

SHARPS COMPLIANCE CORP
Form 10-K
August 26, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended June 30, 2010

OR

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

COMMISSION FILE NUMBER 001-34269

SHARPS COMPLIANCE CORP.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

74-2657168
(I.R.S. Employer
Identification No.)

9220 Kirby Drive, Suite 500, Houston,
Texas
(Address of principal executive offices)

77054
(Zip Code)

Registrant's telephone number, including area code (713) 432-0300
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
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Common Shares, \$0.01 Par Value

The NASDAQ Capital Market

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

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

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

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Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files).

Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

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

As of December 31, 2009, the aggregate market value of the Registrant's Common Stock held by non-affiliates was approximately \$101.3 million (based on the closing price of \$9.60 on December 31, 2009 as reported by The NASDAQ Capital Market).

The number of common shares outstanding of the Registrant was 14,907,091 as of August 24, 2010.

DOCUMENTS INCORPORATED BY REFERENCE:

- (1) Portions of the Registrant's Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for the Annual Meeting of Shareholders to be held on November 18, 2010 are incorporated by reference into Part III.
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SHARPS COMPLIANCE CORP. AND SUBSIDIARIES
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* This Table of Contents is inserted for convenience of reference only and is not a part of this Report as filed.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains certain forward-looking statements and information relating to the Company and its subsidiaries that are based on the beliefs of the Company's management as well as assumptions made by and information currently available to the Company's management. When used in this report, the words "anticipate", "believe", "expect", "estimate", "project" and "intend" and words or phrases of similar import, as they relate to the Company, its subsidiaries or Company management, are intended to identify forward-looking statements. Such statements reflect the current risks, uncertainties and assumptions related to certain factors, including without limitations, competitive factors, general economic conditions, customer relations, relationships with vendors, governmental regulation and supervision, seasonality, distribution networks, product introductions and acceptance, technological change, changes in industry practices, onetime events and other factors described herein. Based upon changing conditions, should any one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, expected or intended. The Company does not intend to update these forward-looking statements.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Sharps Compliance Corp. was formed in November 1992 as a Delaware corporation. The information presented herein is for Sharps Compliance Corp. and its wholly owned subsidiaries, Sharps Compliance, Inc. of Texas (dba Sharps Compliance, Inc.), Sharps e-Tools.com, Inc. ("Sharps e-Tools"), Sharps Manufacturing, Inc., Sharps Environmental Services, Inc. (dba Sharps Environmental Services of Texas, Inc.) and Sharps Safety, Inc. (collectively, "Sharps" or the "Company"). Unless the context otherwise requires, "Company", "we", "us", and "our" refer to Sharps Compliance Corp. and its subsidiaries.

The Company provides access to all of its filings with the Securities and Exchange Commission ("SEC") through its website www.sharpsinc.com, as soon as reasonably practicable after the reports are filed with the SEC. The filings are also available via the SEC's website at www.sec.gov/edgar/searchedgar/companysearch.html.

COMPANY OVERVIEW

The Company is a leading full-service provider of cost-effective solutions for management of medical waste and unused dispensed medications generated outside of the hospital and large health care facility setting, serving more than 4,000 customers in all 50 states. Our solutions facilitate the proper treatment of numerous types of medical waste and unused dispensed medications, including hypodermic needles, lancets and other devices or objects used to puncture or lacerate the skin, or sharps, and unused dispensed prescription and over-the-counter drugs and medications. We serve customers in multiple markets such as government (federal, state and local), home health care, retail clinics and immunizing pharmacies, pharmaceutical manufacturers, professional offices (physicians, dentists and veterinarians), hospitality (including assisted living facilities, hotels, motels and restaurants), consumers, commercial, industrial and agriculture, and distributors to many of the aforementioned markets. We assist our customers in determining which of our distinct solution offerings best fit their needs for the collection, storage, return transportation and treatment of their or their patients' medical waste and unused dispensed medications. Our differentiated approach provides our customers the flexibility to return and ultimately properly treat their or their patients' medical waste or unused dispensed medications through pre-paid mail services primarily through the United States Postal Service ("USPS"). We believe our easy-to-use and convenient solutions are on average up to 50% less than traditional pick-up services for treatment of medical waste outside of the hospital or large health care facility setting. Furthermore, we provide comprehensive tracking and reporting tools that enable our customers to meet complex medical waste disposal and unused dispensed patient medication compliance requirements. The Company's fully-integrated operations are a key factor leading to its success and continued growth. Since 2008, our revenue growth has

accelerated significantly, increasing from \$12.8 million for the fiscal year ended June 30, 2008 to \$20.3 million for the fiscal year ended June 30, 2009, representing a year-over-year growth rate of 58.1%. Revenues for the fiscal year ended June 30, 2010 were \$39.2 million, up 92.9% from the prior year.

