SHARPS COMPLIANCE CORP
Form 10-K
August 23, 2017

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, 2017
OR

TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from ___ to ____ .

Commission File Number: 001-34269
SHARPS COMPLIANCE CORP.
(Exact name of registrant as specified in its charter)

Delaware	74-2657168
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

9220 Kirby Drive, Suite 500, Houston, Texas	77054
(Address of principal executive offices)	(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
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
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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

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

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

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2016, the aggregate market value of the registrant’s Common Stock held by non-affiliates was approximately $48.8 million (based on the closing price of $3.83 on December 31, 2016 as reported by The NASDAQ Capital Market). For purposes of this computation only, all executive officers, directors and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed an admission that such executive offices, directors or 10% beneficial owners are affiliates.

The number of common shares outstanding of the Registrant was 16,008,412 as of August 21, 2017.

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 16, 2017 are incorporated by reference into Part III.

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SHARPS COMPLIANCE CORP. AND SUBSIDIARIES
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ANNUAL REPORT ON FORM 10-K

*This Table of Contents is inserted for convenience of reference only and is not a part of this Report as filed.

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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 "will," "may," "position," "plan," "potential," "continue," "anticipate," "believe," "expect," "estimate," "project" and "intend" and words or p similar import, as they relate to the Company or its subsidiaries or Company management, are intended to identify forward-looking statements. Such statements reflect known and unknown risks, uncertainties and assumptions related to certain factors, including without limitation, 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. Consequently, no forward-looking statements can be guaranteed. When considering these forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Annual Report on Form 10-K. Actual results may vary materially. You are cautioned not to place undue reliance on any forward-looking statements. You should also understand that it is not possible to predict or identify all such factors and as such should not consider the preceding list or the risk factors to be a complete list of all potential risks and uncertainties. The Company does not intend to update these forward-looking statements.

PART I

ITEM 1. 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.), Sharps Safety, Inc., Alpha Bio/Med Services LLC, Bio-Team Mobile LLC and Citiwaste, LLC (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.

COMPANY OVERVIEW

Sharps Compliance Corp. is a leading full-service national provider of comprehensive waste management services including medical, pharmaceutical and hazardous. Our solutions facilitate the proper collection, containment, transportation and treatment of numerous types of healthcare-related materials, including hypodermic needles, lancets and other devices or objects used to puncture or lacerate the skin, or sharps, hazardous waste and unused consumer dispensed medications and over-the-counter drugs. We serve customers in multiple markets, such as home health care, retail clinics and immunizing pharmacies, pharmaceutical manufacturers, professional offices (physicians, dentists and veterinarians), assisted living and long-term care facilities (assisted living, continuing care, long-term acute care, memory care and skilled nursing), government (federal, state and local), consumers, commercial and agriculture, as well as distributors to many of the aforementioned markets. We assist our customers in determining which of our solution offerings best fit their needs for the collection, containment, return transportation and treatment of medical waste, used healthcare materials, pharmaceutical waste, hazardous waste and unused dispensed medications. Our differentiated approach provides our customers the flexibility to return and properly treat medical waste, used healthcare materials or unused dispensed medications through a variety of solutions and products transported primarily through the United States Postal Service ("USPS"). For customers with facilities or locations that may generate larger quantities of waste, we integrate the route-based pickup service into our complete offering. The benefits of this comprehensive offering include single point of contact, consolidated billing, integrated manifest and proof of destruction repository in addition to our cost savings. Furthermore, we provide comprehensive tracking and reporting tools that enable our customers to meet complex medical, pharmaceutical and hazardous waste disposal and compliance requirements. We believe the fully-integrated nature of our operations is a key factor leading to our success and continued recurring revenue growth. We continue to take advantage of the many opportunities in all markets served as we educate the market place and as prospective customers become more aware of alternatives to traditional methods of disposal (i.e., route-based pickup services).

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Our key markets include healthcare facilities, pharmaceutical manufacturers, home healthcare providers, assisted living/long-term care, surgery centers, retail pharmacies and clinics and the professional market, which is comprised of physicians, dentists and veterinary practices. The Company's flagship product, the Sharps® Recovery System, is a comprehensive solution for the containment, transportation, treatment and tracking of medical waste and used healthcare materials. In October 2014, the Company launched MedSafe®, a patent pending solution for the safe collection, transportation and proper disposal of unwanted and expired prescription medications including controlled substances from ultimate users. MedSafe has been designed to meet or exceed the regulations issued by the Drug Enforcement Administration ("DEA") implementing the Secure and Responsible Drug Disposal Act of 2010 (the "Act"), which became effective October 9, 2014. In July 2015 and December 2015, the Company augmented its network of medical and hazardous waste service providers with acquisitions of route-based pickup services in the Northeast serving Pennsylvania, Maryland, Ohio and other neighboring states. Additionally, the Company now services parts of Texas and Louisiana with route-based pickup services. In July 2016, the Company acquired another route-based pickup service which expanded service to New York and New Jersey and strengthened the Company's position in the Northeast. The Company now offers its route-based pickup services in a twenty-three (23) state region of the South, Southeast and Northeast portions of the United States.

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 124 full-time employees and 6 part-time employees. We have manufacturing, assembly, distribution and warehousing operations located in Houston, Texas. We own and operate a fully-permitted treatment facility in Carthage, Texas that incorporates our processing and treatment operations. Over six years ago, we supplemented the treatment facility's existing incineration process with an autoclave system, which is a cost-effective alternative to traditional incineration that treats medical waste with steam at high temperature and pressure to kill pathogens. The autoclave system is utilized alongside the incinerator for day-to-day operations. We believe that our Texas facility is one of only ten permitted commercial facilities in the United States capable of treating all types of medical waste, used healthcare materials and unused or expired dispensed medications (i.e., both incineration and autoclave capabilities). This arrangement not only reduces the Company's return transportation costs associated with its solutions but also provides back-up treatment facility capabilities in the event of disruption at the Company's treatment facilities. The Company's route-based pickup service business covers a twenty-three state region in the South, Southeast and Northeast portions of the United States. In August 2016, the Company received the Commonwealth of Pennsylvania Department of Environmental Protection Bureau of Waste Management permit for the processing of medical waste at its treatment facility located in northeastern Pennsylvania. The 40,000 square foot facility has been permitted as both a medical waste treatment facility, using an autoclave, and as a transfer station for medical, pharmaceutical and trace chemotherapy waste of up to 82 tons per day. The facility is designed to cost-effectively and efficiently process medical waste generated by the Company's route-based and mailback customers and also doubles as a distribution center of mailback solutions and has been in operation since November 2016.

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 twenty-eight gallons; USPS-approved shipping box with prepaid priority mail postage; absorbent material inside the container that can safely hold up to 150 milliliters of fluids; a bag for additional containment and complete documentation and tracking manifest. The Sharps Recovery System is transported to our owned or contracted facilities 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.

TakeAway Medication Recovery System™: a comprehensive solution designed to meet or exceed the regulations issued by the DEA implementing the Act, which became effective October 9, 2014. The solution facilitates the proper disposal of unused medications (including controlled substances) from:

- ultimate users, which is designed for use in the long-term care, hospice and consumer markets.
- DEA registrants, which DEA Reverse Distribution solution is a DEA-compliant collection, return and destruction solution for DEA registrants' expired or unused controlled substances. The system includes prepaid return transportation, materials to package for return, complete documentation of returned pharmaceuticals and proper disposal with online proof of destruction.

