RETRACTABLE TECHNOLOGIES INC
Form 10-K
March 30, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

or

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

For the transition period from to

Commission file number 001-16465

Retractable Technologies, Inc.

(Exact name of registrant as specified in its charter)

Texas (State or other jurisdiction of incorporation or organization)	**75-2599762** (I.R.S. Employer Identification No.)
511 Lobo Lane **Little Elm, Texas** (Address of principal executive offices)	**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	**Name of each exchange on which registered**
Common	**NYSE MKT 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 o No x

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

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

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 x No o

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. x

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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

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, 2015 was $56,495,482, assuming a closing price of $3.80 and outstanding shares held by non-affiliates of 14,867,232.

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 o No o

(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, 2016, there were 28,619,874 shares of our Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (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, 2015

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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 simila 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, 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

On May 9, 1994, our company was incorporated in Texas to design, develop, manufacture, and market innovative patented safety medical products for the healthcare industry. Our goal is to become a leading provider of safety medical products. Advantages of our safety products include protection from needlestick injuries, prevention of cross contamination through reuse, and reduction of disposal and other associated costs.

We have designed, developed, and currently market the VanishPoint® and Patient Safe® products. The VanishPoint® products are designed specifically to prevent needlestick injuries and to prevent reuse. The patented designs permit the automated retraction of the needle directly from the patient after completion of the procedure.

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 embodies a unique patented design and protects patients by reducing the risk of bloodstream infections resulting from catheter hub contamination. Our Patient Safe® products currently consist of 3mL, 5mL, 10mL, 20mL, 30mL, 60mL syringes and the Patient Safe® Luer cap.

On June 17, 2014, we received notice of substantial equivalence from the Food and Drug Administration for the EasyPoint needle. The EasyPoint is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefill syringes to give injections. The EasyPoint needle can also be used to aspirate fluids and blood collection. We have completed installation and validation of the equipment. We are currently building stock for product release.

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

Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by the marketing practices engaged in by BD which dominates our

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market. We initiated a lawsuit in 2007 against BD. As previously reported, the District Court granted us a final judgment for $352 million plus post-judgment interest as well as some injunctive relief. We have not received any payments pursuant to this judgment. BD has appealed to the United States Court of Appeals for the Fifth Circuit. Oral argument was heard on February 29, 2016 and we are still waiting for the appellate decision. An earlier portion of the same case dealt with patent infringement charges against BD. In that portion of the case, the Federal Circuit determined that BD s 1mL Integra syringe violated our patents but that BD s 3mL Integra did not infringe our patents. The District Court had awarded us $5 million plus prejudgment and post-judgment interest based on the finding of infringement by the jury. We received payment of $7,724,826 (the Judgment Amount) from BD in connection with such award. The Judgment Amount was recognized on the income statement in the second quarter of 2015 as the case was concluded with no change to the damages that were awarded.

We continue to attempt to gain access to the market through our sales efforts, our innovative technology, introduction of new products, and, when necessary, litigation.

Section 4191 of the Internal Revenue Code, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act (PPACA), provides for an excise tax of 2.3% on medical devices. The impact of this tax was $360,000 in 2015, $856,000 in 2014, and $758,000 in 2013, and is net of expected refunds attributable to rebate credits. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on December 18, 2015, includes a two year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017.

In 2014, we took steps to decrease our non-litigation legal costs by approximately $1.1 million. Additionally, effective May 9, 2014, we reduced our workforce by 13.7% in an effort to cut costs. In 2015, we further reduced our workforce. The net effect of the lower non-litigation costs and the reduced workforce, offset by a payment to a former executive, was approximately $450,000 in 2015.

We exchanged 728,000 shares of Common Stock for 200,000 shares of our Series IV Class B Convertible Preferred Stock as of November 30, 2015 pursuant to an agreement with a shareholder. Such shareholder agreed to waive all unpaid dividends in arrears associated with the tendered preferred stock, equaling $3,094,795. Future dividend requirements of $200,000 per year are avoided as a result of this transaction.

Financial Information

Please see the financial statements in **Item 8. Financial Statements and Supplementary Data** for information about our revenues, profits, and losses for the last three years and total assets, liabilities, and stockholder equity for the last two years.

