The lower instrument usage fees were primarily the result of the loss of a large instrument customer during 2010, as well as the change in the mix of instrument sets used by our customers. The increase in disposable material costs relates almost entirely to our purchasing disposable materials from Cardinal Health. The disposable products purchased under the Hybrid Preference Pack program have lower margins because we are no longer assembling these products and incur a higher cost per product than in prior years. Prior to February 2010, we received the disposable packs contained in the Hybrid Preference Packs on consignment from Cardinal Health. Consequently, we did not recognize gross revenues or costs associated with these disposable packs. Under the terms of the amended agreement, effective February 2010, we now purchase the disposable packs from Cardinal Health and therefore recognize all associated revenues and costs of the Hybrid Preference Pack. We pay Cardinal Health for the disposable packs that we purchase without regard to our risk of collecting those amounts due from our customers.

Distribution Expenses

Distribution expenses increased \$592,000, or 8.5%, to \$7.5 million for the year ended December 31, 2010, compared to \$6.9 million in the prior year. The increase in distribution expenses in 2010 when compared to the prior year was primarily due to higher vehicle fuel costs, as well as increased labor-related costs and vehicle lease expense, as we added additional drivers and vehicles to service new customer routes. The increase in vehicle fuel costs was caused by the increase in diesel fuel costs and miles driven to service new customer routes.

Selling and Administrative Expenses

Selling and administrative expenses decreased \$244,000, or 1.5%, to \$16.4 million for the year ended December 31, 2010, compared to \$16.6 million in the prior year. The decrease in selling and administrative expenses in 2010 is primarily attributable to the extra week of operations in fiscal 2009 (our 53-week year end), lower other professional fees of \$274,000, lower severance-related costs of \$206,000 primarily due to the departure of a former officer in 2009, and lower payroll-related costs of \$114,000, which were partially offset by higher group purchasing organization (GPO) related marketing and administrative fees of \$208,000, as well as \$120,000 of costs incurred in the fourth quarter relating to the unsolicited expression of interest from a potential acquirer.

Interest Expense

For the year ended December 31, 2010, interest expense increased \$83,000, or 13.4%, to \$702,000, compared to \$619,000 in the prior year. The increase in interest expense is primarily due to higher interest rates as well as generally higher average outstanding balances.

Other Income

Other income was \$361,000 for the year ended December 31, 2010, primarily as a result of rental income, which is essentially the same as the prior year. In 2007, we entered into an agreement to lease to a third party a portion of our corporate headquarters under a non-cancelable operating lease.

Income Tax Expense

Our effective tax rate is a function of our income or loss before taxes and statutory tax rates, as well as minimum taxes, in the various jurisdictions in which we operate. Income tax expense (benefit) is a function of our net income or loss, effective tax rate and valuation allowances. Our effective tax rate for 2010 was 6.8%, compared to 2.2% for 2009, principally because of a valuation allowance recorded in 2010 to reduce certain deferred tax assets and the reduced level of loss in 2010.

Net loss Per Common Share

We recorded a net loss per common share of \$0.24 on a basic and diluted per share basis for 2010 compared with a net loss per common share of \$0.58 in 2009.

Year ended December 31, 2009 compared to year ended December 31, 2008

Revenues

Revenues increased \$1.4 million, or 1.5%, to \$98.4 million for the year ended December 31, 2009, compared to \$97.0 million for the year ended December 31, 2008. The increase in revenues is primarily attributable to the growth of our management of instrumentation and central sterilization department service offering and an extra week of operations in fiscal 2009, partially offset by industry pricing trends. Also, our 2008 revenues were favorably impacted by the reversal of an accrued customer discount of \$440,000 that was not realized.

Gross Profit

Gross profit decreased \$1.3 million, or 6.1%, to \$20.1 million for the year ended December 31, 2009 compared to \$21.4 million for the prior year. As a percentage of revenues, gross profit decreased by 1.7 percentage points to 20.4% for the year ended December 31, 2009 compared to 22.1% for the prior year. The decrease in gross profit was primarily due to our reusable surgical product loss being higher than normal in our

Tampa facility by approximately \$500,000, as well as product loss recognized in 2009 that was not previously captured by our information system in a prior year. As part of our efforts to reduce the level of loss and scrap costs, we performed additional operational reviews of the reusable surgical product usage during the third quarter of 2009, which resulted in identification of additional losses that were not known at January 1, 2009. The amount of the adjustments related to periods prior to January 1, 2009 that were recognized in the three months ended September 30, 2009 decreased gross profit by \$591,000.

Distribution Expenses

Distribution expenses decreased \$294,000, or 4.1%, to \$6.9 million for the year ended December 31, 2009 as compared to \$7.2 million in the prior year primarily due to lower fuel costs, partially offset by an extra week of operations in fiscal 2009.

