

RETRACTABLE TECHNOLOGIES INC
Form 10-K
April 02, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 001-16465

Retractable Technologies, Inc.

(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of
incorporation or organization)

511 Lobo Lane
Little Elm, Texas
(Address of principal executive offices)

75-2599762
(I.R.S. Employer
Identification No.)

75068-5295
(Zip Code)

972-294-1010

Registrant's telephone number, including area code

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

Title of each class
Common

Name of each exchange on which registered
NYSE American LLC

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

Preferred Stock

(Title of class)

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

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

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

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

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 Act). Yes No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. The aggregate market value of the common equity held by non-affiliates as of June 30, 2017, was \$17,327,372, assuming a closing price of \$1.27 and outstanding shares held by non-affiliates of 13,643,600.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13, or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of March 1, 2018, there were 32,666,454 shares of our Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980).

None except exhibits.

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RETRACTABLE TECHNOLOGIES, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2017

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PART I

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words could, may, believes, anticipates, intends, expects, and similar words constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, our ability to maintain liquidity, our maintenance of patent protection, the impact of current and future Court decisions regarding current litigation, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, foreign trade risk, our ability to quickly increase capacity in response to an increase in demand, our ability to access the market, our ability to maintain or lower production costs, our ability to continue to finance research and development as well as operations and expansion of production, the impact of larger market players, specifically Becton, Dickinson and Company (BD), in providing devices to the safety market, and other factors referenced in Item 1A. Risk Factors. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

Item 1. Business.

DESCRIPTION OF BUSINESS

General Development of Business

Retractable Technologies, Inc. was incorporated in Texas in 1994. Our business is the manufacturing and marketing of safety medical products (predominately syringes) for the healthcare industry. We have manufacturing facilities in Little Elm, Texas and use manufacturers in China as well. We have developed several new products in the last few years, including the EasyPoint® needle which can be used with, among other things, prefilled syringes.

In 2007, we filed a lawsuit claiming that we have been blocked from gaining market access due to actions taken by BD. In August 2017, a district court dismissed our remaining claims against BD and entered a take nothing judgment. We have filed for appeal.

Financial Information

We do not report in segments. See Item 8 for our financial statements.

Principal Products, Markets, and Distribution

Our goal is to become a leading provider of safety medical products. Our principal products were designed to protect healthcare workers and others from needlestick injuries, cross-contamination through reuse, and reduce disposal costs. The VanishPoint® products accomplish these goals by retracting the needle when the plunger handle is fully depressed while the needle is still in the patient. This pre-removal activation virtually eliminates exposure to the contaminated needle, reducing the risk of needlestick injuries. Activation is easily accomplished in one step, using one hand. Upon activation of the retraction mechanism, VanishPoint® products are rendered unusable, reducing the risk of disposal-related injuries or reuse.

VanishPoint® syringe sales have historically comprised most of our sales. VanishPoint® syringe sales were 98.2%, 93.0% and 89.9% of our revenues in 2015, 2016, and 2017.

Our VanishPoint® safety products currently consist of tuberculin, insulin, and allergy antigen VanishPoint® syringes; 0.5mL, 1 mL, 2mL, 3mL, 5mL, and 10mL VanishPoint® syringes; and the VanishPoint® autodisable syringe. We also sell the VanishPoint® IV catheter; the VanishPoint® blood collection tube holder; and the VanishPoint® blood collection set. The Patient Safe® syringe protects patients by reducing the risk of bloodstream infections associated with catheter hub contamination. Our Patient Safe® products currently consist of 3mL, 5mL, 10mL, 20mL, 30mL, 60mL syringes and the Patient Safe® Luer cap.

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In the second quarter of 2016, we began selling the EasyPoint® needle. EasyPoint® needles made up 6.0% of revenues in 2017. The EasyPoint® is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefilled syringes to give injections. The EasyPoint® needle can also be used to aspirate fluids and collect blood.

We currently have under development additional safety products that add to or build upon our current product line offering. These products include: retractable needles and syringes, glass syringes, dental syringes, IV catheter introducers, and blood collection sets.