Principal Products

Our products with Notice of Substantial Equivalence to the U.S. Food and Drug Administration (FDA) and which are currently sold include the 1mL tuberculin; insulin syringes; allergy antigen VanishPoint® syringes; 0.5mL, 2mL, 3mL, 5mL, and 10mL

VanishPoint® syringes; the VanishPoint® blood collection tube holder; the VanishPoint® IV safety catheter; small diameter tube adapter; the allergy tray; the Patient Safe® syringes; the Patient Safe® Luer Cap; and the VanishPoint® Blood Collection Set. We are also selling VanishPoint® autodisable syringes in the international market in addition to our other products.

Syringe sales comprised 98.6%, 97.3%, and 98.2% of revenues in 2013, 2014, and 2015, respectively.

Principal Markets

Our products are sold to and used by healthcare providers primarily in the U.S. (with 22.1% of revenues in 2015 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.

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The need to change to safety devices is due to the risk that is carried with each needlestick injury which includes the potential transmission of over 20 bloodborne pathogens, including the human immunodeficiency virus (HIV, which causes AIDS), hepatitis B, and hepatitis C. Because of the occupational and public health hazards posed by conventional disposable syringes, public health policy makers, domestic organizations, and government agencies have been involved in the effort to get more effective safety needle products to healthcare workers. Federal legislation was signed into law on November 6, 2000, by former President William Jefferson Clinton. This legislation, which became effective for most states on April 12, 2001, requires safety needle products be used for the vast majority of procedures. However, even with this requirement, some hospitals are neglecting to follow the law intended to protect healthcare workers.

Methods of Marketing and Distribution

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 the VanishPoint® automated retraction products to customers.

In the needle and syringe market, the market share leader, BD, has utilized, among other things, product disparagement, patent infringement, false advertising, and other deceptive conduct which have restricted the entry of VanishPoint® syringes into the market. Other products manufactured by us that are being denied market access as a result of BD s anticompetitive actions include the IV safety catheters and Patient Safe® syringes.

We have numerous agreements with organizations for the distribution of our products in foreign markets. In Canada, the provinces of Alberta, Manitoba, Ontario, and Saskatchewan have passed laws or regulations regarding healthcare worker safety and the use of safe needle products. The European Union has issued Directive 2010/32/EU regarding safe procedures and the use of safe needle products to prevent needlestick injuries. Brazil is the only country in Latin America that has initiated a regulation requiring the use of safe needle products to prevent needlestick injuries. The Australian states of New South Wales, Queensland, and Victoria have guidelines or directives regarding the prevention of needlestick injuries.

Key components of our strategy to increase our market share are to: (a) defeat anticompetitive practices through litigation; (b) focus on methods of upgrading our manufacturing capability and efficiency in order to enable us to reduce costs and improve profit margins; (c) continue marketing emphasis in the U.S.; (d) continue to add Veterans Administration facilities, health departments, emergency medical services, federal prisons, long-term care, home healthcare facilities, and retail pharmacies as customers; (e) educate healthcare providers, insurers, healthcare workers, government agencies, government officials, and the general public on the reduction of risk and the cost effectiveness afforded by our

products; (f) market product through GPO contracts and supply Integrated Delivery Networks where possible; (g) consider possibilities for future licensing agreements and joint venture agreements for the manufacture and distribution of safety products in the U.S. and abroad; (h) introduce new products; and (i) increase international sales.

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Status of Publicly Announced New Products

We have applied for patent protection and are in the process of developing additional safety medical products.

On June 17, 2014, we received notice of substantial equivalence from the Food and Drug Administration for the EasyPoint needle. The EasyPoint is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefill syringes to give injections. The EasyPoint needle can also be used to aspirate fluids and blood collection. We have completed installation and validation of the equipment. We are currently building stock for product release.

Sources and Availability of Raw Materials

We purchase most of our product components from single suppliers, including needle adhesives and packaging materials. There are multiple sources of these materials. We own the molds that are used to manufacture the plastic components of our products in the U.S. Our current suppliers include Channel Prime Alliance, PolyOne Corporation, Sterigenics, Amcor Flexibles, Bemis Healthcare Packaging, and Kovacmed.

Patents, Trademarks, Licenses, and Proprietary Rights

Soon after the Company was formed in May 1994, in recognition of the preexisting technology, intellectual property rights, products, inventive knowhow and ongoing research and development projects (the Core Technology) that were brought into the Company by Thomas J. Shaw as its founder and CEO, the Company and Mr. Shaw entered into a Technology License Agreement dated June 23, 1995, which was subsequently amended July 3, 2008, and again to its present form September 7, 2012.

