STERICYCLE INC Form 10-K March 06, 2006

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 OF 1934 For the fiscal year ended December 31, 2005 or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to

> Commission File Number 0-21229 Stericycle, Inc. (Exact name of Registrant as Specified in its Charter)

Delaware

36-3640402

(State or Other Jurisdiction of Incorporation or Organization) (I.R.S. Employer Identification Number)

28161 North Keith Drive Lake Forest, Illinois 60045

(Address of Principal Executive Offices including Zip Code)

(847) 367-5910 (Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.01 par value (title of class)

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes o No b

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 b No o

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes þ No o

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

The aggregate market value of voting and non-voting common equity held by non-affiliates computed by reference to the price at which common equity was last sold as of the last business day of the registrant s most recently completed second fiscal quarter (June 30, 2005) was: \$2,147,249,555.

On February 27, 2006, there were 44,002,862 shares of the Registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Items 10, 11, 12 and 13 of Part III of this Report is incorporated by reference from the Registrant s definitive Proxy Statement for the 2006 Annual Meeting of Stockholders to be held on May 3, 2006.

Stericycle, Inc.

2005 ANNUAL REPORT ON FORM 10-K

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PART I

Item 1. Business

Unless the context requires otherwise, we, us or our refers to Stericycle, Inc. and its subsidiaries on a consolidated basis.

Company Overview

Our business is the management of medical waste, infection control and pharmaceutical returns and the provision of related compliance services. Our product and service offerings include:

our industry-leading Stericycle medical waste management services;

our Bio Systems® sharps management services that reduce the risk of needle sticks in hospitals;

our Steri-Safe® OSHA and HIPPA compliance programs;

an assortment of products for infection control; and

our Direct Return[®] pharmaceutical returns and product recall management services under the *Stericycle Pharmaceutical Services* unit.

We are the largest regulated medical waste management company in North America, serving approximately 333,000 customers throughout the United States, Puerto Rico, Canada, Mexico and the United Kingdom. In North America we have a fully integrated, national medical waste management network. Our network includes 45 treatment/collection centers and 105 additional transfer/collection sites. We use this network to provide a broad range of services to our customers. Our medical waste treatment technologies include our proprietary electro-thermal-deactivation system, or ETD, as well as traditional methods such as autoclaving and incineration. In the United Kingdom we have a fully integrated waste management network, which includes 12 treatment/collection centers and two additional transfer/collection sites.

We also serve pharmacies, distributors and manufacturers of pharmaceutical products by managing the return and disposal of expired or surplus pharmaceutical products and by managing the recall of pharmaceutical products being recalled by the manufacturer.

In addition, we offer consulting and regulatory compliance services in areas that are related to our medical waste and pharmaceutical returns services.

We benefit from significant customer diversification, with no single customer accounting for more than 2% of total revenues, and our top 10 customers accounting for approximately 8% of total revenues. Our two principal groups of customers include approximately 325,000 small medical waste generators such as outpatient clinics, medical and dental offices and long-term and sub-acute care facilities and approximately 7,700 large medical waste generators such as hospitals, blood banks and pharmaceutical manufacturers.

Industry Overview

Since the 1980s, government regulation has increasingly required the proper handling and disposal of the medical waste generated by the health care industry. Regulated medical waste is generally considered any medical waste that can cause an infectious disease, including single-use disposable items, such as needles, syringes, gloves and other medical supplies; cultures and stocks of infectious agents; and blood products.

We believe that the United States market for our regulated medical waste services is approximately \$3.0 billion and in excess of \$10.0 billion globally. Industry growth is driven by a number of factors. These factors include:

Pressure To Reduce Healthcare Costs. The health care industry is under pressure to reduce costs and improve efficiency. We believe that our services can help health care providers reduce costs by reducing their handling and compliance costs, reducing their potential liability related to employee exposure to blood borne

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pathogens and other infectious material, and reducing the amount of time and money invested in infection control and compliance.

Shift to Off-Site Treatment. We believe that managed care and other health care cost-containment pressures are causing patient care to continue to shift from institutional higher-cost acute-care settings to less expensive, smaller, off-site treatment alternatives. Many common diseases and conditions are now being treated in smaller non-institutional settings. We believe that these non-institutional off-site health care expenditures will continue to grow as cost-cutting pressures increase.

Aging of U.S. Population. The average age of the U.S. population is increasing. As people age, they typically require more medical attention and a wider variety of tests and procedures. In addition, as technology improves more tests and procedures become available. All of these factors lead to increased medical waste.