In February 2009, we signed a five year contract (one year , plus four option years) with a major U.S. government agency for a \$40 million program to provide our comprehensive Medical Waste Management System™, or Sharps@MWMSTM, which is a rapid-deployment solution offering designed to provide medical waste collection, storage and treatment in the event of

natural disasters, pandemics, man-made disasters, or other national emergencies. Sharps®MWMSTM is unique in that the solution also offers warehousing, inventory management, training, data and other services necessary to provide a comprehensive solution. The Company received a purchase order for \$28.5 million (\$6.0 million of which was recognized in fiscal year 2009, and \$22.5 million was recognized in the first half of fiscal year 2010). In January 2010, Sharps was awarded the first option year (ending January 31, 2011) valued at approximately \$1.6 million and is expected to be recognized from February 1, 2010 through January 31, 2011. There is expected to be approximately \$1.6 million in revenue in calendar 2010 for the maintenance component of the contract including \$0.8 million in the second half of calendar year 2010. The remaining three option years are expected to be approximately \$3.0 million per contract year. Although, the Company believes the amounts above to be reasonable based upon the underlying contract and its current project plan, it makes no assurances regarding the actual recognition of revenue by fiscal year, which could vary significantly from that noted above. The successful launch of this program demonstrates the attractiveness of our integrated, full-service system that enables government agencies and commercial organizations to completely outsource the planning and execution of their emergency preparedness and disaster relief planning as it relates to medical waste handling and rapid response capabilities. In addition to the Sharps®MWMSTM, we continue to add similar full-service, patient support programs with major pharmaceutical manufacturers whereby we provide a customized Sharps® Recovery System™ (formerly Sharps Disposal by Mail System®) along with fulfillment, inventory management, storage and data services, as well as provide critical patient usage data that assists the manufacturers in assessing drug effectiveness and compliance.

The Centers for Disease Control and Prevention (“CDC”), and the United States Environmental Protection Agency (“EPA”), estimate that there are over three billion used syringes disposed of annually outside of the hospital setting in the United States. In addition, industry experts estimate that as much as 40% of dispensed medications outside of the hospital setting in the United States goes unused, generating an estimated 200 million pounds of pharmaceuticals potentially polluting our environment and placing our citizens at risk for accidental poisonings. We estimate the market for our solutions (outside of the hospital and large health care facilities) to be over \$1 billion per year for medical waste disposal and over \$1 billion for the proper disposal of unused dispensed medications.

We believe that demand for our cost-effective medical waste management solutions has been increasing due to several factors. First, communities, consumers, government and health care and commercial organizations are increasingly becoming aware of the need to properly treat medical waste and unused dispensed medication as federal and state regulatory bodies continue to provide guidance and enact legislation which mandate the proper disposal of medical waste outside the hospital setting to protect the general public and workers from potential exposure to contagious diseases and health and safety risks. Second, there is heightened public awareness and growing demand for influenza vaccines that are driving demand for our solutions both in the short-term to address immediate flu shot needs and in the long-term as the public increasingly obtains its immunizations from retail locations and clinics. Finally, we believe that customers in many of the sectors we serve, such as physicians, dentists, veterinarians, clinics and assisted living facilities, are becoming aware of alternatives to the traditional medical waste pick-up service and the lower cost (estimated average savings of up to 50%) and convenience associated with the Sharps® Recovery System™ (formerly Sharps Disposal By Mail System®).

The patent-pending GREEN Waste Conversion Process™, announced by the Company in April 2010, eliminates medical waste processed for the Company’s customers from going into landfills. The process transforms treated medical waste into a new product called PELLA-DRX™ - a clean, raw material used in the manufacture of industrial resource. Treatment of medical waste has presented major concerns for American society as the vast majority of medical waste is ultimately disposed of in landfills, creating massive liabilities for future generations. The Sharps Waste Conversion Process™ creates a sustainable product and a much needed GREEN method to treat medical waste while creating a useable, safe, and clean raw material. We believe PELLA-DRX™ is ideally suited for energy intensive industries like cement, lime, steel, and power plants.