As amended, the Technology License Agreement encompasses the Core Technology, all technology and knowhow arising out of the Core Technology that has been developed since its inception, all related future improvements, and all the related domestic and foreign patents and patent applications naming Mr. Shaw as an inventor. The knowhow component is broadly defined to include both technical and valuable proprietary business information. Under the Technology License Agreement, Mr. Shaw has granted the Company an exclusive worldwide license in the inventions and under his related patent rights to manufacture, market, sell and distribute the licensed technology and improvements that perform the same function in a better or more economical way. The Company has the right to grant sublicenses and assign the Technology License Agreement subject to Mr. Shaw s approval. The term of the Technology License Agreement is coextensive with the life of the patent rights that are subject to it.

In return for the rights granted, the Company paid Mr. Shaw an initial licensing fee and pays a continuing 5% royalty on gross sales, as well as the costs of obtaining and maintaining the patents subject to the license. The Company has reserved the right to control patent prosecution and the right not to pursue or maintain any patent or patent application, in which case the rights in any non-elected technology revert to Mr. Shaw and are excluded from the license. The Technology License Agreement also acknowledges a march-in right held by the U.S. government as a result of federal funding that was provided under Small Business Innovation Research grants made during the early development of what later

became the Company s VanishPoint® product line.

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 patents exclusively licensed by the Company have varying remaining terms and expiration dates. While patents covering some features of the VanishPoint® syringes have recently expired or will expire during 2016, another patent with a later expiration date will continue to provide patent coverage for VanishPoint® syringes until 2020.

The Company has also registered the following trade names and trademarks: VanishPoint®, Easy Point , 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. The Company has also obtained federal trademark protection for the slogan The New Standard for Safety.

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We are involved in patent litigation detailed in **Item 3. Legal Proceedings**. We have decided, on the advice of patent counsel, not to purchase patent insurance because it would require inappropriate disclosure of information that is currently proprietary and confidential.

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 Practices

Cash and cash equivalents include unrestricted cash, restricted cash, money market accounts, and investments with original maturities of three months or less. Restricted cash consisted of a demand deposit used to collateralize a Letter of Credit issued by us for the purchase of manufacturing equipment. The Letter of Credit was utilized in 2015.

We record trade receivables when revenue is recognized. No product has been consigned to customers. Our allowance for doubtful accounts is primarily determined by review of specific trade receivables. Those accounts that are doubtful of collection are included in the allowance. This provision is reviewed to determine the adequacy of the allowance for doubtful accounts. Trade receivables are charged off when there is certainty as to their being uncollectible. Trade receivables are considered delinquent when payment has not been made within contract terms.

Inventories are valued at the lower of cost or market, with cost being determined using actual average cost. The Company compares the average cost to the market price and records the lower value. Management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time to sell such inventory, the shelf life of inventory, and current market conditions when determining excess or obsolete inventories. A reserve is established for any excess or obsolete inventories or they may be written off.

Receivables are established for federal and state taxes where we have determined we are entitled to a refund for overpayments of estimated taxes or loss carrybacks.

Accounts payable and other short-term liabilities include amounts that we believe we have an obligation for at the end of year. These included charges for goods or services received in 2015 but not billed to us at the end of the year. It also included estimates of potential liabilities such as rebates and other fees.

Our domestic return policy is set forth in our standard Distribution Agreement. This policy provides that a customer may return incorrect shipments within 10 days following arrival at the distributor s facility. In all such cases the distributor must obtain an authorization code from us and affix the code to the returned product. We will not accept returned goods without a returned goods authorization number. We may refund the customer s money or replace the product.

Our domestic return policy also generally provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12 month period up to 1% of distributor s total purchase of products for the prior 12 month period upon the following terms: i) an overstocked product is that portion of distributor s inventory of the product which exceeds distributor s sales volume for the product during the preceding four months; ii) distributor must not have taken delivery of the product which is overstocked during the preceding four months; iii) overstocked product held by distributor in excess of 12 months from the date of original invoice will not be eligible for return; iv) the product must have an expiration date of at least 24 months from the date of return; v) the overstocked product must be returned to us in our saleable case cartons which are unopened and untampered, with no broken or re-taped seals; vi) distributor will be granted a credit which may be used only to purchase other products from us, the credit to be in the amount of the invoice price of the returned product less a 10% restocking fee which will be assessed against distributor s subsequent purchase of product; vii) distributor must obtain an authorization code from our distribution department and affix the code to the returned product; and viii) distributor shall bear the cost of shipping the returned products to us. All product overstocks and returns are subject to inspection and acceptance by us.