Environmental and Safety Regulation. We believe that many businesses that are not currently using outsourced medical waste services are unaware either of the need for proper training of employees or the U.S. Occupational Safety and Health Administration, or OSHA, requirements regarding the handling of medical waste. These businesses include manufacturing facilities, schools, restaurants, casinos, hotels and generally all businesses where employees may come into contact with blood borne pathogens. In addition, home health care is currently unregulated and may become subject to similar blood borne pathogen regulations in the future.

The medical waste management industry is subject to extensive regulation beyond the Medical Waste Tracking Act or MWTA. For example, the stringent Clean Air Act regulations adopted in 1997 limit the discharge into the atmosphere of pollutants released by medical waste incineration. These regulations have increased the costs of operating medical waste incinerators and have resulted in significant closures of on-site treatment facilities, thereby increasing the demand for off-site treatment services. In addition, OSHA has issued regulations concerning employee exposure to blood borne pathogens and other potentially infectious materials that require, among other things, special procedures for the handling and disposal of medical waste and annual training of all personnel who may be exposed to blood and other body fluids. These regulations underlie the expansion of our service offerings to include OSHA compliance services for health care providers.

The pharmaceutical returns (or reverse distribution) industry arose in response to the need to facilitate the return of unused, expired or recalled drugs to the manufacturer for credit and proper destruction. *Stericycle Pharmaceutical Services* provides pharmaceutical returns management, recall services and pharmaceutical product disposal services to pharmacies, distributors and manufacturers of pharmaceutical products.

We operate our pharmaceutical services business from five centers located in Florida, Georgia, Illinois, Indiana and New Jersey.

Competitive Strengths

We believe that we benefit from the following competitive strengths, among others:

Broad Range of Services. We offer our customers a broad range of services to help them develop internal systems and processes, which allow them to manage their medical waste efficiently and safely. For example, we have developed programs to help train our customers employees on the proper methods of handling medical waste in order to reduce potential employee exposure. Other services include those designed to help clients ensure and maintain compliance with OSHA regulations, sharps management services (*Bio Systems*), infection control tracking and pharmaceutical returns. We also supply specially designed containers for use by most of our large account customers, including our Steri-Tub[®] container, a reusable leak and puncture-resistant container, made from recycled plastic, which we

developed and patented.

Established National Network. In North America our 45 medical waste treatment/collection centers and five pharmacy returns centers in 28 states, Puerto Rico, Canada and Mexico give us a national network in the regulated medical waste and significant scale in the pharmaceutical services industry. The extensive federal, state and local laws and regulations governing the regulated medical waste industry and the pharmaceutical

services industry typically require some type of governmental approval for new facilities. We have significant experience in obtaining and maintaining these permits, authorizations and other types of governmental approvals. We believe that a network similar in scale and scope to ours would be extremely expensive and time-consuming for a national competitor to develop.

Low-Cost Operations. We are often the low-cost provider of medical waste management within the areas we serve. Our low costs result from our vertically integrated network and broad geographic presence.

Diverse Customer Base and Revenue Stability. We have developed strong contracts and service agreements with a diverse network of established customers. Our top 10 medical waste customers account for approximately 8% of our medical waste revenues, and no single customer accounts for more than 2% of revenues. We are also generally protected from regulatory changes and other factors, which affect our costs, because our medical waste contracts typically contain provisions that allow us to adjust our prices to reflect any additional costs caused by changes in regulations or any other increases in our operating costs.

Strong Sales Network and Proprietary Database. We use both telemarketing and direct sales efforts to obtain new medical waste customers. In addition, we have a large database of potential new small account customers, which we believe gives us a competitive advantage in identifying and reaching this higher-margin sector.

Experienced Senior Management Team. Our five most senior executives collectively have over 100 years of management experience in the health care, consumer and waste management industries.

Business Strategy

Our goals are to strengthen our position as a leading provider of integrated medical waste, pharmaceutical services and compliance services and to continue to improve our profitability. Components of our strategy to achieve these goals include:

Improve Margins. We intend to continue actively to work to improve our margins by increasing our base of small account customers and focusing on service strategies that more efficiently meet the needs of our large account customers. We have successfully raised the percentage of our revenues from small account customers from 33% of domestic revenues in the fourth quarter of 1996 to 63% in the fourth quarter of 2005, which has contributed to an increase in our operating income margins. Small account customers typically do not produce a sufficient volume of regulated medical waste on an individual basis to justify capital expenditures on their own waste treatment facilities or the expense of hiring regulatory compliance personnel. We believe that the number of small account customers and the opportunities for the sale of ancillary services and products to both large and small account customers will continue to grow.