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MedSafe®: a patent-pending solution for the safe collection, transportation and proper disposal of unwanted and expired prescription medications, including controlled substances, from ultimate users. MedSafe has been designed to meet or exceed the regulations issued by the DEA implementing the Act, which became effective October 9, 2014. MedSafe is designed for use in retail pharmacies, long-term care facilities, hospice, hospitals/clinics with on-site pharmacies, narcotic treatment facilities and licensed law enforcement.

Route-Based Pickup Service: as a full-service waste management services company, we offer route-based medical and hazardous waste pickup services to customers and prospects that have facilities or branches that generate larger quantities of medical, pharmaceutical (non-controlled) and limited quantities of hazardous waste or where the route-based pickup service is preferred. This blended service of mailback and pickup provides cost-savings benefits by customizing the right solution with each location to reach the best outcome for the customer.

TakeAway Recycle System™: a solution for the collection and recycling of single-use medical devices from surgical centers and other healthcare facilities. The system consists of containers designed for use in operating rooms or sterile processing departments. The containers are placed in a pre-paid return box for shipping to our treatment facilities where devices are stripped to their basic components and sent to appropriate recycling facilities. The system adds a much needed solution to the market in which many single-use devices are reprocessed or disposed of as regulated medical waste, resulting in wastes that could be recycled.

ComplianceTRAC℠: a more advanced web-based version of the Company's compliance and training program. ComplianceTRAC is designed to improve worker safety while satisfying applicable Occupational Safety and Health Administration ("OSHA") and other requirements for the end-user. The program includes employee training for bloodborne pathogens, compliance with the Health Insurance Portability and Accountability Act of 1996 and the Hazardous Communication Standard. The online program also provides access to a database of over a million safety data sheets (formerly, material safety data sheets), safety plans, regulatory information and facility self-audits. The program is designed to replace outdated hard copy manuals with an updated platform available 24/7.

Universal Waste Shipback Systems: a jointly-promoted program with Veolia Environmental Services using their RECYCLEPAK solutions for the collection, transportation and recycling of light bulbs, batteries and other mercury-containing devices. The solution is marketed to existing and prospective customers as a complement to the Company's line of medical waste and unused medication management solutions.

Other Solutions: a wide variety of other solutions including TakeAway Environmental Return System™, SharpsTracer®, Sharps Secure® Needle Disposal System, Complete Needle™ Collection & Disposal System, Pitch-It IV™ Poles, Asset Return System, Sharps® MWMS™ (a Medical Waste Management System ("MWMS")) and Spill Kit and Recovery System.

MARKET OVERVIEW

The Company continues to focus on core markets and solution offerings that fuel growth. Its key markets include healthcare facilities, pharmaceutical manufacturers, home healthcare providers, assisted living/long-term care, retail pharmacies and clinics and the professional market which is comprised of physicians, dentists, surgery centers and veterinary practices. These markets require cost-effective services for managing medical, pharmaceutical and hazardous waste.

The Company believes its growth opportunities are supported by the following:

- A large professional market that consists of dentists, veterinarians, clinics, private practice physicians, urgent care facilities, ambulatory surgical centers and other healthcare facilities. This regulated market consists of small to medium quantity generators of medical, pharmaceutical and hazardous waste where we can offer a lower cost to service with solutions to match individual facility needs. The Company addresses this market from two directions: (i) field sales which focus on larger-dollar and nationwide opportunities where we can integrate the route-based pickup service along with our mailback solutions to create a comprehensive medical waste management offering and (ii) inside and online sales which focus on the individual or small group professional offices, government agencies, smaller retail pharmacies and clinics and assisted living/long term care facilities. The Company is able to compete more aggressively in the medium quantity generator market with the addition of route-based services where the mailback may not be as cost effective. The Company's route-based business provides direct service to areas encompassing about 155 million people or 48% of the U.S. population.

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- In July 2015 and December 2015, the Company augmented its network of medical and hazardous waste service providers with acquisitions of route-based pickup services in the Northeast serving Pennsylvania, Maryland, Ohio and other neighboring states. In July 2016, the Company acquired another route-based pickup service which expanded service to New York and New Jersey and strengthened the Company's position in the Northeast. Through a combination of acquisition and organic growth, the Company now offers route-based pickup services in a twenty-three (23) state region of the South, Southeast and Northeast portions of the United States. The Company directly serves more than 9,500 customer locations with route-based pickup services. With the addition of these route-based pickup regions and the network of medical and hazardous waste service providers servicing the entire U.S., the Company offers customers a blended product portfolio to effectively manage multi-site and multi-sized locations, including those that generate larger quantities of waste. The network has had a significant positive impact on our pipeline of sales opportunities - over 60% of this pipeline is attributable to opportunities providing comprehensive waste management service offerings where both the mailback and pickup service are integrated into the offering.

- The changing demographics of the U.S. population – according to the U.S. Census Bureau, 2012 Population Estimates and National Projections, one out of five Americans will be 65 years or older by 2030, which will increase the need for cost-effective medical waste management solutions, especially in the long-term care and home healthcare markets. With multiple solutions for managing regulated healthcare-related waste, the Company delivers value as a single-source provider with blended mailback and route-based pickup services matched to the waste volumes of each facility.

- The shift of healthcare from traditional settings to the retail pharmacy and clinic markets, where the Company focuses on driving increased promotion of the Sharps Recovery System. According to the Centers for Disease Control ("CDC"), 24% of flu shots for adults were administered in a retail clinic. Over the flu seasons from 2011 to 2014, the growth in the Retail flu business for Sharps was between 24% and 36%. Despite the decrease in Retail flu business for fiscal year 2017 (the 2016 flu season) of 15% due to a mild flu season and the loss of one retail pharmacy customer, Sharps believes the Retail market should continue to contribute to long-term growth for the Company as consumers increasingly use alternative sites, such as retail pharmacies, to obtain flu and other immunizations.

- The passage of regulations for ultimate user medication disposal allows the Company to offer new solutions (MedSafe and TakeAway Medication Recovery System envelopes) that meet the regulations for ultimate user controlled substances disposal (Schedules II-V) to retail pharmacies. Additionally, with the new regulations, the Company is able to provide the MedSafe and TakeAway Medication Recovery Systems to assisted living and hospice to address a long standing issue within long-term care.

- Local, state and federal agencies have growing needs for solutions to manage medical and pharmaceutical waste — the Company's Sharps Recovery System is ideal for as-needed disposal of sharps and other small quantities of medical waste generated within government buildings, schools and communities. The Company also provides TakeAway Medication Recovery System envelopes and MedSafe solutions to government agencies in need of proper and regulatory compliant medication disposal.

- With an increased number of self-injectable medication treatments and local regulations, the Company believes its flagship product, the Sharps Recovery System, continues to offer the best option for proper sharps disposal at an affordable price. The Company delivers comprehensive services to pharmaceutical manufacturers that sell high-dollar, self-injectable medications, which include data management, compliance reporting, fulfillment, proper containment with disposal, branding and conformity with applicable regulations. In addition, the Company provides self-injectors with online and retail purchase options of sharps mailback systems, such as the Sharp Recovery System and Complete Needle Collection & Disposal System, respectively.

- A heightened interest by many commercial companies who are looking to improve workplace safety with proper sharps disposal and unused medication disposal solutions — the Company offers a variety of services to meet these needs, including the Sharps Secure Needle Disposal System, Sharps Recovery System, Spill Kits and TakeAway Medication Recovery System envelopes.