Our principal executive offices are located at 9220 Kirby Drive, Suite 500, Houston, Texas. Our telephone number at that location is (713) 432-0300. We currently have 67 employees, of which 65 were full time employees. We have manufacturing, assembly, distribution and warehousing operations and our corporate offices in Houston, Texas. We maintain a warehouse facility in College Park, Georgia. We own and operate a facility in Carthage, Texas that houses our processing and treatment operations. The Company is committed to mitigating the effects of medical waste and unused dispensed medications on the environment and our citizens through our environmentally conscious treatment process. We have supplemented our incinerator at this facility with an autoclave system. Autoclaving is a process that treats medical waste with steam at high temperature and pressure to kill pathogens, and is a cost-effective alternative to traditional incineration. The autoclave system is utilized alongside the incinerator for day-to-day operations. We believe that our facility is one of only

ten permitted commercial facilities in the United States capable of treating all types of medical waste and unused dispensed medications.

SOLUTIONS OVERVIEW

We offer a broad line of product and service solutions to manage the medical waste and unused dispensed medications generated by our customers. Our primary solutions include the following:

Sharps® Recovery System™ (formerly Sharps Disposal by Mail System)®: a comprehensive solution for the containment, transportation, treatment and tracking of medical waste generated outside the hospital and large health care facility setting. The Sharps® Recovery System™ includes a securely sealed, leak and puncture resistant sharps container in several sizes ranging from one quart to eighteen gallons; USPS approved shipping carton with pre-paid priority mail postage; absorbent material inside the container that can safely hold up to 150 milliliters of fluids; a red bag for additional containment; and complete documentation and tracking manifest. The Sharps® Recovery System™ is transported to our facility for treatment. Upon treatment or conversion of the waste, we provide electronic proof of receipt and treatment documentation to the customer through our proprietary SharpsTracer™ system.

RxTakeAway™ System: a comprehensive solution that facilitates the proper disposal or treatment of unused dispensed medications and includes the TakeAway™ Environmental Return System and the RxTakeAway™ Recovery and Reporting System. The solution provides a means for individual consumers, communities and facilities, such as pharmacies, assisted living facilities, long-term care facilities, mail-order pharmacies and correctional operations, to manage their unused dispensed medications (other than controlled substances) and consists of customized containment, transportation, destruction or conversion and tracking services. Our proprietary tracking system, MedsTracer™, is designed for tracking unused dispensed medications, which assists pharmaceutical manufacturers in monitoring drug usage and provides critical data for patient management and compliance. Our proprietary tracking system is a highly value-added component of our solution as it enhances pharmaceutical manufacturers' ability to monitor patient drug usage.

Sharps®MWMSTM: a comprehensive solution designed for rapid deployment in emergency situations and features the Sharps® Recovery System™ and TakeAway™ Environmental Return System products combined with warehousing, inventory management, training, data and other services. Sharps®MWMSTM is designed to be an integral part of governmental and commercial emergency preparedness programs for large scale or catastrophic situations such as natural disasters, pandemics, terrorist events, or other national emergencies. Also available with the Sharps®MWMSTM is the Sharps® Rx Recovery and Reporting System, which delivers a turn-key approach to the collection, storage, audit, treatment and documentation of unused dispensed medications. The Medical Waste Management System™ can be used in virtually any location where patients may be treated or shots administered. This system is designed to be portable, allowing medical waste to be collected where it is generated, properly stored, and transported with no special pick-up arrangements.

SharpsTracer™: a comprehensive solution that provides customers with an electronic record of receipt and treatment of their waste to meet regulatory requirements. SharpsTracer™ eliminates the need for traditional paper-based methods of tracking and is designed to enhance customer efficiencies with an automatic evidence of proof of receipt and treatment and market data capabilities. This cost-effective and regulatory compliant tracking and documentation system is an important part of our full-service and comprehensive suite of solutions.

Other Solutions: a wide variety of other logistical products solutions including Pitch-It™ IV Poles, Trip LesSystem®, Sharps® Pump and Asset Return Box, Sharps Secure® Needle Recovery System, Sharps SureTemp Tote®, IsoWash® Linen Recovery System, Biohazard Spill Clean-Up Kit and Disposal System and Sharps Environmental Services.

MARKET OVERVIEW

The CDC and the EPA estimate that there are over three billion used syringes disposed of annually in the United States outside of the hospital setting. We estimate that it would require 30 to 50 million Sharps® Recovery System™ (formerly Sharps Disposal by Mail System®) products to properly dispose of all such syringes, which would equate to a market opportunity of over \$1 billion. We estimate that we have penetrated approximately 1% of this market. Additionally, we believe that there has been and will continue to be a significant increase in self-injectable medications utilized by patients, further increasing the number of syringes used and disposed of in the United States.