Expand Range of Services and Products. We believe that we have the opportunity to expand our business by increasing the range of products and services that we offer to our existing medical waste customers. For example, through our Steri-Safesm program, we now offer OSHA compliance services to health care providers, and our mercury mail-back program enables customers to manage waste that should be handled separately. Our acquisition of Scherer Healthcare, Inc. in January 2003 provided the opportunity to market its *Bio Systems* sharps management program in new geographic service areas, and we continually research and test new products and service offerings for our customers. After establishing our first center in Lake Forest, Illinois in 2003, we have expanded our pharmaceutical returns and recall business through our acquisitions in 2005 of Automated Health Technologies, Universal Solutions, Inc., L.L. Horizons, Inc. and NNC Group, LLC.

Seek Complementary Acquisitions. As described below, we actively seek strategic opportunities to acquire businesses that expand our national and international network of treatment centers and increase our customer and product base. We also consider acquisitions that can leverage the skills and infrastructure that we have in place, for example, our acquisition of the *Bio Systems* sharps management program. We believe that strategic acquisitions can enable us to gain operating efficiencies through increased utilization of our service infrastructure as well as to expand our services offered to our customers and to expand the product offerings and geographic service areas in which we operate.

Acquisitions

Evaluation and Integration. Our management team has substantial experience in evaluating potential acquisition candidates and determining whether a particular medical waste management or related service business can be successfully integrated into our business.

We have established an efficient procedure for integrating newly acquired companies into our business while minimizing disruption of our operations. Once a business is acquired, we implement programs designed to improve customer service, sales, marketing, routing, equipment utilization, employee productivity, operating efficiencies and overall profitability.

Acquisitions History. We completed a total of 100 acquisitions from 1993 through 2005, including nine domestic medical waste management businesses in 2005. The most significant of these was our acquisition in November 1999 of the medical waste business of Browning Ferris Industries, Inc. (BFI) in the United States, Canada and Puerto Rico. At the time, BFI was the largest provider of regulated medical waste services in the United States.

In 2005, our majority owned subsidiary in Mexico completed the acquisition of seven medical waste management companies in Mexico, and our United Kingdom subsidiary completed two acquisitions in the United Kingdom.

In addition, in 2005 we acquired four pharmaceutical returns and product recall businesses: Automated Health Technologies, Inc., Universal Solutions, Inc., L.L. Horizons, Inc and NNC Group, LLC.

Collection and Transportation. We consider efficiency of collection and transportation to be a critical element of our medical waste operations because it represents the largest component of our operating costs.

The use of transfer stations is an important component of our collection and transportation operations. We utilize transfer stations in a hub and spoke configuration, which allows us to expand our geographic service area and increase the volume of medical waste that can be treated at a particular facility.

As part of our collection operations, we supply specially designed containers for use by most of our large account customers and many of our larger small account customers. We have developed a comprehensive line of reusable leak and puncture-resistant plastic containers. The containers enable our customers to reduce costs by reducing the number of times that materials and supplies are handled, eliminate the cost of corrugated boxes and potentially reduce liability resulting from human contact with medical waste. In order to maximize regulatory compliance and minimize potential liability, we will not accept medical waste unless it is properly packaged by customers in containers that we have either supplied or approved.

Treatment and Disposal. Upon arrival at a treatment facility, containers or boxes of medical waste are typically scanned to verify that they do not contain any unacceptable substances like radioactive material. Any container or box that is discovered to contain unacceptable waste is returned to the customer and the appropriate regulatory authorities are informed. After inspection, the waste is treated using one of our various treatment technologies. Upon completion of the particular process, the resulting waste or incinerator ash is transported for resource recovery, recycling or disposal in a landfill operated by third parties unaffiliated with us. We do not own any landfills. After the plastic containers such as our Steri-Tub® or *Bio Systems* containers have been emptied, they are washed, sanitized and returned to customers for re-use.

Consulting Services. Before our trucks pick up medical waste, our integrated waste management approach attempts to build in efficiencies that will yield logistical advantages. For example, our consulting services can assist our customers in reducing the volume of medical waste that they generate. In addition, we provide customers with the

documentation necessary for compliance with applicable regulations, which, if they complete the documentation properly, will reduce regulatory interruptions to their businesses to verify compliance.