- The Company continually develops new solution offerings such as ultimate user medication disposal (MedSafe and TakeAway Medication Recovery System), mailback services for DEA registrant expired inventory of controlled substances (TakeAway Medication Recovery System DEA Reverse Distribution for Registrants) and shipback services for collection and recycling of single-use medical devices from surgical centers and other healthcare facilities (TakeAway Recycle System).

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COMPETITIVE STRENGTHS

We believe our competitive strengths include the following:

Leading full-service national provider of comprehensive and cost-effective waste management services, including medical, pharmaceutical, and hazardous.

We offer a full line of solutions and services that address the proper management of medical waste, used healthcare materials and medication or pharmaceuticals (including controlled substances). We offer a blended product portfolio that includes both a mailback and route-based pickup service to target prospective customers with multi-site and multi-sized locations that may include facilities that generate larger quantities of waste, including medical, pharmaceutical and hazardous. This blended offering includes a single point of contact, consolidated billing, regulatory support and complete integration of our SharpsTracer system. Our proprietary SharpsTracer tracking and documentation systems provide customers a comprehensive electronic record of receipt and treatment of their waste to meet regulatory requirements. The Company's mail or ship-back based services are generally offered at a significantly lower cost as compared to the traditional route-based pickup services for small quantity generators since the Company utilizes the existing infrastructure of USPS or in some cases United Parcel Service ("UPS") for return transportation. While competitors may attempt to replicate our comprehensive solution offerings, we believe the ability to offer such a comprehensive, value-added turnkey solution is a significant competitive advantage. We have only begun to offer this comprehensive solution over the past five years with the primary focus of our marketing efforts on educating the marketplace about us as an alternative to the historical provider of waste services, including medical, pharmaceutical and hazardous.

Vertically-integrated full-service operations.

Our operations are fully integrated, including manufacturing, assembly, distribution, treatment, online tracking and customer reporting. We have manufacturing, assembly, distribution and warehousing operations in Houston, Texas. We own and operate a fully-permitted treatment facility in Carthage, Texas, that incorporates our processing and treatment operations. Over six years ago, we supplemented the treatment facility's existing incineration process with an autoclave system, which is a cost-effective alternative to traditional incineration that treats medical waste with steam at high temperature and pressure to kill pathogens. The autoclave system is utilized alongside the incinerator for day-to-day operations. We believe that our Texas facility is one of only ten permitted commercial facilities in the United States capable of treating all types of medical waste, used healthcare materials and unused or expired medications including controlled substances (i.e., both incineration and autoclave capabilities). In August 2016, the Company received the Commonwealth of Pennsylvania Department of Environmental Protection Bureau of Waste Management permit for the processing of medical waste as its treatment facility located in northeastern Pennsylvania. The 40,000 square foot facility has been permitted as both a medical waste treatment facility, using an autoclave, and as a transfer station for medical, pharmaceutical and trace chemotherapy waste of up to 82 tons per day. The facility is designed to cost-effectively and efficiently process medical waste generated by the Company's route-based and mailback customers and also doubles as a distribution center of mailback solutions and has been in operation since November 2016. We track the movement of each shipment from outbound shipping to ultimate treatment and provide confirmation to the customer for their records using our proprietary SharpsTracer tracking and documentation system. We also track treatment volumes associated with pickup services provided as part of our blended product portfolio using SharpsTracer. We also provide customized reporting and comprehensive regulatory support for many of our customers. 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 for our customers. We believe the fully-integrated nature of our operations is a key factor and differentiator leading to our success and leadership position in our industry.

Highly scalable business model.

Because of our business model, we can add new business while leveraging our existing infrastructure. Our facilities are able to accommodate significant additional volume, incurring only variable costs of transportation and processing. Once we gain a new customer, our profitability typically increases as our customer base grows with minimal additional overhead expense due to the embedded nature of our products and the ease with which we can accommodate additional volume.

Diverse product markets.

Sharps offers services and products to a wide variety of end markets. The Company’s growth strategies are focused on our key markets which include healthcare facilities, pharmaceutical manufacturers, home healthcare providers, assisted living/long-term care, surgery centers, retail pharmacies and clinics and the professional market, which is comprised of physicians, dentists and veterinary practices.

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Our billings by market for the years ended June 30, 2017, 2016 and 2015 are below (as expressed in percentages of revenues):

	Year Ended June 30,		
	2017	2016	2015
BILLINGS BY MARKET:			
Professional	31 %	22 %	20 %
Home Health Care	21 %	22 %	22 %
Retail	19 %	26 %	28 %
Pharmaceutical Manufacturer	16 %	17 %	15 %
Assisted Living	6 %	6 %	6 %
Government	4 %	4 %	5 %
Environmental	1 %	1 %	1 %
Other	2 %	2 %	3 %
	100 %	100 %	100 %

Increased state and federal regulatory attention.

To protect citizens and waste workers from needle stick injuries, ten states have passed state-wide legislation or regulations making it illegal to discard used sharps into household trash. Numerous cities, such as Seattle, have passed ordinances making household sharps disposal illegal. Almost all other states, as well as the District of Columbia and territories have passed educational requirements, or released strict guidelines regarding home sharps disposal. Whether legislation or strict guidelines, most of the U.S. population is required or strongly encouraged to not place used sharps in the household trash. In addition, several states and counties have passed ordinances requiring businesses such as hospitals and those that sell syringes to the public, such as retail pharmacies and veterinary clinics, to take back syringes, once used, in regulatory-compliant sharps containers at no charge to the consumer.

In order to reduce accidental poisonings and pollution of our water and municipal water systems, twenty-two states and the District of Columbia have introduced legislation over the last few years intended to manage the disposal of consumer unused medications. Seven states and the District of Columbia have successfully passed such legislation. Passed or pending legislation related to disposal of consumer medications covers about two-thirds of the U.S. population. Further, since 2009, the federal government, nine states and several counties have introduced legislation requiring manufacturer responsibility for consumer generated unused medications. State regulatory agencies are also addressing this issue, including multiple states which now require healthcare providers to avoid sewer and trash disposal of non-hazardous unused medications within their facilities. States such as California, Washington and Minnesota have required assessment and proper treatment by a medical waste disposal company for years. However, other states such as Colorado and Florida are now requiring even small healthcare providers to segregate unused medications for proper disposal. In 2010, Congress passed the Secure and Responsible Drug Disposal Act, leading to DEA changes to the Controlled Substances Act in 2014, allowing certain DEA registrants to collect controlled substances from the public. Collection receptacles can now be found in retail pharmacies, long-term care facilities and hospitals throughout the country. In addition, states are beginning to more closely scrutinize generators returning through reverse distribution unused inventory medications classified as qualifying for manufacturer credit that are actually waste pharmaceuticals and should be disposed of as such. As state and federal enforcement of these statutes increases, more companies could turn to solutions such as ours to help manage their medical waste and regulatory compliance. We believe we are well positioned to benefit given our strict adherence to established standards and extensive documentation and records.

Environmentally-conscious solution provider.