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Our international contracts generally do not provide for any returns.

Dependence on Major Customers

Two customers accounted for an aggregate of 45.7% of our revenue in 2015. We have numerous other customers and distributors that sell our products in the U.S. and internationally.

Backlog Orders

Order backlog is not material to our business inasmuch as orders for our products generally are received and filled on a current basis, except for items temporarily out of stock.

Government Funding of Research and Right to License

Thomas J. Shaw received grants from the federal government for his initial 1991 version of a safety syringe, which may give the federal government the right to allow others to manufacture that syringe. However, we believe the government has no right to allow others to manufacture the current version of the VanishPoint® syringe.

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.

For all products manufactured for sale in the foreign market, we hold a certificate of Quality System compliance with ISO 13485. We also have approval to label products for sale into European Union countries with a CE Mark. We will continue to comply with applicable regulations of all countries in which our products are registered for sale.

Competitive Conditions

Our products are sold to and used by healthcare providers primarily in the U.S. (with 22.1% of revenues in 2015 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.

We compete primarily on the basis of 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.

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.

Founded in 1897, BD is headquartered in New Jersey. BD s safety-engineered device sales accounted for approximately 25.3% of BD s total 2015 sales. BD s classification of safety-engineered devices include the SafetyLok syringe, which features a tubular plastic sheath that must be manually slid over the needle after removal from the patient, and the SafetyGlide hypodermic needle which utilizes a manually activated hinged lever to cover the needle tip after removal from the patient. BD markets the SafetyGlide blood collection set that has a manually activated cover designed to extend over the needle after use. The BD Eclipse safety blood collection needle and hypodermic needle is also designed to manually cover the needle after removal from the patient. BD

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manufactures the Integra 3mL retracting needle and syringe product, as well as a spring activated Vacutainer® Passive Shielding Blood Collection Needle and spring activated retracting Vacutainer® blood collection set. BD s Vacutainer® brand name is commonly used as industry jargon to refer to blood collection products in general.

Medtronic offers the Monoject® safety syringe, which, like the BD SafetyLok , requires the use of two hands to manually extend the tubular plastic shield to cover the needle after removal from the patient. Medtronic also markets the Magellan needle, similar to BD s SafetyGlide needle, which has a manually activated hinged lever to cover the needle tip after removal from the patient.

Many of BD s and Medtronic s products result in exposure to the contaminated needle or allow for needle removal and potential syringe reuse.

In contrast, VanishPoint® syringes can be used without significant changes in injection technique. The automated needle retraction is activated when the plunger handle is fully depressed, in conjunction with the delivery of the complete medication dose, 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® syringes are rendered unusable, reducing the risk of disposal-related injuries or reuse.

Our safety needle products have several advantages over non-retracting safety needles, including, but not limited to: pre-removal activation; automated needle retraction; integrated safety mechanism; reuse prevention; ease of use; and minimal training.

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.

Several factors could materially and beneficially affect the marketability of our products. Demand could be increased by existing legislation and other legislative and investigative efforts. Licensing agreements could provide entry into new markets and generate additional revenue. Further, outsourcing arrangements could increase our manufacturing capacity with little or no capital outlay and provide a competitive cost.

Litigation could also provide more access to the market. For example, if upheld on appeal, the injunctive relief we obtained in litigation means that BD would have to notify end use customers such as nurses, hospitals, clinics, and nursing homes that it had misrepresented information about our products and its own products with regard to sharpness and medication waste and that such statements were false and misleading, and, in part, based on false and inaccurate measurements of the VanishPoint® products. BD has already taken some measures to advise its employees, distributors, and GPOs of its actions in accordance with injunctive provisions that were not stayed pending appeal.

Our competitive position is weakened by the method that providers use for making purchasing decisions and the fact that our initial price per unit for our safety needle products may be higher than some of the less effective safety needle products that are on the market.