Industry experts estimate that approximately 40% of the dispensed medication from four billion annual prescriptions in the United States goes unused, resulting in over 200 million pounds of pharmaceuticals which can adversely affect the environment if disposed of improperly. Most unused dispensed medications are either (i) disposed of untreated in the garbage or flushed down the toilet, ending up in landfills and polluting rivers and water supply systems, lakes and streams with trace amounts of unused dispensed medications or (ii) stored in medicine cabinets that are accessible to children and teenagers. Improperly disposed of or diverted unused dispensed medications have been shown to increase the risk of accidental poisoning of citizens, including children and teenagers. The Company has estimated that the market for the proper disposal of unused dispensed medications outside the hospital setting is over \$1 billion.

We continue to take advantage of the many opportunities in our markets served as communities, consumers, governments and industries become more aware of the need for the proper disposal of medical sharps and unused dispensed medications. There have been several key events that have contributed to this education process, including:

- in December 2004, the EPA issued its new guidelines for the proper disposal of medical sharps, revising the previous guidance that advised patients to dispose of used syringes in the trash;
- in July 2006, the states of California and Massachusetts passed legislation designed to mandate appropriate disposal of sharps waste necessary to protect the general public and workers from potential exposure to contagious diseases and health and safety risks;
- beginning September 1, 2008, California's legislation regulating sharps disposal became effective and began to be enforced, making it illegal to dispose of used sharps through the normal garbage disposal system. Other states, such as Massachusetts and Louisiana, have enacted similar measures that became effective in 2008 and 2009, respectively. Currently, nine states ban the disposal of used syringes in the trash and four states are considering or have introduced similar legislation, while the remaining states operate under the EPA guidance noted above. In August 2008, the United States House of Representatives and Senate introduced bills which, if enacted, would provide for Medicare reimbursement, under part D, for the safe and effective disposal of used needles and syringes; and
- in October 2009, California passed Senate Bill 486 requiring drug companies that market and sell prescribed medications that are routinely injected at home to submit plans to the California Integrated Waste Management Board on or before July 1, 2010 (and annually thereafter) describing how they support safe needle collection and disposal programs for patients using their drugs.
- In 2009 and 2010, the states of Iowa and North Dakota introduced state funded programs to properly dispose of unused medications.

Among the methods of disposal recommended as part of the above noted regulatory actions are mail-back programs such as the solutions we offer. We believe that other states will continue introducing similar legislation and that these developments will drive additional demand for our solutions.

COMPETITIVE STRENGTHS

We believe our competitive strengths include the following:

Leading comprehensive provider of cost-effective medical waste management solutions.

We offer a broad line of solutions to meet the medical and pharmaceutical waste management needs of our customers. Through partnerships with the USPS and UPS, the Company is able to offer our mail-based services at a significantly lower cost to customers as compared to the traditional model of physical pick-up from individual

locations. In contrast to route-based service providers which generally make periodic pick-ups whether customers need them or not and charge higher prices to cover transportation and labor expenses, our mail-based service is a convenient, on-demand, reduced cost option to better serve our customers. Our proprietary SharpsTracer™ tracking and documentation systems provide customers a comprehensive electronic record of receipt and treatment of their waste to meet regulatory requirements. Our Medical Waste Management System™ provides a complete solution for customers seeking to completely outsource the management of all

aspects of their waste management, including warehousing, inventory management, training, and data collection in addition to treatment services. While competitors may attempt to replicate our mail-based return services, we believe the ability to offer such a comprehensive, value-added turnkey solution is a significant competitive advantage.

Environmentally-conscious solution provider.

In addition to providing cost-effective solutions for our customers, the Company is committed to mitigating the effects of medical and pharmaceutical waste on the environment through our treatment processes and marketing efforts. Most used sharps and unused dispensed medications are currently disposed of untreated in the garbage, ending up in landfills and polluting rivers, lakes and streams with trace amounts of pharmaceuticals. Our products and services provide an environmentally cleaner alternative process for treatment. Our GREEN Waste Conversion Process™ eliminates medical waste processed for the Company's customers from going into landfills. The process transforms treated medical waste into PELLA-DRX™ - a clean, raw material used in the manufacture of industrial resource. The use of recycled paper and plastic materials for our products further demonstrates our total commitment to environmentally sound business practices. As an organization, the Company is a leading proponent for the development of solutions for the safe disposal of sharps and unused dispensed medications in the community and continually work to raise public awareness of the issue.