Our products are sold to and used by healthcare providers primarily in the U.S. (with 21.7% of revenues in 2017 generated from sales outside the U.S.) which include, but are not limited to, acute care hospitals, alternate care facilities, doctors' offices, clinics, emergency centers, surgical centers, long-term care facilities, Veterans Administration facilities, military organizations, public health facilities, and prisons.

Under the current supply chain system in the U.S. acute care market, the vast majority of decisions relating to the contracting for and purchasing of medical supplies are made by the representatives of group purchasing organizations (GPOs) and purchasing representatives rather than the end-users of the product (nurses, doctors, and testing personnel). The GPOs and larger manufacturers often enter into contracts which can prohibit or limit entry in the marketplace by competitors.

We distribute our products throughout the U.S. through general line and specialty distributors. We also use international distributors. We have developed a national direct marketing network in order to market our products to health care customers and their purchaser representatives. Our marketers make contact with all of the departments that affect the decision-making process for safety products, including the purchasing agents. They call on acute care and alternate care sites and speak directly with the decision-makers of these facilities. We employ trained sales representatives and clinicians, including nurses and/or medical technologists that educate healthcare providers and healthcare workers on the use of safety devices through on-site clinical training, exhibits at related tradeshows, and publications of relevant articles in trade journals and magazines. These employees provide clinical support to customers. In addition to marketing our products, the network demonstrates the safety and cost effectiveness of our products to customers.

The *American Journal of Infection Control* published an article in its November 2017 issue that estimates that more than 300,000 healthcare workers in the United States suffer sharps injuries (such as needlesticks) annually. The article is the most recent of a series of articles published over the past few years (several of which were published in the *AOHP Journal*). The data shows that the number of sharps injuries has remained essentially unchanged over the past several years.

Sources and Availability of Raw Materials

We own the printing plates used to print artwork on packaging and the molds used to manufacture the plastic components of our products in the U.S. Other product components, including needle adhesives and packaging materials, are purchased from various suppliers. There are a variety of such suppliers in the United States.

Intellectual Property

Intellectual property rights are material to our business, particularly patent rights. The patents licensed to us by Thomas J. Shaw, our founder and CEO, have varying expiration dates. Importantly, the VanishPoint® syringes, which are constructed using a variety of patents, will cease to be covered by a patent in 2020 unless further patented improvements are made to the design. All of our products are manufactured using patents owned by Thomas J. Shaw and we have a Technology License Agreement with Mr. Shaw granting us the exclusive right to manufacture, market, and sell the products. Mr. Shaw is paid a 5% royalty on our gross sales pursuant to the terms of the Technology License Agreement.

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The Company has registered the following trade names and trademarks for our products: VanishPoint®, EasyPoint®, Patient Safe®, VanishPoint® logos, RT with a circle mark, the Spiral Logo used in packaging VanishPoint® products, the color coded spots on the ends of our VanishPoint® syringes and others. Company slogans The New Standard for Safety and We Make Safety Safe also have been granted registered trademark protection.

We are involved in patent litigation detailed in Item 3.

Seasonality

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season.

Working Capital Items

Our significant accounting policies are set forth in the notes to our financial statements in Item 8. Our inventory practices will vary in response to demand. Order backlog is not material to our business.

Dependence on Customers

Although our business has historically derived significant percentages of its revenues from a few customers, we do not believe that the loss of any one of these customers would have a material adverse effect on our business.

We do not believe that existing contracts or subcontracts with the government are reasonably likely to be renegotiated or terminated.

Government Approval and Government Regulations

For all products manufactured for sale in the domestic market, we have given notice of intent to market to the FDA, and the devices were shown to be substantially equivalent to the predicate devices for the stated intended use.

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For all products manufactured for sale in the domestic market and foreign market, we hold a Quality Management System certification to ISO 13485. For all products manufactured for sale into European Union countries, we hold a Full Quality Assurance System certification to Directive 93/42/EEC Annex II (excluding section 4). Both of these certifications are issued by our notified body, bsi, and are reviewed annually.