In addition to providing cost-effective solutions for our customers, the Company is committed to discovering new sustainable initiatives that mitigate the effects of potentially hazardous waste on the environment. Our patented Waste Conversion Process™ repurposes regulated medical waste and unused medications into new resources used in industrial applications, such as the generation of electricity or recycled plastics used in the industrial sector. Our TakeAway Recycle System is a solution for the collection and recycling of single-use medical devices from surgical centers and other healthcare facilities. The system consists of containers designed for use in operating rooms or sterile processing departments. The containers are placed in a pre-paid return box for shipping to our treatment facilities where devices are stripped to their basic components and sent to appropriate recycling facilities. The system adds a much needed solution to the market in which many single-use devices are reprocessed or disposed of as regulated medical waste, resulting in wastes that could be recycled. Our Universal Waste Shipback Program recycles the materials in light bulbs, batteries and other mercury-containing devices for use in new applications. In addition, the use of recycled paper and plastic materials for many of 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, unused medications (including controlled substances), light bulbs, batteries and other mercury-containing devices in the community and continually works to raise public awareness of the issue.

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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. Mr. David P. Tusa, CEO and President, in addition to his ten-plus years with the Company has over 20 years of business and public company experience in multiple industries and in companies with revenues up to $500 million. Ms. Diana P. Diaz, CPA, MBA, Vice President and Chief Financial Officer, has over 25 years of finance, accounting, healthcare and public company industry experience. Mr. Gregory C. Davis, Vice President of Operations, has over 20 years of information technology and operations-related experience. Mr. Khairan Aladwani, Vice President of Assurance/Quality Control, has over 25 years of quality assurance and operations experience, including medical devices, at a variety of companies both private and public. Mr. Dennis Halligan, Vice President of Marketing, has broad marketing experience with the Company and at a variety of firms, including Stir Creative and R.J. Reynolds.

GROWTH STRATEGIES

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

Further penetrate existing customers and markets.

Many of our customers who currently use the Sharps Recovery System could also benefit from the TakeAway Medication Recovery System, Medsafe, our hazardous waste solutions, our universal waste solutions or other specialized products. Although currently focused primarily on the proper management of medical and pharmaceutical wastes generated by medical professionals, 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 has the ability to capture incremental business from our existing customers.

The Company's Pharmaceutical Manufacturer billings have grown from $0.3 million to $6.0 million for the years ended June 30, 2011 and 2017, respectively. We continue to see increased interest in our patient support program solution among pharmaceutical manufacturers as it relates to self-injectable medications especially related to new drug launches. We believe manufacturers are now, more than ever, focused on (i) product differentiation, (ii) improved interaction with patients and (iii) creating a touch point for individual patient follow-up that could lead to improved therapy outcomes. The patient support programs include the direct fulfillment of the Sharps Recovery System to the pharmaceutical manufacturers' program participants, which provides the proper containment, return and treatment of the needles or injection devices utilized in therapy. Sharps' proprietary SharpsTracer system tracks the return of the Sharps Recovery System by the patient to the treatment facility and then makes available to the pharmaceutical manufacturer electronic data. This data assists them in monitoring medication discipline and provides them with a touch point for individual patient follow-up, which potentially could lead to better outcomes. We believe the Company is the leader in providing solutions of this type to this market.

We are positive about anticipated growth opportunities in the Retail market. According to the CDC, 24% of flu shots for adults were administered in a retail clinic. Over the flu seasons from 2011 to 2014, the growth in the Retail flu business for Sharps was between 24% and 36%. Despite the decrease in Retail flu business for fiscal year 2017 (the 2016 flu season) of 15% due to a mild flu season and the loss of one retail pharmacy customer, Sharps believes the Retail market should continue to contribute to long-term growth for the Company as consumers increasingly use alternative sites, such as retail pharmacies, to obtain flu and other immunizations.

Active Acquisition Program

Over the past five years, the Company has developed a network of medical and hazardous waste service providers including those with route-based pickup services, which allows the Company to serve the entire U.S. medical and hazardous waste market. In July 2015 and December 2015, the Company augmented its network of medical and hazardous waste service providers with acquisitions of route-based pickup services in the Northeast serving Pennsylvania, Maryland, Ohio and other neighboring states. On July 1, 2016, the Company acquired another route-based pickup service which expanded service to New York and New Jersey and strengthened the Company's position in the Northeast. Through a combination of acquisitions and organic growth, the Company now offers route-based pickup services in a twenty-three (23) state region of the South, Southeast and Northeast portions of the United States. The Company directly serves more than 9,500 customer locations with route-based pickup services offered to areas encompassing about 155 million people or 48% of the U.S. population. With the addition of these route-based pickup regions and the network of medical and hazardous waste service providers serving the entire U.S., the Company offers clients a blended product portfolio to effectively target current and prospective customers with multi-site and multi-sized locations including those that generate larger quantities of medical and hazardous waste. The offering includes a single point of contact, consolidated billing, regulatory support and complete integration of our SharpsTracer system. The Company believes the comprehensive offering will continue to assist the Company in obtaining larger opportunities whereby the customer has both larger and smaller facilities generating medical waste, used healthcare materials and hazardous waste resulting in a more consistent and predictable revenue base for the Company.

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Develop new products and services.

We continue to develop new solution offerings including ultimate user medication disposal (MedSafe and TakeAway Medication Recovery System), mailback services for DEA registrant expired inventory of controlled substances (TakeAway Medication Recovery System DEA Reverse Distribution for Registrants) and shipback services for the collection and recycling of single-use devices (TakeAway Recycle System). These innovative 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 solution offerings designed to facilitate the proper and cost effective management of medical waste, used healthcare materials, pharmaceutical waste, hazardous waste and unused dispensed medications to better serve our customers and the environment. Additionally, we will continue to seek out and identify prospective new customers and markets for new solutions designed to meet the needs of these new customer segments.

Enhance sales and marketing efforts.

Over the past five years, the Company has made ongoing investments in sales and marketing initiatives to drive growth in two areas:

- Web and Inside Sales — Through targeted telemarketing initiatives (inside sales), e-commerce driven website and web-based promotional activities, we believe we can drive significant additional growth as we increase awareness of the Company's innovative solution offerings with a focus on individual or small group professional offices, government agencies, smaller retail pharmacies and clinics and assisted living/long-term care facilities.

- Field Sales – The field sales team focuses on larger dollar and nationwide opportunities in most of the markets served. The field sales team is able to address larger opportunities where we can integrate the route-based pickup service along with our mailback solutions to create a comprehensive waste management offering.

We have seen success with this approach in fiscal years 2014 through 2017 and believe the comprehensive offering capabilities will continue to accelerate revenue growth of the Company.

Improve product and service awareness to attract new customers.

As we grow, we continue to focus additional marketing and sales efforts designed to educate professional offices, retail pharmacies and clinics, assisted living and long-term care facilities, home healthcare, government, pharmaceutical manufacturers and other commercial organizations that require cost-effective services for managing medical, pharmaceutical and hazardous waste of the benefits of our solution offerings and the need for safe, cost-effective and environmentally-friendly methods of waste treatment, including medical, pharmaceutical, and hazardous. We believe that the full-service nature of our solution offerings, ease of our mail and ship-back based delivery system and convenience 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 and used healthcare materials treatment, we believe future growth will be driven by the need for our customers to properly document and track the disposal of their waste to maintain compliance with new and existing legislation. We believe our understanding of 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.