Documentation. We provide complete documentation to our customers for all medical waste that we collect, including the name of the generator, date of pick-up and date of delivery to a treatment facility. We believe that our documentation system meets all applicable federal, state and local regulations including those mandated by the U.S. Department of Transportation, or DOT.

Marketing and Sales

Marketing Strategy. We use both telemarketing and direct sales efforts to obtain new customers.

Our more than 1,300 drivers also may participate in our marketing and sales efforts by actively soliciting small account customers while they service their routes.

Small Account Customers. We have targeted small account customers as a growth area of our medical waste business. We believe that these customers offer a higher relative profit potential on small revenue per customer compared to other potential customers. We believe that these customers view the potential risks of non-compliance with applicable state and federal medical waste regulations as disproportionate to the cost of the services that we provide. We believe that this factor has been the basis for the significantly higher gross margins that we have achieved with our small account customers relative to our large account customers.

Steri-Safesm. Our Steri-Safesm OSHA compliance program provides an integrated medical waste management and compliance-assistance service for small account customers and other healthcare providers who typically lack the internal personnel and systems to comply with OSHA blood borne regulations. Customers for our Steri-Safesm service pay a predetermined subscription fee in advance for medical waste collection and treatment services and can also choose from available packages of training and education services and products designed to help them to comply with OSHA regulations. Approximately 95,000 small account customers are enrolled in this program. We believe that the implementation of our Steri-Safesm service will provide us with new and enhanced opportunities to leverage our existing customer base through the program s prepayment structure and diversified product and service offerings.

We also operate several mail-back programs through which we can reach small account customers located in outlying areas that would be inefficient to serve using our regular route structure. Mail-back programs are also used in home care patient settings where there is a focus on reducing the potential injuries to workers at recycling centers or other solid waste handling locations.

Large Account Customers. We believe that we have been successful in serving large account customers and plan to continue to serve those customers as long as satisfactory levels of profitability can be maintained. Our marketing and sales efforts to large account customers are conducted by full-time account executives whose responsibilities include identifying and attracting new customers and serving our existing account base of approximately 7,700 large account customers. In addition to securing new contracts, our marketing and sales personnel provide consulting services to our health care customers, assisting them in reducing the amount of medical waste that they generate, training their employees on safety issues and implementing programs to audit, classify and segregate medical waste in a proper manner.

Our *Bio Systems* sharps management offering can enhance our revenue and margin potential per account. The *Bio Systems* service offering can help our customers eliminate plastic and cardboard from their waste stream while providing a safe and cost effective way for them to deal with the disposal of their sharp objects (such as needles, syringes, etc.).

Our *Stericycle Pharmaceutical Services* unit can streamline manufacturer return credits, recalls, enhance inventory management capabilities and deliver online business information related to expired medications.

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We believe that the implementation of more stringent Clean Air Act and other federal regulations directly and indirectly affecting medical waste will continue to enable us to improve our marketing efforts to large account customers because the additional costs that they will incur to comply with these regulations will make the costs of our services more attractive, particularly in the event they use their own incinerators.

National Accounts. As a result of our extensive geographic coverage, we are capable of servicing national account customers (i.e., customers requiring medical waste disposal services at various geographically dispersed locations). We will continue to selectively focus on national accounts.

Contract and Service Agreements. We have long-term contracts with substantially all of our customers. We negotiate individual service agreements with each large account and small account customer. Although we have a standard form of agreement, particularly for small account customers, terms may vary depending upon the customer s service requirements and the volume of medical waste generated and, in some jurisdictions, requirements imposed by statute or regulation. Service agreements typically include provisions relating to the types of containers, frequency of collection, pricing, treatment of waste and documentation for tracking purposes. Each agreement also specifies the customer s obligation to pack its medical waste in approved containers. Substantially all of our agreements with small account customers contain automatic renewal provisions.

International

In 1998, we formed Medam S.A. de C.V., or Medam, a Mexican joint venture company, in which we now have a 64.5% interest, to utilize our ETD technology to treat medical waste primarily in the Mexico City market. From 2001 through 2004, Medam completed the acquisition of five medical waste businesses in Mexico and, as noted, in 2005, it completed seven acquisitions.

In 1999, we established a joint venture in Argentina, Medam, B.A. Srl, in which we have a 37.5% interest, to utilize our ETD technology to treat medical waste primarily in the Buenos Aires market.