We will continue to comply with applicable regulations of all countries in which our products are registered for sale.

Competitive Conditions

Major domestic competitors include BD and Medtronic Minimally Invasive Therapies (Medtronic, formerly known as Covidien). Terumo Medical Corp., Smiths Medical, and B Braun are additional competitors with smaller market shares. BD and Medtronic have controlling U.S. market share; greater financial resources; larger and more established sales, marketing, and distribution organizations; and greater market influence, including long-term and/or exclusive contracts. Additionally, BD may be able to use its resources to improve its products through research or acquisitions or develop new products which may compete with our products.

We compete primarily on the basis of healthcare worker and patient safety, product performance, and quality. We believe our competitive advantages include, but are not limited to, our leadership in quality and innovation. We believe our products continue to be the most effective safety devices in today's market. Our syringe products include passive safety activation, require less disposal space, and are activated while in the patient, reducing exposure to the contaminated needle. Our price per unit is competitive or even lower than the competition once all the costs incurred during the life cycle of a syringe are considered. Such life cycle costs include disposal costs, testing and treatment costs for needlestick injuries, and treatment for contracted illnesses resulting from needlestick injuries.

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EasyPoint® retractable needles offer unique safety benefits not found in other commercially available safety needles. Manually activated safety needles, such as BD's SafetyGlide and Eclipse needles, and Medtronic's Magellan needle, must be removed from the patient, exposing the contaminated needle prior to activation of the manual safety mechanism. EasyPoint® needles allow for activation of the automated retraction mechanism while the needle is still in the patient, reducing exposure to the contaminated needle and effectively reducing the risk of needlestick injuries. BD's Integra needle allows for retraction from the patient but must be used in conjunction with a BD Integra 3mL syringe. The Integra needle does not have a luer fitting, making it incompatible with commonly used luer-fitting syringes and pre-filled syringes. In addition, the safety feature of the Integra needle/syringe combination can only be activated when the plunger handle is fully depressed and the contents have been expelled. EasyPoint® retractable needles are compatible with luer-fitting syringes, including pre-filled syringes. In addition, EasyPoint® retractable needles may be activated with fluid in the syringe, making it applicable for aspiration procedures such as blood collection.

Research and Development

We spent approximately \$609,000; \$572,000; and \$608,000 in 2017, 2016, and 2015, respectively, on research and development.

Environmental Compliance

We believe that we do not incur material costs in connection with compliance with environmental laws.

Employees

As of March 1, 2018, we had 150 employees. 146 of such employees were full time employees.

Financial Information about Geographic Areas

We have minimal long-lived assets in foreign countries. Shipments to international customers generally require a prepayment either by wire transfer or an irrevocable confirmed letter of credit. We do extend credit to international customers on some occasions depending upon certain criteria, including, but not limited to, the credit worthiness of the customer, the stability of the country, banking restrictions, and the size of the order. All transactions are in U.S. currency. If customers designate a specific destination for its order, we attribute sales to countries based on the destination of shipment.

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	2017		2016		2015	
U.S. sales	\$	27,015,712	\$	26,308,246	\$	23,029,976
North and South America sales (excluding U.S.)		6,380,745		2,741,518		5,668,785
Other international sales		1,097,381		776,872		853,439
Total sales	\$	34,493,838	\$	29,826,636	\$	29,552,200
Long-lived assets						
U.S.	\$	11,215,583	\$	11,930,293	\$	11,282,192
International	\$	137,619	\$	161,744	\$	185,869

Most large international sales of VanishPoint® products are filled by production from Chinese manufacturers. In the event that we become unable to purchase such product from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes.

We do not maintain patent or trademark protection in all foreign countries, but, where possible, have taken steps to protect our patents and trademarks in those countries where we routinely conduct a material amount of business. Our lack of patent and trademark protection, particularly in certain foreign countries, heightens the risk that our designs may be copied by a competitor.

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We cannot anticipate the impact of potential changes in trade policy from the current administration.