Research and Development

We spent $608,000; $617,000; and $837,000 in 2015, 2014, and 2013, respectively, on research and development. Costs in 2015 were primarily for compensation and related benefits, along with engineering samples and testing. Our ongoing research and development activities are performed by an internal research and development staff and includes developing process improvements for current and future automated machines. Our limited access to the market has slowed the introduction of products.

Possible future products include safety medical devices and other needle devices to which automated retraction can be applied. We have additional safety product designs that add to or build upon our current product line offering. These product designs include: retractable needle syringe designs, retractable needle designs, glass

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syringe designs, retractable needle dental syringe designs, retractable needle IV catheter designs, and retractable needle blood collection product designs. While these product designs are in various stages of development, we have recently focused on the design and manufacture of our next generation of needle products which are needle-based retractable safety products intended for use with devices to inject fluids, aspirate fluids, and obtain blood collection. These retractable needle-based products are designed to offer effective sharps injury prevention by: being easily operated using one-handed activation; keeping the user s hands behind the needle at all times; having a low manufacturing cost; and having new applications and uses that expand into markets in addition to those already addressed by VanishPoint® and Patient Safe® products, such as prefilled syringes, fluid aspiration, partial injection, blood collection, and dental injections.

Environmental Compliance

We believe that we do not incur material costs in connection with compliance with environmental laws. We are considered a Conditionally Exempt Small Quantity Generator because we generate less than 100 kilograms (220 lbs.) of hazardous waste per month. Therefore, we are exempt from the reporting requirements set forth by the Texas Commission on Environmental Quality. The waste that is generated at our facility is primarily made up of flammable liquids and paint-related waste and is sent for fuel blending by Safety Kleen. This fuel blending process completely destroys our waste and satisfies our cradle-to-grave responsibility.

Other nonhazardous production waste includes clean polypropylene regrind, paper, and corrugated material that is recycled. All other nonhazardous waste produced is considered municipal solid waste and sent to a sanitary landfill by CWD.

We also produce small amounts of regulated biohazardous waste from contaminated sharps and laboratory wastes. This waste is sent for incineration by Stericycle.

Employees

As of March 1, 2016, we had 136 employees. 134 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.

	2015	2014	2013
U.S. sales	$ 23,029,976	$ 27,649,974	$ 24,843,200
North and South America sales (excluding U.S.)	5,668,785	5,651,426	4,453,151
Other international sales	853,439	1,219,230	1,488,776
Total sales	$ 29,552,200	$ 34,520,630	$ 30,785,127
Long-lived assets			
U.S.	$ 11,282,192	$ 10,642,859	$ 10,676,053
International	$ 185,869	$ 209,994	$ 234,119

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

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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.

Available Information

We make available, free of charge on our website (www.vanishpoint.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 an Anticompetitive Marketplace

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 pending resolution of the patent dispute. The antitrust and false advertising claims resulted in a final judgment for $352 million plus prejudgment and post-judgment interest as well as some injunctive relief. We have not received any of the amounts indicated by the District Court in its final judgment. BD has appealed to the United States Court of Appeals for the Fifth Circuit. Oral argument was heard on February 29, 2016 and we are still waiting for the appellate decision.

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 the anticompetitive market, 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 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 patents exclusively licensed by the Company have varying remaining terms and expiration dates. While patents covering some features of the VanishPoint® syringes have recently expired or will expire during 2016, another patent with a later expiration date will continue to provide patent coverage for VanishPoint® syringes until 2020.

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Patent life may be extended, not through the original patents, but through related improvements. As our technology ages (and the associated patent life expires), our competitive position in the marketplace could weaken. The patent protection may decrease and make us vulnerable to other competitors utilizing our technology.

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.

Our Patents Are Subject to Litigation

We have been sued by BD and MDC Investment Holdings, Inc. for patent infringement. This case is has been administratively closed until the appeal is resolved in our case against BD. 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.

The Majority of Our Sales Are Filled Using One Third Party Manufacturer

Most international syringe sales, as well as a substantial portion of domestic sales, are filled by production from a Chinese manufacturer. In the event that we become unable to purchase such product from our Chinese manufacturer, we would need to find an alternate manufacturer for the 0.5mL insulin syringe, the 0.5mL autodisable syringe, and the 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 2015, the 1mL and 3mL syringes made up 94.5% of our unit sales and 91.5% of our revenues.