In 2000, we entered into agreements with Aso Cement Co., Ltd and Aso Mining Co., Ltd, to establish an ETD treatment facility in Japan. In 2002, we entered into agreements with Medical Safety Systems of Hokkaido, Japan to establish a second ETD treatment facility in Japan, and in 2003, we entered into agreements with Shiraishi-Sogyo Co. Ltd. of Tochigi, Japan to establish a third ETD treatment facility. Under these agreements, we supplied ETD treatment equipment and provide ongoing consulting assistance in the operation of the equipment.

In 2001, we concluded an agreement with SteriCorp Limited, an Australian company, under which we provided financing to SteriCorp through the purchase of convertible notes, licensed our ETD technology to it for use in Australia and certain other countries, and agreed to sell to it an ETD processing line and assist in its installation.

In 2004, we completed our first acquisition in Europe with the purchase of White Rose Environmental, Ltd in Leeds, England. In 2005, our United Kingdom subsidiary completed the acquisitions of Healthcare Waste Limited, which operated a medical waste business in England, and Indigo Equity Holdings Limited (formerly known as Waste Solutions, Inc.), which operated a medical waste business in England and Wales.

Treatment Technologies

We currently use both non-incineration technologies (our proprietary ETD technology and autoclaving) and incineration technologies for treating regulated medical waste.

Stericycle was founded on the belief that there was a need for safe, secure, and environmentally responsible management of regulated medical waste. From our beginning we have championed the use of non-incineration, alternate treatment technologies such as our patented ETD process. While we recognize that some state regulations as currently in force mandate that some types of medical waste must be incinerated, we also know from years of experience working with our customers that there are ways to reduce the amount of waste that is ultimately incinerated. The most effective strategy that we have seen involves comprehensive education of our customers in

waste minimization and segregation. Working in cooperation with our customers, we have made tremendous strides in shifting away from incineration and moving towards alternate treatment technologies. At the end of 2005, incineration constituted less than 9% of our treatment capacity in North America.

Autoclaving. Autoclaving treats medical waste with steam at high temperature and pressure to kill pathogens. Autoclaving alone does not change the appearance of waste, and some landfill operators may not accept recognizable medical waste, but autoclaving may be combined with a shredding or grinding process to render the medical waste unrecognizable.

ETD Treatment Process. ETD includes a system for grinding medical waste. After grinding, ETD uses an oscillating field of low-frequency radio waves to heat medical waste to temperatures that destroy pathogens such as viruses, bacteria, fungi and yeast, without melting the plastic content of the waste.

We believe that ETD offers advantages over many other methods of treating medical waste. We believe that it is easier to get permits for ETD facilities than for incineration facilities because ETD does not produce regulated air or water emissions. ETD facilities also can be more cost-effective to construct than incinerators or autoclaves with shredding capability. ETD also renders medical waste unrecognizable and thus more acceptable for landfills and reduces the volume of waste as well.

Incineration. Incineration burns medical waste at elevated temperatures and reduces it to ash. Incineration reduces the volume of waste, and it is the recommended treatment and disposal option for some types of medical waste such as anatomical waste or residues from chemotherapy procedures. Air emissions from incinerators can contain certain byproducts, which are subject to federal, state and, in some cases, local regulation. In some circumstances the ash byproduct of incineration may be regulated.

Competition

The medical waste services industry is highly competitive, and barriers to entry into the collection and disposal business are very low. The industry consists of many different types of service providers, including a large number of regional and local companies. Another major source of competition is the on-site treatment of medical waste by some large-quantity generators, particularly hospitals.

In addition, we face potential competition from businesses that are attempting to commercialize alternate treatment technologies or products designed to reduce or eliminate the generation of medical waste, such as reusable or degradable medical products.

We compete for service agreements primarily on the basis of cost-effectiveness, quality of service and geographic location. We also compete by trying to demonstrate to customers that we can do a better job in reducing their potential liability. Our ability to obtain new service agreements may be limited by the fact that a potential customer s current vendor may have an excellent service history or a long-term service contract or may offer prices to the potential customer that are lower than ours.

Governmental Regulation

The medical waste management industry is subject to extensive and frequently changing federal, state and local laws and regulations. This statutory and regulatory framework imposes compliance burdens and risks on us, including requirements to obtain and maintain government permits. These permits grant us the authority, among other things:

to construct and operate treatment and transfer facilities;

to transport medical waste within and between relevant jurisdictions; and

to handle particular regulated substances.

Our permits must be periodically renewed and are subject to modification or revocation by the regulatory authority. We are also subject to regulations that govern the definition, generation, segregation, handling, packaging, transportation, treatment, storage and disposal of medical waste. We are also subject to extensive regulations designed to minimize employee exposure to medical waste. In addition, we are subject to foreign laws and regulations.