CONCENTRATION OF CREDIT AND SUPPLIERS

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, 2017, one customer represented approximately 17% of revenue. This customer also represented approximately 10%, or $0.8 million, of the total accounts receivable balance at June 30, 2017. For the fiscal year ended June 30, 2016, one customer represented approximately 17% of revenue and 17%, or $1.0 million, of the total accounts receivable balance at June 30, 2016. For the fiscal year ended June 30, 2015, one customer represented approximately 17% of revenue. We may be adversely affected by our 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 high quality and reputation of the Company and its solution offerings and (iii) the continued diversification of our solution offerings into additional markets outside of our traditional customer base.

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We currently transport (from the patient or user to the Company's facility or subcontracted treatment facilities) the majority of our solution offerings using USPS; therefore, any long-term interruption in USPS delivery services would disrupt the return transportation and treatment element of our business. Postal delivery interruptions are rare. Additionally, since USPS employees are federal employees, such employees may be prohibited from engaging in or continuing a postal work stoppage, although there can be no assurance that such work stoppage can be avoided. We also have an arrangement with UPS whereby UPS transports certain other solution offerings. The ability to ship items, whether through the USPS or UPS, is regulated by the government and related agencies. Any change in regulation restricting the shipping of medical waste, used healthcare materials or unused or expired dispensed pharmaceuticals through these channels would be detrimental to our ability to conduct operations.

We maintain 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 solutions, we own proprietary molds and dies and utilize several contract manufacturers for the production of the primary raw materials. We believe that alternative suitable contract manufacturers are readily available to meet the production specifications of our products and solutions. We utilize national suppliers for the majority of the raw materials used in our other products and solutions and international suppliers for Pitch-It IV Poles.

INTELLECTUAL PROPERTY

We have a portfolio of trademarks and patents, both granted and pending. We consider our trademarks important in the marketing of our products and services, including the Sharps logo, Sharps Recovery System, TakeAway Medication Recovery System, MedSafe, SharpsTracer, Sharps Secure, TakeAway Environmental Return System, Complete Needle and PELLA-DRX™ among others. With respect to our registered marks, we continue using such marks and will file all necessary documentation to maintain their registrations for the foreseeable future. We have a number of patents issued, including those applicable to our PELLA-DRX waste conversion process (patent numbers US 8,163,045, US 8,100,989, US 8,268,073 and US 4,440,534), our Sharps Secure Needle Disposal System (patent numbers US 8,162,139 and US 8,235,883), our unique design features related to the TakeAway Environmental Return System drop-off boxes (patent number US 8,324,443) and our Complete Needle Collection & Disposal System (patent number US 4,463,106). We have patents pending on our MWMS rapid deployment system and our MedSafe solution.

Solely for convenience, the trademarks and service marks referred to in this Annual Report on Form 10-K may appear without the ® or ™, but such references are not intended to indicate, in any way, that we will not assert to the fullest extent under applicable law our rights to such trademarks and service marks.

COMPETITION

There are several competitors who offer similar or identical products and services that facilitate the disposal of smaller quantities of medical waste. 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 companies. Additionally, we compete in certain markets with Stericycle, the largest medical waste company in the country, which focuses primarily on a pickup service business model. With the addition of the route-based pickup services offered on a direct basis in a twenty-three (23) state region of the South, Southeast and Northeast portions of the United States and through a network of medical and hazardous waste services providers, the Company believes it is better positioned with its comprehensive medical waste management offering to compete with Stericycle. As Sharps continues to grow and increase awareness of the proper disposal of syringes and unused medications (including controlled substances), it could face additional and possibly significant competition. We believe our comprehensive line of proven solution offerings, comprehensive medical waste management service offerings, first mover advantages, excellent industry reputation, significant history of market and customer success, quality solutions and products, as well as our capabilities as a vertically-integrated producer of products and services provide significant differentiation in the current competitive market.

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GOVERNMENT REGULATION

Sharps is subject to extensive federal, state and/or local laws, rules and regulations. We are required to obtain permits, authorizations, approvals, certificates and other types of governmental permission from the EPA, the Department of Transportation, the U.S. Food and Drug Administration, the State of Texas, the State of Pennsylvania and local governments with respect to our facilities and operations. 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 transported medical waste. Our estimated annual costs of complying with these laws, regulations and guidelines, including environmental laws, is currently less than $200,000 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.

ITEM 1A. RISK FACTORS

We may be unable to manage our growth effectively.

We continued to experience core revenue growth in fiscal year 2017 as we saw the benefits of our marketing activities in all of our target markets. Revenue increased 14% to $38.2 million for the fiscal year ended June 30, 2017 driven by increases in the professional market due primarily to targeted telemarketing initiatives and promotional activities, continued rollout of new patient support programs in the pharmaceutical market and increases in the home health care and assisted living markets. The increase in revenue and execution of our growth strategies 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 at some point to add operations, administrative and other personnel and 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, do so on a timely basis or expand our operations and systems to the extent and in the time required.

If the flu related business of our customers decreases, the revenues generated by our business could decrease.

Our operating results are dependent in part upon the amount and types of solutions necessary to service our customers' needs which are heavily influenced by the total number of patients our customers are serving at any time, especially related to the administration of flu shots. At times of lower patient activity, our customers have a decreased need for our services on a supplemental or peak needs basis. Our operating results can vary depending on the timing and severity of the flu season as well as other factors affecting the volume of flu shots administered in the retail setting.

Our quarterly results may fluctuate significantly.

Our operating results have historically varied on a quarterly basis and may continue to fluctuate significantly in the future. Factors that may affect our quarterly operating results, some of which are beyond the control of management, include, but are not limited to, seasonality; the timing of inventory builds for patient support programs of our pharmaceutical manufacturer customers; the timing and severity of the flu season; fluctuations in inventory, energy, transportation, labor, healthcare and other costs; significant acquisitions, dispositions, joint ventures and other strategic initiatives; and many of the other risk factors discussed herein. Accordingly, we believe that quarter-to-quarter comparisons of our operating results are not necessarily meaningful and investors should not rely on the results of any particular quarter as an indication of our future performance.

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, 2017, one customer represented approximately 17% of revenue. This customer also represented approximately 10%, or $0.8 million, of the total accounts receivable balance at June 30, 2017. To the extent 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.

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

Our growth and development to date has been largely dependent on the active participation and leadership of our senior management team consisting of the Company's CEO and President, Vice President and CFO, Vice President of Operations, Vice President of Quality Assurance and Vice President of Marketing. We believe that the continued success of the business is largely dependent upon the continued employment of the senior management team and have, therefore, (i) entered into individual employment arrangements with key personnel and (ii) approved the Compensation and Incentive Plan for participation by the senior management team 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.

Risks associated with our acquisition strategy could adversely affect our operating results.

We expect a portion of our growth to come from acquisitions, and we continue to evaluate opportunities for acquiring businesses that may supplement our internal growth. However, there can be no assurance that we will be able to identify and purchase suitable operations. In addition, the success of any acquisition depends in part on our ability to integrate the acquired business. The process of integrating acquired businesses may involve unforeseen difficulties and may require a disproportionate amount of management's attention and the Company's financial and other resources. There can be no assurance that any acquisitions, if completed, will be successful.

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 smaller quantities of medical waste. 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 companies. Additionally, we compete in certain markets with Stericycle, the largest medical waste company in the country, which focuses primarily on a pickup service business model. As Sharps continues to grow and increase awareness of the proper disposal of syringes and unused medications, it could face additional and possibly significant competition. As a result, we could experience increased pricing pressures that could reduce our margins. In addition, as we expand our business into other markets, the number, type and size of our competitors may expand. Many of these potential competitors may have greater financial and operational resources, flexibility to reduce prices and other competitive advantages that could adversely impact our current competitive position.