Vertically integrated full-service operations.

Our products and services encompass the entire range of the medical waste and unused dispensed medications disposal life cycle. We provide our customers with a wide variety of products and sizes to meet their individual needs. Various sizes of TakeAway™ Environmental Return System boxes provide similar customizability for our pharmaceutical customers. Once filled, these containers are shipped back to our treatment facility which has the capacity to process up to 40 tons of waste per day (currently permitted to process up to 18 tons of waste per day). We carefully track the movement of each shipment from mailing to ultimate treatment and provide confirmation to the customer for their records. By controlling all aspects of the process internally, the Company is able to provide a one-stop solution and simplify the tracking and record-keeping processes to meet regulatory requirements. Other products such as Pitch-It™ IV Poles and pump return boxes meet additional specialized needs for the home health care industry.

Well-positioned to capitalize on the growing need for government and commercial preparedness to address emergency and disaster relief situations.

Federal and state government agencies as well as commercial organizations are increasingly focused on having programs in place for emergency and disaster relief situations such as natural disasters (hurricanes, flooding and earthquakes), pandemics (H1N1 flu strain), acts of terrorism (September 11th) and other national emergencies. The Sharps@MWMS™ is designed to be an integral part of governmental and commercial emergency preparedness programs. The successful launch of our government agency program demonstrates the attractiveness of our integrated, full-service solution that enables government agencies and commercial organizations to completely outsource the planning and execution of their emergency preparedness and disaster relief planning as it relates to medical waste handling and rapid response capabilities. We believe this program will generate additional demand from other government agencies at the federal, state and local level.

Increased state and federal regulatory attention.

As the movement to increase regulation of sharps and unused dispensed medications disposal gains momentum at both the state and federal level, we believe the Company is well positioned to benefit given our strict adherence to established standards and extensive documentation and records. Currently, 13 states restrict or have introduced legislation to restrict the disposal of used sharps in household trash and 11 states have also enacted or introduced

legislation to regulate the disposal of pharmaceuticals to reduce pollution of the environment. As state and federal enforcement of these statutes increases, more companies will turn to solutions such as ours to help manage their medical waste and regulatory compliance.

Diverse product markets.

Sharps offers services and products to a wide variety of end markets. The Company's primary end markets ranked by revenue in fiscal year 2010 were federal, state and local government agencies (61%), home health care companies (17%), retail pharmacies and clinics (11%), professional physician, dental and veterinary clinics (4%), pharmaceutical manufacturers (2%), and other (5%) which includes hotel, retirement and assisted living facilities, commercial and industrial and agriculture. The Company's primary end markets ranked by revenue in fiscal year 2009 were home health care companies (36%), federal, state and local government agencies (30%), retail pharmacies and clinics (9%), pharmaceutical manufacturers (8%), professional physician, dental and veterinary clinics (5%), and other (12%) which includes hotel, retirement and assisted living facilities, commercial and industrial and agriculture.

Highly scalable business model.

Because of our mail-based service model, we can add new business while leveraging our existing fixed cost structure. Until capacity limitations are reached on our incinerator and autoclave systems, our facility can accommodate significant additional volume, incurring only variable costs of transportation, storage and processing. Once we gain a new customer, our business typically increases as our customer grows without additional sales and marketing efforts due to the embedded nature of our products and the ease with which we can accommodate additional volume through larger container sizes or faster cycle times.

Experienced and accomplished management team.

Our senior management team has extensive industry experience, and is committed to the continued growth and success of our company. Dr. Burton Kunik, our Chairman and CEO, founded Sharps Compliance, Inc., now a wholly owned subsidiary of the Company, in 1994 and also founded two other medical waste management companies. In 2004, he was awarded the International Sharps Injury Prevention Award. Mr. David P. Tusa, CPA, President, in addition to his seven plus years with the Company has over 25 years of financial, accounting, business and public company experience in multiple industries and in companies with revenues up to \$500 million. Mr. Claude Dance, Senior Vice President of Sales and Marketing, has broad health care and reverse logistics industry experience at a variety of firms including Pharmacia, Cardinal Health and Wyeth Pharmaceuticals. Ms. Diana Diaz, CPA, MBA, Vice President and Chief Financial Officer, has over 25 years of finance, accounting, health care and public company industry experience.