Federal Regulation. Four federal agencies have authority over medical waste. These agencies are the U.S. Environmental Protection Agency or EPA, Occupational Safety and Health Administration or OSHA,

Department of Transportation or DOT and the U.S. Postal Service. These agencies regulate medical waste under a variety of statutes and regulations.

Medical Waste Tracking Act of 1988. In the late 1980s, the EPA outlined a two-year demonstration program pursuant to MWTA, which was added to the Resource Conservation and Recovery Act of 1976.

In regulations implementing the MWTA, the EPA defined medical waste and established guidelines for its segregation, handling, containment, labeling and transport. The MWTA demonstration program expired in 1991, but the MWTA established a model followed by many states in developing their specific medical waste regulatory frameworks.

Clean Air Act Regulations. In August 1997, the EPA adopted regulations under the Clean Air Act Amendments of 1990 that limit the discharge into the atmosphere of pollutants released by medical waste incineration. These regulations required every state to submit to the EPA for approval a plan to meet minimum emission standards for these pollutants. See State and Local Regulation. We currently operate six incinerators in the United States. We believe these incinerators are in compliance with applicable state requirements.

Occupational Safety and Health Act of 1970. The Occupational Safety and Health Act of 1970 authorizes OSHA to issue occupational safety and health standards. Various standards apply to certain aspects of our operations, and govern such matters as exposure to blood borne pathogens and other potentially infectious materials.

Resource Conservation and Recovery Act of 1976. The Resource Conservation and Recovery Act of 1976, or RCRA created standards for the generation, transportation, treatment, storage and disposal of solid and hazardous wastes. Medical wastes are currently considered non-hazardous solid wastes under RCRA. However, some substances collected by us from some of our customers, including photographic fixer developer solutions, lead foils and dental amalgam, are considered hazardous wastes.

We use landfills operated by parties unrelated to us for the disposal of treated medical waste from our ETD facilities and for the disposal of incinerator ash and autoclaved waste. We do not own or operate any landfills.

Following treatment, waste from our ETD and autoclave facilities is disposed of as nonhazardous waste. At our incineration facilities, we test ash from the incineration process to determine whether it must be disposed of as hazardous waste.

We employ quality control measures to check incoming medical waste for specific types of hazardous substances. Our customer agreements also require our customers to exclude different kinds of hazardous substances or radioactive materials from the medical waste they provide us. We use a different type of contract for the relatively small number of customers from whom we pick up hazardous wastes.

DOT Regulations. The U.S. DOT has put regulations into effect under the Hazardous Materials Transportation Authorization Act of 1994 which require us to package and label medical waste in compliance with designated standards, and which incorporate blood borne pathogens standards issued by OSHA. Under these standards, we must, among other things, identify our packaging with a biohazard marking on the outer packaging, and our medical waste container must be sufficiently rigid and strong to prevent tearing or bursting and must be puncture-resistant, leak-resistant, properly sealed and impervious to moisture.

Comprehensive Environmental Response, Compensation and Liability Act of 1980. The Comprehensive Environmental Response, Compensation and Liability Act of 1980, or CERCLA, established a regulatory and remedial program to provide for the investigation and cleanup of facilities that have released or threaten to release

hazardous substances into the environment. CERCLA and state laws similar to it may impose strict, joint and several liability on the current and former owners and operators of facilities from which releases of hazardous substances have occurred and on the generators and transporters of the hazardous substances that come to be located at these facilities. Responsible parties may be liable for substantial site investigation and cleanup costs and natural resource damages, regardless of whether they exercised due care and complied with applicable laws and regulations. If we were found to be a responsible party for a particular site, we could be

required to pay the entire cost of the site investigation and cleanup, even though other parties also may be liable. This result would be the case if we were unable to identify other responsible parties, or if those parties were financially unable to contribute money to the cleanup.

United States Postal Service. We have obtained permits from the U.S. Postal Service to conduct our mail-back programs, pursuant to which customers mail approved sharps (needles, knives, broken glass and the like) containers directly to our treatment facilities.

State and Local Regulation. We conduct business in 47 states. Each state has its own regulations related to the handling, treatment and storage of medical waste. Although there are many differences among the various state laws and regulations, many states have followed the medical waste model under the MWTA and have implemented programs under RCRA. In each of the states where we operate a treatment facility or a transfer station, we are required to comply with numerous state and local laws and regulations as well as our operating plan for each site. In addition, many local governments have ordinances, local laws and regulations, such as zoning and health regulations, which affect our operations.