The lack of customer long-term volume commitments could adversely affect the Company's profits and future growth.

Although we enter into exclusive contracts with the majority of our enterprise customers, these contracts do not have provisions for firm long-term volume commitments. In general, customer purchase orders may be canceled and order volume levels can be changed or delayed with limited or no penalties. Canceled, delayed or reduced purchase orders could significantly affect our financial performance.

The Company is subject to extensive and costly federal, state and local laws, and existing or future regulations may restrict the Company's operations, increase our costs of operations and subject us to additional liability.

We are subject to extensive federal, state and/or local laws, rules and regulations. We are required to obtain permits, authorizations, approvals, certificates and other types of governmental permission from the EPA, the Department of Transportation, the U.S. Food and Drug Administration, the State of Texas, the State of Pennsylvania and local governments with respect to our facilities and operations. 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 transported medical waste. We believe that we are currently in compliance in all material respects with all applicable laws and regulations governing our business, including the permits and authorizations for our incinerator facility. Our estimated annual costs of complying with these laws, regulations and guidelines, including environmental laws, is currently less than $200,000 per year. In the event additional laws, rules or regulations are adopted which affect our business, additional expenditures may be required in order for us to be in compliance with such changing laws, rules and regulations. Furthermore, any material relaxation of any existing regulatory requirements governing the transportation and disposal of medical waste could result in a reduced demand for our products and services and could have a material adverse effect on our revenues and financial condition. The scope and duration of existing and future regulations affecting the medical and solid waste disposal industry cannot be anticipated and are subject to change.

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The inability of the Company to operate its treatment facilities would adversely affect its operations

Our business utilizes a treatment facility for the proper disposal or treatment of medical waste, used health care materials and unused pharmaceuticals. Our owned facility has both incineration and autoclave technologies in Carthage, Texas. In August 2016, the Company received the Commonwealth of Pennsylvania Department of Environmental Protection Bureau of Waste Management permit for the processing of medical waste at its treatment facility located in northeastern Pennsylvania. The 40,000 square foot facility has been permitted as both a medical waste treatment facility, using an autoclave, and as a transfer station for medical, pharmaceutical and trace chemotherapy waste of up to 82 tons per day. The facility is designed to cost-effectively and efficiently process medical waste generated by the Company’s route-based and mailback customers and also doubles as a distribution center of mailback solutions and has been in operation since November 2016. Sharps believes it operates and maintains the facilities in compliance in all material respects with all federal, state and local laws and/or any other regulatory agency requirements involving treatment and disposal and the operation of the incinerator and autoclave facilities. The failure to maintain the permits for the treatment facility or unfavorable conditions contained in the permits or new regulations could substantially impair our operations and reduce our revenues. Any disruption in the availability of a disposal or treatment facility, whether as a result of action taken by governmental authorities, natural disasters or otherwise, would have an adverse effect on our operations and results of operations.

The handling and disposal or treatment of regulated 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. Although our products and procedures are designed to minimize exposure to these materials, 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 regulated 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 regulated 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.

Restrictions in our Credit Agreement could adversely affect our business, financial condition, results of operations and value of our securities.

The Credit Agreement contains affirmative and negative covenants that, among other things, require the Company to maintain, beginning with the twelve-month period ending September 30, 2017, a maximum cash flow leverage ratio of no more than 3.5 to 1.0 and a minimum debt service coverage ratio of not less than 1.15 to 1.00. The maximum cash flow leverage ratio decreases to 3.25 to 1.0 on December 31, 2017 and to 3.0 to 1.0 on March 31, 2018. The Credit Agreement, which expires on March 29, 2019, also contains customary events of default which, if uncured, may terminate the Credit Agreement and require immediate repayment of all indebtedness to the lenders. These covenants could affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities as they arise.

Our ability to comply with the covenants and restrictions contained in the Credit Agreement may be affected by events beyond our control, including prevailing economic, financial, and industry conditions. If market or other economic conditions deteriorate, our ability to comply with these covenants may be impaired. A failure to comply with these provisions could result in a default or an event of default. Upon an event of default, unless waived, the lenders could elect to terminate commitments, cease making further loans, require cash collateralization of letters of credit, cause its loans to become due and payable in full and force us into bankruptcy or liquidation. If the payment of our debt is accelerated, our assets may be insufficient to repay such debt in full, and the holders of our stock could experience a partial or total loss of their investment.

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An inability to win additional government contracts could have a material adverse effect on our operations and adversely affect our future revenue.

Although the Company has secured some U.S. government business during fiscal year 2017, there can be no assurances that future periods will include similar business. All contracts with, or subcontracts involving, the federal government are terminable or subject to renegotiation by the applicable governmental agency on 30 days' notice at the option of the governmental agency. If a material contract is terminated or renegotiated in a manner that is materially adverse to us, our revenues and future operations could be materially adversely affected.

As a government contractor, we are subject to extensive government regulation, and our failure to comply with applicable regulations could subject us to penalties that may restrict our ability to conduct our business.

Governmental contracts or subcontracts involving governmental facilities are often subject to specific procurement regulations, contract provisions and a variety of other requirements relating to the formation, administration, performance and accounting of these contracts. Many of these contracts include express or implied certifications of compliance with applicable regulations and contractual provisions. If we fail to comply with any regulations, requirements or statutes, our existing governmental contracts or subcontracts involving governmental facilities could be terminated, or we could be suspended from government contracting or subcontracting. If one or more of our governmental contracts or subcontracts are terminated for any reason, or if we are suspended or barred from government work, we could suffer a significant reduction in expected revenues and profits. Furthermore, as a result of our governmental contracts or subcontracts involving governmental facilities, claims for civil or criminal fraud may be brought by the government for violations of these regulations, requirements or statutes.

The possibility of postal work interruptions and restrictions on shipping through the mail would adversely affect the disposal or treatment element of the Company's business and have an adverse effect on our operations, results of operations and financial condition.

We currently transport (from the patient or user to the Company's facility or subcontracted treatment facilities) the majority of our solution offerings using USPS; therefore, any long-term interruption in USPS delivery services would disrupt the return transportation and treatment element of our business. Postal delivery interruptions are rare. Additionally, since USPS employees are federal employees, such employees may be prohibited from engaging in or continuing a postal work stoppage, although there can be no assurance that such work stoppage can be avoided. As noted above, we entered into an arrangement with UPS whereby UPS transports certain other solution offerings. The ability to ship items, whether through the USPS or UPS, is regulated by the government and related agencies. Any change in regulation restricting the shipping of medical waste, used healthcare materials or unused or expired dispensed pharmaceuticals through these channels would be detrimental to our ability to conduct operations. Any disruption in the transportation of products would have an adverse effect on our operations, results of operations and financial condition.

The Company's stock has experienced, and may continue to experience, low trading volume and price volatility.

The Company's common stock is quoted on the NASDAQ Capital Market ("NASDAQ") under the symbol "SMED." The daily trading volumes for our common stock are, and may continue to be, relatively small compared to many other publicly traded securities. Over the past three years, the Company's common stock has had an average trading volume of approximately 55,000 shares traded per month. It may be difficult for investors to sell shares in the public market at any given time at prevailing prices, and the price of our common stock may, therefore, be volatile.

We may be subject to information technology system failures, network disruptions and breaches in data security.