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, would have investment or voting power over a total of 49.5% of the outstanding Common Stock if he exercised his options as of March 1, 2016. Mr. Shaw will, therefore, have the ability to direct our operations and financial affairs and to substantially influence the election of 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

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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.

Current Economic Conditions May Decrease Collectability of Accounts

Although we believe that we have granted credit to credit-worthy firms, current economic conditions may affect the timing and/or collectability of some accounts.

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.

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 house our administrative offices and manufacturing facility. The manufacturing facility produced approximately 21.9% of the units that were manufactured in 2015. In the event that we become unable to purchase product from our Chinese manufacturer, we would need to find an alternate manufacturer for the 0.5mL insulin syringe, the 0.5mL autodisable syringe, and the 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 2015, we used approximately 25.6% of our current U.S. productive capacity for VanishPoint® syringes.

A loan in the original principal amount of $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 Eastern District of Texas, Tyler Division, and the jury found that BD illegally engaged in anticompetitive conduct with the intent to acquire or maintain monopoly power in the safety syringe market and engaged in false advertising under the Lanham Act. The jury awarded us $113,508,014 in damages, which was trebled pursuant to statute. The Court granted injunctive relief to take effect January 15, 2015. In doing so, the Court found that BD s business practices limited innovation, including false advertisements that suppressed sales of the VanishPoint®. The specific injunctive relief includes: (1) enjoining BD s use of World s Sharpest Needle or any similar assertion of superior sharpness; (2) requiring notification to all customers who purchased BD syringe products from July 2, 2004 to date that BD wrongfully claimed that its syringe needles were sharper and that its statement that it had data on file was false and misleading; (3) requiring notification to employees, customers, distributors, GPOs, and government agencies that the deadspace of the VanishPoint® has been within ISO standards since 2004 and that BD overstated the deadspace of the VanishPoint® to represent that it was higher than some of BD s syringes when it was actually less, and that BD s statement that it had data on file was false and misleading, and, in addition, posting this notice on its website for a period of three years; (4) enjoining BD from advertising that

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its syringe products save medication as compared to VanishPoint® products for a period of three years; (5) requiring notification to all employees, customers, distributors, GPOs, and government agencies that BD s website, cost calculator, printed materials, and oral representations alleging BD s syringes save medication as compared to the VanishPoint® were based on false and inaccurate measurement of the VanishPoint®, and, in addition, posting this notice on its website for a period of three years; and (6) requiring the implementation of a comprehensive training program for BD employees and distributors that specifically instructs them not to use old marketing materials and not to make false representations regarding VanishPoint® syringes. Final judgment was entered on January 15, 2015, awarding us $340,524,042 in damages and $11,722,823 in attorneys fees, as well as granting injunctive relief consistent with the orders as indicated above. The parties stipulated that the amount of litigation costs recoverable by us is $295,000. On January 14, 2015, the District Court stayed the portion of the injunctive relief that requires BD to notify end-user customers but also ordered BD to comply with internal correction activities as well as mandatory disclosures as set out above to its employees, customers, distributors and Group Purchasing Organizations. BD filed an appeal of that ruling with the 5th Circuit Court of Appeals and that appeal was denied on February 3, 2015. On February 12, 2015, BD filed a motion to amend the judgment directed most specifically to the issue of award of prejudgment interest. On April 23, 2015, the Court entered an Amended Final Judgment that removed prejudgment interest but kept all other monetary and injunctive relief the same as was granted in the original Final Judgment. BD filed its brief in the appeal on July 20, 2015. We filed our responsive brief on September 18, 2015 and BD filed its brief in reply on October 19, 2015 to complete the briefing. Oral argument occurred on Monday, February 29, 2016. In many cases the 5th Circuit Court of Appeals issues its decision several months after oral argument, but there is no set time limit.

In September 2007, BD and MDC Investment Holdings, Inc. (MDC) sued us in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that we are infringing two U.S. patents of MDC (6,179,812 and 7,090,656) that are licensed to BD. BD and MDC seek injunctive relief and unspecified damages. We counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patents. The plaintiffs subsequently dropped allegations with regard to patent no. 7,090,656 and we subsequently dropped our counterclaims for unenforceability of the asserted patents. On June 30, 2015, the Court ordered that further proceedings in this matter be stayed and that this case remain administratively closed until resolution of all appeals in the case detailed in the preceding paragraph.