The Company's Board of Directors oversees CEO and senior management succession planning. The process focuses on building management depth, considers continuity and stability within the Company, and responds to Sharps' evolving needs and changing circumstances.

GROWTH STRATEGIES

We plan to grow our business by employing the following primary growth strategies:

Further penetrate existing customers.

Many of our customers who currently use the Sharps® Recovery System™ (formerly Sharps Disposal by Mail System®) could also benefit from the TakeAway™ Environmental Return System products or other specialized products. Although currently focused primarily on sharps disposal, pharmacies (including chains and mail order), assisted living facilities and other related organizations will develop needs for our other product lines as they expand their patient service offerings. As an entrenched and value-added supplier of treatment solutions, we believe the Company is well-positioned to capture incremental business from our existing customers.

We believe the recent passage of new regulations, such as California Senate Bill 486, will generate the sale of additional patient support programs with pharmaceutical manufactures as they respond to the requirements of the legislation. We have programs in place with five pharmaceutical manufacturers and we believe the Company is the leader in providing solutions of this type to this market.

Increase adoption of our product lines among federal, state and local government agencies.

We believe that our recent successful launch of a \$40 million MWMSTM program with a major U.S. government agency is leading to additional business from other government agencies at the federal, state and local level. In January 2010, we launched a pilot program with the United States Department of Veterans Affairs ("VA") within the VA Capitol Health Care Network ("Veterans Integrated Service Network" or "VISN"). The VISN is part of the Veterans

Health Administration which encompasses the largest integrated health care system in the United States, consisting of 153 medical centers, in addition to numerous community based outpatient clinics, community living centers and Vet Centers. Together these health care facilities provide comprehensive care to over 5.5 million Veterans each year. The pilot allows each of the participating medical centers within the VISN, both inpatient and outpatient, to provide the Sharps® Recovery System™ (formerly known as the Sharps Disposal By Mail System®) and the TakeAway™ Environmental Return System solutions to their patients. Since its original launch, the pilot program has now expanded to three other VISNs. In addition, we believe there are additional sales opportunities with a major U.S. government agency, including additional products and services, as well as the potential for more Medical Waste Management System™ orders. These successes demonstrate the attractiveness of our integrated, full-service system that allows government agencies to completely outsource the medical waste handling aspects of their disaster relief programs and rapid response capabilities. Once the system has been proven at the government level,

we expect additional growth through commercial emergency preparedness programs as well.

Enhance sales and marketing efforts.

Through the expansion of our sales force, development of additional marketing materials, increased use of trade magazine advertising and implementation of a call center for direct marketing efforts, we believe we can drive significant additional growth. Capitalizing on the increased regulatory attention directed at medical waste management initiatives, we have had significant contract wins at the state government level and received significant press coverage of our new TakeAway™ Environmental Return System product line. Additionally, given the last year's H1N1 flu concerns and subsequent demand for flu shots and vaccines, our sales and marketing efforts are gaining substantial traction and our products are quickly becoming a more standard fixture in the retail channel.

Improve product and service awareness to attract new customers.

As we grow, we intend to focus additional marketing and sales efforts toward educating home health care providers, physician and dental clinics, pharmaceutical manufacturers, communities and government agencies of the benefits of our products and the need for safe and environmentally-friendly methods of medical waste treatment. We believe that the full-service nature of our product offerings, ease of our mail-based delivery system and convenience of our products will attract new customers who are not yet aware of the services we provide. In addition to providing a convenient, cost-effective solution to waste treatment, we believe future growth will be driven by the need for our customers to properly document and track the disposal of their hazardous waste to maintain compliance with new and existing legislation. We believe our participation in the legislative process and focus on accurate and thorough electronic tracking of waste disposal or treatment will provide substantial benefits to new customers looking to comply with new standards and promote environmentally cleaner business practices.

Develop new products and services.

We continue to develop new products and services including the Sharps® Medical Waste Management System™, the TakeAway™ line of products for unused medications (including the TakeAway™ Environmental Return System), the 18 gallon and 28 gallon Medical/Professional TakeAway™ Recovery System and the new RxTakeAway™ Recovery and Reporting System which offers the collection, storage, audit, witnessed treatment and documentation of unused medications such as flu vaccines, Tamiflu, and Relenza. These new product and service offerings allow us to gain further sales from existing customers as well as gain new customers who have a need for more comprehensive products. We will continue our efforts to develop new products and services designed to facilitate the proper and cost effective solutions for management of medical waste and of unused dispensed medications to better serve our customers and the environment. Additionally, we will continue to seek out and identify new small quantity medical waste generators and develop solutions to meet the needs of these new customer segments. Research and development expenses were \$41 thousand and \$20 thousand for the fiscal year ended June 30, 2010 and 2009, respectively.