Available Information

We make available, free of charge on our website (www.retractable.com), our Form 10-K Annual Report and Form 10-Q Quarterly Reports and Current Reports on Form 8-K (and any amendments to such reports) as soon as reasonably practical after such reports are filed.

Item 1A. Risk Factors.

We could be subject to complex and costly regulatory activities. Our business could suffer if we or our suppliers encounter manufacturing problems. We could be subject to risks associated with doing business outside of the U.S. Current or worsening economic conditions may adversely affect our business and financial condition.

You should carefully consider the following material risks facing us. If any of these risks occur, our business, results of operations, or financial condition could be materially affected.

We Compete in a Marketplace Dominated by BD

We operate in an environment that is dominated by BD, the major syringe manufacturer in the U.S. We initiated a lawsuit in 2007 against BD. The suit was for patent infringement, antitrust practices, and false advertising. The court severed the patent claims from the other claims. The antitrust and false advertising case was dismissed in district court in August 2017 and we were awarded a take nothing judgment. We have filed for appeal.

Although we have made limited progress in some areas, such as the alternate care and some international markets, our volumes are not as high as they should be given the nature and quality of our products and the federal and state legislation requiring the use of safe needle devices. We believe this is due to BD's activities, despite our litigation efforts described briefly above.

We Have Generally Been Unable to Gain Sufficient Market Access to Achieve Profitable Operations

We have a history of incurring net operating losses. We may experience operating losses in the future. If we are unable to gain sufficient market access and market share, we may be unable to continue to finance research and development as well as support operations and expansion of production.

We Are Dependent on Our Aging Patent Protection

Our main competitive strength is our technology. We are dependent on patent rights, and if the patent rights are invalidated or circumvented, our business would be adversely affected. Patent protection is considered, in the aggregate, to be of material importance in the design, development, and marketing of products.

The Company holds exclusive rights under domestic and foreign patents and has pending applications related to the technology embodied in products that are currently marketed. The Company also holds rights related to new products under development. The patent rights held by the Company for various commercial products have remaining terms and expiration dates presently ranging from 2020 to 2032. Those patent rights cover significant features of the VanishPoint® syringes, blood collection sets and IV catheters, and of the Patient Safe® syringes and EasyPoint® retractable needles.

VanishPoint® syringes comprised 89.9% of sales in 2017 and patent coverage for those products will expire in 2020. When the current patents for those syringes and other products expire in coming years, the Company may experience a significant and rapid loss of sales, and our competitive position in the marketplace may weaken if the Company becomes vulnerable to other competitors utilizing its technology. Such occurrences could have a material adverse effect on profitability.

We do not maintain patent or trademark protection in all foreign countries, but, where possible, have taken steps to protect our patents and trademarks in those countries where we routinely conduct a material amount of business. Our lack of patent and trademark protection, particularly in certain foreign countries, heightens the risk that our designs may be copied by a competitor.

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Our Patents Are Subject to Litigation

We have been sued by BD and MDC Investment Holdings, Inc. for patent infringement. This case has been administratively closed until our case against BD is resolved. We expect this case may be reopened in 2018. Patent litigation and challenges involving our patents are costly and unpredictable and may deprive us of market exclusivity for a patented product or, in some cases, third party patents may prevent us from marketing and selling a product in a particular geographic area.

We Are Vulnerable to New Technologies

Because we have a narrow focus on particular product lines and technology (currently, predominantly retractable needle products), we are vulnerable to the development of superior competing products and to changes in technology which could eliminate or reduce the need for our products. If a superior technology is created, the demand for our products could greatly diminish.

Our Competitors Have Greater Resources

Our competitors have greater financial resources, larger and more established sales and marketing and distribution organizations, and greater market influence, including long-term contracts. These competitors may be able to use these resources to improve their products through research and acquisitions or develop new products, which may compete more effectively with our products. If our competitors choose to use their resources to create products superior to ours, we may be unable to sell our products and our ability to continue operations would be weakened.