Selling and Administrative Expenses

Selling and administrative expenses increased \$318,000, or 2.0%, to \$16.6 million for the year ended December 31, 2009 compared to \$16.3 million in the prior year. The increase in selling and administrative expenses for 2009 is primarily attributable to the extra week of operations in fiscal 2009 (our 53-week year end), as well as higher marketing costs and bank fees, partially offset by lower stock option expense. Additionally, selling and administrative expenses in 2008 were lower as a result of a reduction in the provision for doubtful accounts by \$759,000, primarily as a result of a customer that made substantial payment of past due amounts and brought its account current.

Interest Expense

For the year ended December 31, 2009, interest expense decreased \$458,000, or 42.5%, to \$619,000 compared to \$1.1 million in the prior year. The lower expense when compared to 2008 is due primarily to generally lower interest rates and lower average outstanding balances under our revolving credit facility during the year. During the third quarter of 2009, we converted \$4.0 million of our outstanding line of credit and \$4.0 million of our term loan to a LIBOR-based rate which had a lower interest rate compared to the Prime based rate.

Other Income

Other income was \$367,000 for the year ended December 31, 2009, primarily as a result of rental income, which is essentially the same as the prior year. Effective March 1, 2007, we entered into an agreement to lease to a third party a portion of our corporate headquarters under the terms of a non-cancelable operating lease.

Income Tax Expense (Benefit)

Our effective tax rate is a function of our income or loss before taxes and statutory tax rates, as well as minimum taxes, in the various jurisdictions in which we operate. Income tax expense (benefit) is a function of our net income or loss, effective tax rate and valuation allowances. The effective tax rate for the year ended December 31, 2009 was 2.2% compared to (7.7)% for the year ended December 31, 2008. The primary reason for the lower effective tax rate for the year ended December 31, 2009, as compared to the same period last year is primarily attributable to a valuation allowance recorded in 2009 to reduce certain deferred tax assets to the amount that will more likely than not be realized and a deferred tax adjustment recorded during the fourth quarter 2009.

Net loss Per Common Share

We recorded a net loss per common share of \$0.58 on a basic and diluted per share basis for 2009 compared with a net loss per common share of \$0.40 in 2008.

Liquidity and Capital Resources

Our principal sources of capital have been cash flows from operations and borrowings under our revolving credit facility. As of December 31, 2010, we had approximately \$1.3 million in cash and cash equivalents, compared to approximately \$802,000 as of December 31, 2009. In addition, as of December 31, 2010, we had \$9.6 million available under our credit facility, after accounting for amounts outstanding under the credit facility, certain letters of credit principally associated with our bonds payable (described below) and a general reserve.

Net cash provided by operating activities for 2010 was \$8.5 million as compared to \$10.3 million last year. Net cash from operations during 2010 primarily related to depreciation and amortization expense of \$8.8 million, an increase in accounts payable of \$1.3 million, the provision for slow moving reusable surgical products and shrinkage of \$1.2 million and stock-based compensation expense of \$636,000, which was partially offset by a decrease in employee-related and other accrued expenses of \$833,000, an increase in our accounts receivable of \$682,000, and our net loss of \$1.6 million. When compared to cash from operations during 2009, the decrease is primarily attributable to the decrease in inventories in 2009, as well as the decrease in our provision for slow moving reusable surgical products and shrinkage. The decrease in inventories in 2009 is the result of the Co-Marketing Agreement with Cardinal Health, as we no longer carry the same levels of raw materials and finished goods and we no longer have work in process. The decrease in the provision for slow moving reusable surgical products and shrinkage and lost products in 2010 when compared to 2009.

Net cash used in investing activities in 2010 was \$7.2 million as compared to \$7.5 million in 2009. Cash used in investing activities primarily related to purchases of property, plant and equipment and reusable surgical products. We estimate that our expenditures in 2011 for property, plant and equipment will be approximately \$2.5 million and reusable surgical products expenditures will be approximately \$7.0 million, an amount that may fluctuate depending on the growth of our business. We expect instrument revenues will continue to grow and, as a result, we expect our instrument inventory will continue to grow. We estimate that our expenditures in 2011 for instrument inventory will be approximately \$1.2 million.

As noted under *Item 1. Business Products*, as a result of Gore s intent to exit the medical fabrics market, we intend to make advance purchases of fabric to bridge the process of transitioning to another supplier. We anticipate this purchase will cause us to incur between \$10 million and \$13 million of capital expenditures in 2012, which we intend to finance through our renewal or replacement credit facility. There is no assurance that we will be able to secure financing on acceptable terms, if at all.