CONCENTRATION OF CREDIT AND SUPPLIERS

Although Sharps has experienced growth in revenues over the past few years, there is an inherent concentration of credit risk associated with accounts receivable arising from sales to its major customers. For the fiscal year ended June 30, 2010, two customers represented approximately 68% of revenues. Those two customers represented approximately 27%, or \$546 thousand of the total accounts receivable balance at June 30, 2010. For the fiscal year ended June 30, 2009, four customers represented approximately 48% of revenues. Those same four customers represented approximately 28%, or \$504 thousand of the total accounts receivable balance at June 30, 2009. The Company may be adversely affected by its dependence on a limited number of high volume customers. Management believes that the risks are mitigated by, (i) the contractual relationships with key customers, (ii) the reputation of the

Company and its high quality products and (iii) the continued diversification of the Company's products and services into additional markets outside of its traditional Health care customer base.

Currently, the majority of Sharps transportation is sourced with the USPS, which consists of delivering the Sharps® Recovery System™ (formerly Sharps Disposal by Mail System®) from the end user to the Company's facility. The Company also has an arrangement with UPS whereby UPS transports the Company's Sharps® Recovery System™ products from the end user to the Company's facility. The Company began selling a UPS product to select customers in fiscal year

2007. Management believes the risk of dependence on the USPS is mitigated by (i) the arrangement with UPS and (ii) the long-standing business relationship with and successful performance by USPS.

The Company maintains relationships with multiple raw materials suppliers and vendors in order to meet customer demands and assure availability of our products and solutions. With respect to the Sharps® Recovery System™ (formerly Sharps Disposal by Mail System®) solutions, the Company owns all proprietary molds and dies and utilizes three contract manufacturers for the production of the primary raw materials. The Company believes that alternative suitable contract manufacturers are readily available to meet the production specifications of the Company's products and solutions. With respect to the Company's Pitch-It™ IV Poles, the Company maintains an exclusive manufacturing relationship with Drive Medical Design & Manufacturing. The Company utilizes national suppliers such as Southern Container, Uline and W. W. Grainger, Inc. for the majority of the raw materials used in the Company's other products and solutions.

INTELLECTUAL PROPERTY

The Company has a portfolio of trademarks and patents, both granted and pending. The Company considers its trademarks important in the marketing of its products and services, including Sharps Disposal by Mail System®, TakeAway™ Environmental Return System, Sharps®MWMS™, Pitch-It™ IV Poles, Trip LesSystem®, GREEN Waste Conversion Process™ and PELLA-DRX™ among others. With respect to their registered marks, the Company will continue using such marks and will file all necessary documentation to maintain their registrations for the foreseeable future. The Company maintains patents on its Pitch-It™ IV Poles which are scheduled to expire in 2012. The Company has a number of patents pending, including those applicable to the Company's Sharps Secure® Needle Recovery System, the Sharps® Medical Waste Management System™, and the GREEN Waste Conversion Process™, and is in the process of applying for other trademarks and patents.

COMPETITION

There are several competitors who offer similar or identical products and services that facilitate the disposal of medical waste outside the hospital and large health care setting. There are also a number of companies that focus specifically on the marketing of products and services which facilitate disposal through transport by the USPS (similar to the Company's products). These companies include (i) smaller private companies or (ii) divisions of larger medical or solid waste companies. Additionally, the Company does compete, in certain markets, with Stericycle, the largest medical waste company in the country, which focuses primarily on a pick-up service business model. As Sharps continues to grow and increase awareness of the proper disposal of syringes and unused medications it does believe it may face more and possibly significant competition. The Company believes its patent-pending Waste Conversion Process™, first mover advantages, excellent industry reputation, quality solutions and products, as well as its capabilities as a vertically integrated producer of products and services, provides significant differentiation in the current competitive market.