States usually regulate medical waste as a solid or special waste and not as a hazardous waste under RCRA. State definitions of medical waste include:

microbiological waste (cultures and stocks of infectious agents);

pathology waste (human body parts from surgical procedures and autopsies);

blood and blood products; and

sharps.

Most states require segregation of different types of medical waste at the hospital or other location where they were created. A majority of states require that the universal biohazard symbol or a label appear on medical waste containers. Storage regulations may apply to the party generating the waste, the treatment facility, the transport vehicle, or all three. Storage rules seek to identify and secure the storage area for public safety as well as set standards for the manner and length of storage. Many states require employee training for safe environmental cleanup through emergency spill and decontamination plans. Many states also require that transporters carry spill equipment in their vehicles. Those states whose regulatory framework relies on the MWTA model have tracking document systems in place. One state (Washington) regulates the prices that we may charge. We maintain numerous governmental permits and licenses to conduct our business. Our permits vary from state to state based upon our activities within that state and on the applicable state and local laws and regulations.

We believe that we are currently in compliance in all material respects with our permits and applicable laws and regulations, including state requirements regarding air emissions from incinerators.

Foreign Territorial Regulation. We are subject to substantial regulation by the governments of the foreign jurisdictions in which we do business. We believe that we have obtained all permits required by the relevant regulatory authorities.

If we expand our operations into other foreign jurisdictions, we will be required to comply with the laws and regulations of each of those jurisdictions.

Permitting Process. Each state in which we currently operate, and each state in which we may operate in the future, has a specific permitting process.

We have been successful in obtaining permits for our current medical waste transfer, treatment and processing facilities and for our transportation operations. Several of our past attempts to construct and operate medical waste treatment facilities, however, have met with significant community opposition. In some of these cases, we have withdrawn our permit application.

The pharmaceutical returns business is highly regulated, both on the federal and state level.

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Once out-dated or recalled pharmaceutical products have been sorted at our returns center, pharmaceutical products that will be disposed of instead of being returned to their manufacturer may be considered hazardous waste and require handling in compliance with U.S. Food and Drug Administration or FDA, EPA, RCRA and DOT regulations.

Most states have licensing requirements for reverse distributors of pharmaceutical products. We believe we are in compliance with all federal and state licensing requirements applicable to our pharmaceutical services business.

Patents and Proprietary Rights

We consider the protection of our technology to be important to our business. Our policy is to protect our technology by a variety of means, including applying for patents in the United States and in some foreign countries.

We hold 14 United States patents relating to the ETD treatment process and other aspects of processing medical waste. We have filed or have been assigned patent applications in several foreign countries and we have received patents in Australia, Canada, France, Mexico and the United Kingdom.

The term of the first-to-end of our existing United States patents relating to our ETD treatment process will currently end in May 2009 and the term of the last-to-end will currently end in January 2019.

We own federal registrations of the trademarks Steri-Fuel, Steri-Plastic Steri-Tub Direct Return the service mark Stericycle[®] and a service mark consisting of a nine-circle design.

Potential Liability and Insurance

The medical waste industry involves potentially significant risks of statutory, contractual, tort and common law liability claims. Potential liability claims could involve, for example:

cleanup costs;

personal injury;

damage to the environment;

employee matters;

property damage; or

alleged negligence or professional errors or omissions in the planning or performance of work.

We could also be subject to fines or penalties in connection with violations of regulatory requirements.

We carry \$35 million of liability insurance (including umbrella coverage), and under a separate policy, \$10 million of aggregate pollution and legal liability insurance (\$5 million per incident), which we consider sufficient to meet regulatory and customer requirements and to protect our employees, assets and operations. Our pollution liability insurance excludes liabilities under CERCLA. There can be no assurance that we will not face claims under CERCLA or similar state laws resulting in substantial liability for which we are uninsured and which could have a material adverse effect on our business.

Our insurance programs utilize large deductible plans offered by a commercial insurance company. Large deductible plans allow us the benefits of cost-effective risk financing while protecting us from catastrophic risk with specific stop loss insurance limiting the amount of self-funded exposure for any one loss and aggregate stop loss insurance limiting the self-funding exposure for any one year.

Employees

As of December 31, 2005, we had 4,320 full-time and 111 part-time employees (including employees of our subsidiaries). Approximately 347 of our drivers, transportation helpers and plant workers are covered by a total of eight collective bargaining agreements with local unions of the International Brotherhood of Teamsters.