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

Our Common Stock has been listed on the NYSE MKT (or its predecessor entities) under the symbol RVP since May 4, 2001. Our closing price on March 1, 2016, was $2.40 per share. Shown below are the high and low sales prices of our Common Stock as reported by the NYSE MKT for each quarter of the last two fiscal years:

2015	**High**	**Low**
Fourth Quarter	$ 3.85	$ 2.77
Third Quarter	$ 4.34	$ 3.60
Second Quarter	$ 4.55	$ 3.73
First Quarter	$ 5.70	$ 3.80

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2014	High	Low
Fourth Quarter	$ 5.39	$ 3.31
Third Quarter	$ 3.27	$ 2.54
Second Quarter	$ 3.74	$ 2.50
First Quarter	$ 4.00	$ 2.93

SHAREHOLDERS

As of March 1, 2016, there were 28,619,874 shares of Common Stock held by 204 shareholders of record not including shareholders who beneficially own Common Stock held in nominee or street name.

DIVIDENDS

We have not ever declared or paid any dividends on the Common Stock. We have no current plans to pay any cash dividends on the Common Stock. We intend to retain all earnings, except those required to be paid to the holders of the Preferred Stock as resources allow, to support operations and future growth. Dividends on Common Stock cannot be paid so long as preferred dividends are unpaid. As of December 31, 2015, there was an aggregate of $10.3 million in preferred dividends in arrears. As of December 31, 2014, there was an aggregate of $12.8 million in preferred dividends in arrears.

EQUITY COMPENSATION PLAN INFORMATION

See **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters** for a chart describing compensation plans under which equity securities are authorized.

STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total return for our Common Stock from December 31, 2010 to December 31, 2015, to the total returns for the Russell Microcap® and Becton, Dickinson and Company (or BDX), a peer issuer. The graph assumes an investment of $100 in the aforementioned equities as of December 31, 2010, and that all dividends are reinvested.

RECENT SALES OF UNREGISTERED SECURITIES

We exchanged 728,000 shares of Common Stock for 200,000 shares of our Series IV Class B Convertible Preferred Stock as of November 30, 2015 pursuant to an agreement with a shareholder. Such shareholder agreed to waive all unpaid dividends in arrears associated with the tendered preferred stock, equaling $3,094,795. Future dividend requirements of $200,000 per year are avoided as a result of this transaction. This transaction was exempt from registration under the Securities Act pursuant to Section 3(a)(9) of the Securities Act because the securities

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were exchanged with an existing security holder exclusively where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

As discussed immediately above, 200,000 shares of our Preferred Stock were purchased by us as of November 30, 2015 in exchange for 728,000 shares of our Common Stock.

Item 6. Selected Financial Data.

The following selected financial data is qualified by reference to, and should be read in conjunction with, our audited financial statements and the notes to those statements and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere herein. The selected Statements of Operations data presented below for the years ended December 31, 2012 and 2011 and the Balance Sheet data as of December 31, 2013, 2012, and 2011 have been derived from our audited financial statements, which are not included herein.

(In thousands except for earnings per share, shares, and percentages)*

	As of and for the Years Ended December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Sales, net	$ 29,552	$ 34,521	$ 30,785	$ 33,644	$ 32,102
Cost of sales	18,987	22,499	20,475	22,468	21,199
Gross profit	10,565	12,022	10,310	11,176	10,903
Total operating expenses	13,773	14,180	16,241	15,115	14,993
Loss from operations	(3,208)	(2,158)	(5,931)	(3,939)	(4,090)
Interest income	25	34	39	47	63
Interest expense, net	(220)	(223)	(231)	(231)	(241)
Litigation proceeds	7,725				
Litigation settlements, net					5,700
Income (loss) before income taxes	4,322	(2,347)	(6,123)	(4,123)	1,432
Provision (benefit) for income taxes	8	8	91	10	14
Net income (loss)	4,314	(2,355)	(6,214)	(4,133)	1,418
Deemed capital contribution on extinguishment of preferred stock	2,306				
Preferred Stock dividend requirements	(709)	(915)	(916)	(918)	(964)
Income (loss) applicable to common shareholders	$ 5,911	$ (3,270)	$ (7,130)	$ (5,051)	$ 454
Earnings (loss) per share basic	$ 0.21	$ (0.12)	$ (0.26)	$ (0.19)	$ 0.02
Earnings (loss) per share diluted	$ 0.20	$ (0.12)	$ (0.26)	$ (0.19)	$ 0.02
Weighted average shares outstanding basic	27,822,593	27,375,450	26,999,698	26,219,728	24,171,238
	29,481,294	27,375,450	26,999,698	26,219,728	26,354,786