Net cash used in financing activities in 2010 was \$793,000 compared to \$2.5 million in 2009. Cash used in financing activities was primarily a result of slightly higher repayments on our outstanding notes and mortgage payable, partially offset by our borrowings on our notes payable.

Credit Facility

On August 7, 2008, we entered into a three-year \$24.3 million credit facility (the Credit Facility), which includes a revolving loan of up to \$20 million for working capital, letters of credit, capital expenditures and other purposes, and a \$4.3 million term loan, which replaced a prior mortgage loan on our Tampa headquarters. Actual amounts available under the revolving loan are determined by a defined borrowing base, which primarily relates to outstanding receivables, inventories and reusable surgical products. As a result of the borrowing base calculation as of December 31, 2010, we had \$17.3 million available for advances, of which we used \$7.7 million of the revolving loan, including \$5.6 million of advances, \$2.0 million of availability for letters of credit to support our bonds and self-insurance policies, and \$0.1 million to maintain a required reserve. As of December 31, 2010, we had \$3.8 million outstanding on the term loan, which is classified as a mortgage payable. The term loan amortizes based on a 20-year schedule, with the remaining principal balance due when the Credit Facility expires on August 7, 2011. The Credit Facility is secured by substantially all of our assets.

On March 30, 2010, the Credit Facility was amended to require us to maintain a minimum tangible net worth covenant of at least \$35 million through December 31, 2010 and \$37.5 million thereafter, and to set the fixed charge coverage ratio as no less than 0.90 to 1.00 through August 31, 2010 and 1.10 to 1.00 thereafter. As of December 31, 2010, we were in compliance with all the financial and non-financial covenants under the amended credit facility. As of January 1, 2011, the tangible net worth requirement will increase, as noted above, and based on our current projections we likely will not be in compliance with the tangible net worth requirement in the first quarter of 2011. There can be no assurance that our lender will issue a waiver.

As amended, the interest rate on the revolving loan varies between 250 and 300 basis points over LIBOR or between 150 and 200 basis points over the Prime Rate, depending on the level of the fixed charge coverage ratio. Interest on the term loan varies between 275 and 325 basis points over LIBOR or between 175 and 225 basis points over the Prime Rate, depending on the level of the fixed charge coverage ratio. The type of interest rate is an election we periodically make. As of December 31, 2010, \$5.5 million of the outstanding revolving loan balance was based on LIBOR plus 3.00% (3.375% at December 31, 2010) and the remaining outstanding balance of \$0.1 million was at the Prime Rate plus 2.00% (5.25% at December 31, 2010). As of December 31, 2010, \$3.6 million of the outstanding term loan was based on LIBOR plus 3.25% (3.625% at December 31, 2010) and the remaining outstanding balance of approximately \$0.2 million was at the Prime Rate plus 2.25% (5.50% at December 31, 2010).

The Credit Facility includes typical provisions restricting us from paying dividends, incurring additional debt, making loans and investments, encumbering our assets, entering into a business outside our current operations, or entering into certain merger, consolidation, or liquidation transactions.

Our current Credit Facility expires on August 7, 2011. We are in discussions with our current lender as well as other lenders in regards to establishing a new long-term credit facility. We intend to enter into a new credit facility agreement prior to the expiration of the current Credit Facility. Although it is difficult for us to predict our future liquidity needs with certainty, our continued access to a credit facility is an essential requirement for our continued operations.

Bonds and Insurance Financing

We have outstanding public bonds that we issued to fund the construction of two of our reusable processing facilities. Interest expense on these bonds adjusts based on rates that approximate LIBOR (0.34% at December 31, 2010). Starting in 2004, we began amortizing the bonds through quarterly payments of \$165,000. A balloon principal payment of \$3.1 million is due on the bonds in 2014. The bonds are secured by the two reusable processing facilities and backed by letters of credit issued under the Credit Facility. The letters of credit must be renewed in January of each year through maturity in 2014 and we have complied with this requirement.

In October 2008, \$6.0 million of the bonds were tendered. The holders of the tendered bonds were paid from draws against the letters of credit under our Credit Facility, and will be reflected as outstanding notes payable until they are remarketed. Under the terms of the indentures relating to the bonds, the tendered bonds can be remarketed at any time prior to their maturity in 2014. Letters of credit issued by our lenders for amounts totaling \$7.2 million secure these bonds; however, only \$520,000 of the letters of credit are outstanding as of December 31, 2010 as a result of the bonds being tendered.

Contractual Obligations

Our contractual cash obligations for future minimum payments, including interest, under our notes payable to bank, bonds payable, mortgage and operating leases as of December 31, 2010, are as follows:

Payments due by period (000 s)

TotalLess than 1 year2-3 years4-5 years