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These agreements expire at various dates from October 2006 to June 2010. We consider our employee relations to be satisfactory.

Website Access

We maintain an Internet website, *http://www.stericycle.com*, providing a variety of information about us. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, that we file with the Securities and Exchange Commission are available, as soon as reasonably practicable after filing, at the investors page on our website, *http://www.stericycle.com/investor.htm*, or by a direct link to our filings on the SEC s free website, *http://www.sec.gov*.

Item 1A. Risk Factors

We are subject to extensive governmental regulation which it is frequently difficult, expensive and time-consuming to comply with.

The medical waste management industry is subject to extensive federal, state and local laws and regulations relating to the collection, transportation, packaging, labeling, handling, documentation, reporting, treatment and disposal of regulated medical waste. Our business requires us to obtain many permits, authorizations, approvals, certificates or other types of governmental permission from every jurisdiction where we operate. We believe that we currently comply in all material respects with all applicable permitting requirements. State and local regulations change often, however, and new regulations are frequently adopted. Changes in the regulations could require us to obtain new permits or to change the way in which we operate under existing permits. We might be unable to obtain the new permits that we require, and the cost of compliance with new or changed regulations could be significant.

Many of the permits that we require, especially those to build and operate treatment plants and transfer facilities, are difficult and time-consuming to obtain. They may also contain conditions or restrictions that limit our ability to operate efficiently, and they may not be issued as quickly as we need them (or at all). If we cannot obtain the permits that we need when we need them, or if they contain unfavorable conditions, it could substantially impair our operations and reduce our revenues.

The handling and treatment of hazardous medical waste carries with it the risk of personal injury to employees and others.

Our business requires us to handle materials that may be infectious or hazardous to life and property in other ways. While we try to handle such materials with care and in accordance with accepted and safe methods, the possibility of accidents, leaks, spills, and acts of God always exists. Examples of possible exposure to such materials include:

truck accidents;

damaged or leaking containers;

improper storage of medical waste by customers;

improper placement by customers of materials into the waste stream that we are not authorized or able to process, such as certain body parts and tissues; or

malfunctioning treatment plant equipment.

Human beings, animals or property could be injured, sickened or damaged by exposure to medical waste. This in turn could result in lawsuits in which we are found liable for such injuries, and substantial damages could be awarded against us.

While we carry liability insurance intended to cover these contingencies, particular instances may occur that are not insured against or that are inadequately insured against. An uninsured or underinsured loss could be substantial and could impair our profitability and reduce our liquidity.

The handling of medical waste exposes us to the risk of environmental liabilities, which may not be covered by insurance.

As a company engaged in medical waste management, we face risks of liability for environmental contamination. The federal Comprehensive Environmental Response, Compensation and Liability Act of 1980, or CERCLA, and similar state laws impose strict liability on current or former owners and operators of facilities that release hazardous substances into the environment as well as on the businesses that generate those substances and the businesses that transport them to the facilities. Responsible parties may be liable for substantial investigation and clean-up costs even if they operated their businesses properly and complied with applicable federal and state laws and regulations. Liability under CERCLA may be joint and several, which means that if we were found to be a business with responsibility for a particular CERCLA site, we could be required to pay the entire cost of the investigation and clean-up even though we were not the party responsible for the release of the hazardous substance and even though other companies might also be liable.

Our pollution liability insurance excludes liabilities under CERCLA. Thus, if we were to incur liability under CERCLA and if we could not identify other parties responsible under the law whom we are able to compel to contribute to our expenses, the cost to us could be substantial and could impair our profitability and reduce our liquidity. Our customer service agreements make clear that the customer is responsible for making sure that only appropriate materials are disposed of. If there were a claim against us that a customer might be legally liable for, we might not be successful in recovering our damages from the customer.

The level of governmental enforcement of environmental regulations has an uncertain effect on our business and could reduce the demand for our services.

We believe that the government s strict enforcement of laws and regulations relating to medical waste collection and treatment has been good for our business. These laws and regulations increase the demand for our services. A relaxation of standards or other changes in governmental regulation of medical waste could increase the number of competitors or reduce the need for our services.

If we are unable to acquire other medical waste businesses, our revenue and profit growth may be slowed.

Historically our growth strategy has been based in substantial part on our ability to acquire other medical waste businesses. We do not know whether in the future we will be able to:

identify suitable businesses to buy;

complete the purchase of those businesses on terms acceptable to us;

improve the operations of the businesses that we do buy and successfully integrate their operations into our own; or

avoid or overcome any concerns expresse