International operations may be affected by legislation

We are subject to risks associated with our international operations. In 2017, we used Chinese manufacturers to produce 82.9% of our products. Trade protection measures and/or changes to import or export requirements could adversely impact our operations. We cannot predict the impact of potential changes to U.S. foreign trade policy. Additionally, we derive 21.7% of our revenues from international sales. International sales, particularly in emerging market countries, are further subject to a variety of regulatory, economic, and political risks as well.

Our New Products May Not Replace Lost Vanishpoint® Sales After 2020

Presently existing patent coverage for VanishPoint® syringes will expire in 2020. Following the patent expiration, expected declines in sales of VanishPoint® syringes, which currently comprise 89.9% of our revenues, means that our future success is dependent on new products. We have engaged in research and development for many years to develop other commercially successful products. Often, new products take a number of years to develop and sales of a new

product may be disappointing. Based on industry-wide trends, we anticipate that demand may increase for one of our newer products, the EasyPoint® needle. Sales in 2017 for this product were 6.0% of our total revenues.

The Majority of Our Sales Are Filled Using Third Party Manufacturers

Most international sales, as well as a substantial portion of domestic sales, are filled by production from Chinese manufacturers. In the event that we become unable to purchase such product from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes. Even with increased domestic production, we may not be able to avoid a disruption in supply. In 2017, the 1mL and 3mL syringes made up 83.4% of our unit sales and 82.0% of our revenues. We have a strong relationship with our Chinese manufacturers and we communicate with them frequently.

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Fluctuations in Supplies of Inventory Could Temporarily Increase Costs

Fluctuations in the cost and availability of raw materials and inventory and the ability to maintain favorable third party manufacturing arrangements and relationships could result in the need to manufacture all of our products in the U.S. This could temporarily increase unit costs as we ramp up domestic production.

We Are Controlled by One Shareholder

Thomas J. Shaw, our President and Chief Executive Officer, has investment or voting power over a total of 53.8% of the outstanding Common Stock. Mr. Shaw therefore has the ability to direct our operations and financial affairs and to elect members of our Board of Directors. His interests may not always coincide with the Company's interests or the interests of other stockholders. This concentration of ownership, for example, may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could materially adversely affect the market price of our Common Stock. Mr. Shaw's rights under the Technology License Agreement, as the owner of the technology we produce, present similar conflicts of interest.

We Face Inherent Product Liability Risks

As a manufacturer and provider of safety needle products, we face an inherent business risk of exposure to product liability claims. If a product liability claim is made and damages are in excess of our product liability coverage, our competitive position could be weakened by the amount of money we could be required to pay to compensate those injured by our products. In the event of a recall, we have recall insurance.

Our Business May Be Affected By Changes in The Health Care Regulatory Environment

In the U.S. and internationally, government authorities may enact changes in regulatory requirements, reform existing reimbursement programs, and/or make changes to patient access to health care, all of which could adversely affect the demand for our products and/or put downward pressure on our prices. Future health care rulemaking could affect our business. We cannot predict the timing or impact of any future rulemaking or changes in the law.

Item 1B. Unresolved Staff Comments.

Not applicable and none.

Item 2. Properties.

Our headquarters is located at 511 Lobo Lane, on 35 acres, which we own, overlooking Lake Lewisville in Little Elm, Texas. The headquarters is in good condition and houses our administrative offices and manufacturing facility. The manufacturing facility produced approximately 17.4% of the units that were manufactured in 2017. In the event that we become unable to purchase product from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes. The 5mL and 10mL syringes are sold principally in the international market. In 2017, we used approximately 15% of our current U.S. productive capacity.

A loan in the original principal amount of approximately \$4,210,000 is secured by our land and buildings. See Note 7 to our financial statements for more information.

In the opinion of Management, the property and equipment are suitable for their intended use and are adequately covered by an insurance policy.

Item 3. Legal Proceedings.

In May 2010, our and Mr. Shaw's suit against BD in the U.S. District Court for the Eastern District of Texas, Marshall Division alleging violations of antitrust acts, false advertising, product disparagement, tortious interference, and unfair competition was reopened. The trial commenced on September 9, 2013 in the U.S. District Court for the