We rely upon sophisticated information technology systems, infrastructure and security procedures and systems to operate our business and ensure the secure storage and transmission of information. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, computer networks and the internet are, by nature, vulnerable to unauthorized access. An accidental or willful security breach could result in unauthorized access and/or use of sensitive data. Our security measures could be breached by third-party action, computer viruses, accidents or error or misconduct by an employee or contractor. Because techniques used to obtain unauthorized access, disable or degrade service or to sabotage computer systems change frequently, it may be difficult to detect immediately and we may be unable to implement adequate preventive measures. Unauthorized parties may also attempt to gain access to our systems or facilities through various means, including hacking into our systems or facilities, fraud, trickery or other means of deceiving employees, contractors and temporary staff. We have encountered threats of this type from time to time, none of which have materially impacted our operations or financial results. Although we maintain a system of information security and controls, a party that is able to circumvent our security measures could cause interruption in our operations, damage our computers or those of our users or otherwise damage our reputation. Depending on the severity, any of these events could adversely affect our operations and financial results. In addition, if we were to experience an information security breach, we may be required to expend significant amounts of time and money to remedy, protect against or mitigate the effect of the breach, and we may not be able to remedy the situation in a timely manner, or at all. While we have invested in protection of data and information technology, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

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ITEM 1B. UNRESOLVED STAFF COMMENTS.

As of the date of this report, we do not have any unresolved staff comments.

ITEM 2. PROPERTIES.

The Company utilizes approximately 200,000 square feet of space across the U.S. including space for corporate offices in Houston, Texas. Sharps has manufacturing, assembly, storage, distribution and warehousing operations as well as two (2) fully-permitted facilities that house our processing and treatment operations. Our processing and treatment facilities are currently permitted to treat and process 182 tons of medical, pharmaceutical and other healthcare related waste per day. The Company owns one of these processing and treatment facilities and leases all other spaces. The leases expire between 2020 to 2022 with options to renew ranging from 3 years to 10 years.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, the Company is involved in legal proceedings and litigation in the ordinary course of business. In the opinion of management, the outcome of such matters will not have a material adverse effect on the Company's consolidated financial position or consolidated results of operations.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information: The Company's common stock is quoted on the NASDAQ under the symbol "SMED". Over the past three years, the Company's common stock has had an average trading volume of approximately 55,000 shares traded per month. The table below sets forth the high and low closing prices of the Company's common stock on the NASDAQ (July 1, 2015 through August 23, 2017) for each quarter within the last two fiscal years.

	Common Stock	
	High	Low
Fiscal Year Ending June 30, 2016		
First Quarter	$9.53	$6.10
Second Quarter	$10.11	$7.32
Third Quarter	$8.57	$4.75
Fourth Quarter	$6.03	$4.16
Fiscal Year Ending June 30, 2017		
First Quarter	$5.84	$4.29
Second Quarter	$4.51	$3.40
Third Quarter	$4.86	$4.17
Fourth Quarter	$4.61	$4.00
Fiscal Year Ending June 30, 2018		
First Quarter (August 21, 2017)	$5.67	$4.17

Stockholders: At August 21, 2017, there were 16,008,412 shares of common stock held by approximately 151 holders of record; however, the Company believes the number of beneficial owners exceeds this number. The last reported sale of the common stock on August 21, 2017 was $5.26 per share.

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Dividend Policy: The Company has never declared nor paid any cash dividends on its common stock. The Company currently intends to retain its cash generated from operations for working capital purposes and to fund the continued expansion of its business and does not anticipate paying any dividends on our common stock in the foreseeable future. Moreover, future payment of dividends may be restricted by credit or other agreements to which the Company is a party.

Issuer Purchases of Equity Securities: On January 7, 2013, the Company announced that its Board of Directors approved a stock repurchase program effective January 3, 2013, authorizing the Company to repurchase in the aggregate up to $3 million of its outstanding common stock over a two-year period. On March 5, 2015, the Board approved a two-year extension of the stock repurchase program through January 1, 2017. The program has not been further extended. There were no repurchases of shares during the year ended June 30, 2017.

Securities Authorized for Issuance under Equity Compensation Plans:

The following equity compensation plan information is provided as of June 30, 2017:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
2010 Stock Plan as approved by shareholders (1) (2)	877,904	$ 4.53	1,561,891

Notes:

(1) Represents stock options issued under the Sharps Compliance Corp. 2010 Stock Plan. The 2010 Stock Plan replaced the Sharps Compliance Corp. 1993 Stock Plan in November 2010.

(2) Number of securities to be issued and weighted average exercise price include the effect of 13,248 shares of restricted stock issued to the Board of Directors.

ITEM 6. SELECTED FINANCIAL DATA.

The following selected historical financial data has been derived from our audited financial statements and should be read in conjunction with the historical Consolidated Financial Statements and related notes and Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations (in thousands except earnings per share data):

	For the Year Ended June 30,				
	2017	2016	2015	2014	2013
Revenues	$38,188	$33,383	$30,902	$26,570	$21,530
Operating Income (Loss)	$(1,187)	$5	$1,236	$965	$(2,709)
Net Income (Loss)	$(1,293)	$13	$1,160	$956	$(2,712)
Net Income (Loss) per share:					
Basic	$(0.08)	$0.00	$0.08	$0.06	$(0.18)

Diluted	$(0.08)	$0.00	$0.07	$0.06	$(0.18)
Total Assets	$34,464	$30,147	$29,751	$26,461	$25,532
Total Debt	$2,603	$-	$-	$-	$-
Cash and Cash Equivalents	$4,675	$12,435	$15,157	$13,717	$15,503
Working Capital	$10,488	$17,232	$19,623	$17,888	$16,643
Total Stockholders' Equity	$25,287	$23,843	$23,586	$21,904	$21,070

Notes:

- 2014 Operating income and net income include $1.5 million for a legal settlement received by the Company.
- 2016 Revenues, operating income and net income include the results of operations for the acquisitions during the year which were not individually or in the aggregate material to the Company's financial position. Additionally, the acquisitions pro forma results would not have a material impact on the Company's results had the acquisitions occurred at the beginning of the current year or previous year.
- 2017 Revenues, operating income and net income include the results of operations for the acquisition during the year. See Note 12 in the notes to the consolidated financial statements for acquisition pro forma results.

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

The discussion and analysis presented below should be read in conjunction with the consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. See "Information Regarding Forward Looking Statements."