GOVERNMENT REGULATION

Sharps is subject to extensive federal, state, and/or local laws, rules and regulations. The Company is required to obtain permits, authorizations, approvals, certificates and other types of governmental permission from the EPA, the State of Texas and the local governments in Carthage, Texas with respect to our facility. Such laws, rules and regulations have been established to promote occupational safety and health standards and certain standards have been established in connection with the handling, transportation and disposal of certain types of medical and solid wastes, including mailed sharps. Our estimated annual costs of complying with these laws, regulations and guidelines is currently less than \$100,000 per year. In the event additional laws, rules or regulations are adopted which affect our business, additional expenditures may be required in order for Sharps to be in compliance with such changing laws, rules and regulations.

COMPLIANCE WITH ENVIRONMENTAL LAWS

In November 2005 and September 2009, the EPA and the Texas Commission on Environmental Quality promulgated new regulations under the Clean Air Act and associated state statutes which will affect the operations of the incineration facility located in Carthage, Texas. These regulations modify the emission limits and monitoring procedures required to operate an incineration facility. The new rules will necessitate changes to the Company's owned incinerator and pollution control equipment at the facility or require installation of an alternative treatment method to ensure compliance. These regulations will also require the Company to obtain a Title V permit and conduct additional monitoring. The Company is required to

comply with these new standards by the end of 2012. Such changes will require the Company to incur capital expenditures in order to meet the requirements of the regulations. The Company has studied these amended regulations and their options, and decided in the interim to move forward with the process of adding alternative technology, autoclaving, which meets the EPA Clean Air Act requirements, for medical waste disposal which became fully operational in February 2009 at its current facility in Carthage, Texas. The Company believes autoclaving is environmentally cleaner and a less costly method of treating medical waste than incineration. Due to its continued growth, the Company anticipates that it will incur additional capital expenditures needed in order to meet the new air emission regulations. The additional capital expenditures are not expected to exceed \$1.0 million. The Company expects capital expenditures related to these new regulations to be made by the end of the first half of fiscal year 2013.

ITEM 1A. RISK FACTORS

We may be unable to manage our growth effectively.

We have experienced significant growth, with revenues increasing more than 58% for the fiscal year ended June 30, 2009 from the prior fiscal year and 93% from fiscal year ended June 30, 2009 to fiscal year ended June 30, 2010. This growth has placed and will continue to place significant demands on our financial, operational and management resources. In order to continue our growth, we may need to add operations, administrative and other personnel, and may need to make additional investments in the infrastructure and systems. There can be no assurance that we will be able to find and train qualified personnel, or do so on a timely basis, or expand our operations and systems to the extent, and in the time, required.

The loss of the Company's senior executives could affect the Company's ability to manage the business profitability.

Sharps' growth and development to date has been largely dependent on the active participation and leadership of its senior management team consisting of the Company's Chairman and CEO, President, Senior Vice President of Sales, and Vice President and CFO. The Company believes that the continued success of the business is largely dependent upon the continued employment of the senior management team and has, therefore, (i) entered into individual employment agreements with key personnel and (ii) granted equity-based stock compensation to senior management members in order to provide an incentive for their continued employment with the Company. The unplanned loss of one or more members of the senior management team and our inability to hire key employees could disrupt and adversely impact the Company's ability to execute its business plan.

The Company's Board of Directors oversees CEO and senior management succession planning. The process focuses on building management depth, considers continuity and stability within the Company, and responds to Sharps' evolving needs and changing circumstances. The Board approves continuity plans for the CEO and senior management succession planning to enable the Board to respond to planned or unexpected vacancies in key positions. The Board considers optimizing the ongoing safe and sound operation of the Company and minimizing any potential disruption or loss of continuity to our business and operations as it evaluates the plan.

Our business is dependent on a small number of customers. To the extent we are not successful in winning additional business mandates from our government and commercial customers or attracting new customers, our results of operations and financial condition would be adversely affected.

We are dependent on a small group of customers. In addition, there is an inherent concentration of credit risk associated with accounts receivable arising from sales to our major customers. For the fiscal year ended June 30, 2010, two customers represented approximately 68% of revenues, of which the contract with the government represented 86% of revenues. Those two customers represented approximately 27%, or \$546 thousand, of the total accounts receivable balance at June 30, 2010. To the extent these significant customers are delinquent or delayed in paying or we are not successful in obtaining consistent and additional business from our existing and new customers, our results of operations and financial condition would be adversely affected.

Aggressive pricing by existing competitors and the entrance of new competitors could drive down the Company's profits and slow its growth.

There are several competitors who offer similar or identical products and services that facilitate the disposal of medical waste outside the hospital and large health care setting. There are also a number of companies that focus specifically on the marketing of products and services which facilitate disposal through transport by the USPS (similar to the Company&