RESULTS OF OPERATIONS

The following analyzes changes in the consolidated operating results and financial condition of the Company during the years ended June 30, 2017, 2016 and 2015, respectively. The following table sets forth for the periods indicated certain items from the Company's Consolidated Statements of Operations (dollars in thousands except for percentages expressed as a percentage of revenues):

	Year Ended June 30,					
	2017	%	2016	%	2015	%
Revenues	$38,188	100.0%	$33,383	100.0%	$30,902	100.0%
Cost of revenues	26,351	69.0 %	22,272	66.7 %	19,907	64.4 %
Gross profit	11,837	31.0 %	11,111	33.3 %	10,995	35.6 %
SG&A expense	12,223	32.0 %	10,812	32.4 %	9,496	30.7 %
Depreciation and amortization	801	2.1 %	294	0.9 %	263	0.9 %
Operating income (loss)	(1,187)	(3.1 %)	5	0.0 %	1,236	4.0 %
Other income (expense)	(102)	(0.3 %)	32	0.1 %	36	0.1 %
Income (loss) before income taxes	(1,289)		37		1,272	
Income tax expense	4	0.0 %	24	0.1 %	112	0.4 %
Net income (loss)	$(1,293)	(3.4 %)	$13	0.0 %	$1,160	3.8 %

YEAR ENDED JUNE 30, 2017 AS COMPARED TO YEAR ENDED JUNE 30, 2016

Total revenues for the fiscal year ended June 30, 2017 of $38.2 million increased by $4.8 million, or 14%, from the total revenues for the fiscal year ended June 30, 2016 of $33.4 million. Billings by market are as follows (in thousands):

	Year Ended June 30,		
	2017 (Unaudited)	2016 (Unaudited)	Variance (Unaudited)
BILLINGS BY MARKET:			
Professional	$11,962	$ 7,571	$ 4,391
Home Health Care	7,901	7,378	523
Retail	7,010	8,798	(1,788)
Pharmaceutical Manufacturer	5,961	5,708	253
Assisted Living	2,442	2,194	248
Government	1,680	1,541	139
Environmental	414	259	155
Other	763	845	(82)
Subtotal	38,133	34,294	3,839
GAAP Adjustment *	55	(911)	966
Revenue Reported	$38,188	$ 33,383	$ 4,805

*Represents the net impact of the revenue recognition adjustments required to arrive at reported generally accepted accounting principles (“GAAP”) revenue. Customer billings include all invoiced amounts associated with products shipped or services rendered during the period reported. GAAP revenue includes customer billings as well as numerous adjustments necessary to reflect, (i) the deferral of a portion of current period sales and (ii) recognition of certain revenue associated with products returned for treatment and destruction. The difference between customer billings and GAAP revenue is reflected in the Company’s balance sheet as deferred revenue. See Note 2 “Revenue Recognition” in “Notes to Consolidated Financial Statements”.

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The components of billings by solution are as follows (in thousands except for percentages expressed as a percentage of total billings):

	Year Ended June 30,					
	2017	% Total		2016	% Total	
REVENUES BY SOLUTION:						
Mailbacks	$24,080	63.1	%	$24,654	71.9	%
Route-based pickup services	6,348	16.6	%	2,061	6.0	%
Unused medications	3,377	8.9	%	3,531	10.3	%
Third party treatment services	413	1.1	%	258	0.8	%
Other[(1)]	3,915	10.3	%	3,790	11.0	%
Total billings	$38,133	100.0	%	$34,294	100.0	%
GAAP adjustment[(2)]	55			(911)		
Revenue reported	$38,188			$33,383		

(1) The Company's other products include IV poles, accessories, containers, asset return boxes and other miscellaneous items.

(2) Represents the net impact of the revenue recognition adjustments required to arrive at reported generally accepted accounting principles ("GAAP") revenue. Customer billings include all invoiced amounts associated with products shipped or services rendered during the period reported. GAAP revenue includes customer billings as well as numerous adjustments necessary to reflect, (i) the deferral of a portion of current period sales and (ii) recognition of certain revenue associated with products returned for treatment and destruction. The difference between customer billings and GAAP revenue is reflected in the Company's balance sheet as deferred revenue.

The increase in billings was primarily attributable to increased billings in the Professional ($4.4 million), Home Health Care ($0.5 million), Pharmaceutical Manufacturer ($0.3 million) and Assisted Living ($0.2 million) markets. The increase was partially offset by decreased billings in the Retail market ($1.8 million). The increase in Professional market billings is due to a combination of acquired and organic growth as the Company continued its focus on securing customers from the small to medium quantity generator sector, which consists largely of physicians, clinics, dentists, surgery centers, veterinarians and other healthcare professionals, who benefit from the cost-effective and convenient Sharps Recovery System and the Company's route-based pickup services. Of the $4.4 million increase in Professional billings, $3.1 million was generated from our acquired businesses based on their pre-acquisition run-rate with the difference being attributable to organic growth. The increase in Home Health Care market billings is due to the timing of distributor purchases. The increase in Pharmaceutical Manufacturer market billings is primarily due to inventory builds for patient support programs. The increase in Assisted Living market billings is primarily a result of the increased sales focus as well as the Company's route-based services. The decrease in Retail market billings was the result of a decrease in billings for the TakeAway Medication Recovery System envelopes which were launched by several Retail customers in the prior year, a decline in overall flu shot related orders and the loss of one retail pharmacy customer. Billings for Mailbacks in the year ended June 30, 2017 decreased 2.3% to $24.1 million as compared to $24.7 million in 2016 and represented 63.1% of total billings. Billings for Route-Based Pickup Services increased 208% to $6.3 million in the year ended June 30, 2017 as compared to $2.1 million in 2016 and represented 16.6% of total billings. Of the $4.3 million increase in billings for Route-Based Pickup Services, $3.1 million was generated from our acquired businesses based on their pre-acquisition run-rate with the difference being attributable to organic growth.

Cost of revenue for the year ended June 30, 2017 of $26.4 million was 69.0% of revenue. Cost of revenue for the year ended June 30, 2016 of $22.3 million was 66.7% of revenue. The lower gross margin for the year ended June 30, 2017 of 31.0% (versus 33.3% for the year ended June 30, 2016) was primarily due to the adverse impact of duplicative costs as the Company transitioned from third-party processing of medical waste in the Northeast Region to internal processing at the new facility in Pennsylvania.

Selling, general and administrative (“SG&A”) expenses for the year ended June 30, 2017 and 2016 were $12.2 million and $10.8 million, respectively. SG&A expenses for the year ended June 30, 2017 included $0.7 million of acquisition related costs associated with the completion of the Company’s acquisition of Citiwaste. Without these acquisition related costs and the $0.2 million of acquisition related costs incurred in the prior year, SG&A increased 8% compared to the prior year period due to the Company’s ongoing investment in sales and marketing initiatives.

The Company recorded an operating loss of $1.2 million for the year ended June 30, 2017 compared to minimal operating income for the year ended June 30, 2016. The operating loss was negatively impacted by lower gross profit and higher SG&A expense (discussed above).

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The Company reported loss before income taxes of $1.3 million for the year ended June 30, 2017 compared to minimal income before income taxes for the year ended June 30, 2016. Loss before income taxes was negatively impacted by the operating loss (discussed above).

The Company's effective tax rate for the year ended June 30, 2017 and 2016 was (0.3%) and 64.9%, respectively, reflecting estimated state income taxes. The Company's net deferred tax assets have been fully reserved by a valuation allowance.

The Company reported a net loss of $1.3 million for the year ended June 30, 2017 compared to minimal net income for the year ended June 30, 2016. Net loss was negatively impacted by the net loss before income taxes (discussed above).

YEAR ENDED JUNE 30, 2016 AS COMPARED TO YEAR ENDED JUNE 30, 2015

Total revenues for the fiscal year ended June 30, 2016 of $33.4 million increased by $2.5 million, or 8%, from the total revenues for the fiscal year ended June 30, 2015 of $30.9 million. Billings by market are as follows (in thousands):

	Year Ended June 30,		
	2016 (Unaudited)	2015 (Unaudited)	Variance (Unaudited)
BILLINGS BY MARKET:			
Retail	$8,798	$ 8,726	$ 72
Professional	7,571	6,225	1,346
Home Health Care	7,378	6,802	576
Pharmaceutical Manufacturer	5,708	4,855	853
Assisted Living	2,194	1,879	315
Government	1,541	1,756	(215)
Environmental			