Weighted average shares outstanding diluted					
Current assets	$ 30,810	$ 34,230	$ 37,907	$ 35,441	$ 35,903
Current liabilities	$ 8,096	$ 15,100	$ 16,621	$ 8,077	$ 6,125
Property, plant, and equipment, net	$ 11,468	$ 10,853	$ 10,910	$ 11,900	$ 12,654
Total assets	$ 42,541	$ 45,353	$ 49,097	$ 47,632	$ 48,920
Long-term debt, net of current maturities	$ 3,417	$ 3,425	$ 3,577	$ 3,826	$ 4,143
Stockholders equity	$ 31,028	$ 26,828	$ 28,900	$ 35,729	$ 38,651
Redeemable Preferred Stock (in shares)	781,445	987,445	994,945	1,001,552	1,001,552
Capital leases					
Cash dividends per common share	$	$	$	$	$
Gross profit margin	35.8%	34.8%	33.5%	33.2%	34.0%

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* Events that could affect the trends indicated above include continued reductions in manufacturing costs, changing average sales prices, changing raw material cost, the gaining of market access, the effect of injunctive relief, protection of our patents, foreign currency exchange rates, the Medical Device Excise Tax, the impact of flu season requirements, new or changing regulations, and new products. As our products are made from petroleum products, the changing cost of oil and transportation may have an impact on our costs to the extent increases may not be recoverable through price increases of our products and reductions in oil prices may not quickly affect petroleum product prices. Receipt of settlement proceeds and option payments from Abbott and Hospira positively affected 2011 results. Our purchase in 2011 of a total of 1,277,464 shares of our Preferred Stock (which purchase required the selling Preferred Stockholder to waive all unpaid dividends in arrears) in exchange for our Common Stock and cash have reduced our Preferred Stock Dividend Requirements. Our similar purchase of 200,000 of our Preferred Stock in 2015 also reduced Preferred Stock Dividend Requirements. The receipt of $7,724,826 from BD pursuant to litigation affects both the current assets and current liabilities in 2013 and 2014. The recognition of the $7,724,826 in the second quarter of 2015 had a significant impact on 2015 income. The introduction of the Medical Device Excise Tax in 2013 affects comparability between 2013 and prior years. The Medical Device Excise Tax was suspended for two years beginning January 1, 2016. In 2014, we took steps to decrease our non-litigation legal costs by approximately $1.1 million. Additionally, in 2014, we reduced our workforce by 13.7% in an effort to cut costs. A 2015 judgment in our favor for $352 million is not included in the data presented and, if received, could materially affect our future financial condition.

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

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words could, may, believes, anticipates, intends, expects, and simila 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, 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 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.

Overview

We have been manufacturing and marketing our products since 1997. Safety syringes comprised 98.2% of our sales in 2015. We also manufacture and market the blood collection tube holder, IV safety catheter, and VanishPoint® Blood Collection Set. We currently provide other safety medical products in addition to safety products utilizing retractable technology. One such

product is the Patient Safe® syringe, which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination.

On June 17, 2014, we received notice of substantial equivalence from the Food and Drug Administration for the EasyPoint needle. The EasyPoint is a retractable needle that can be used with Luer lock syringes, Luer

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slip syringes, and prefill syringes to give injections. The EasyPoint needle can also be used to aspirate fluids and blood collection. We have completed installation and validation of the equipment. We are currently building stock for product release.

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

Our products have been and continue to be distributed nationally and internationally through numerous distributors. Although we have made limited progress in some areas, such as the alternate care market, 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. The alternate care market is composed of facilities that provide long-term nursing and out-patient surgery, emergency care, physician services, health clinics, and retail pharmacies.

We continue to pursue various strategies to have better access to the hospital market, as well as other markets, including attempting to gain access to the market through our sales efforts, our innovative technology, introduction of new products, and, when necessary, litigation.

We have reported in the past that our progress is limited principally due to the marketing practices engaged in by BD, the dominant maker and seller of disposable syringes. In our litigation against BD alleging anticompetitive conduct and false advertising, a final judgment for $352 million plus post-judgment interest and costs as well as some injunctive relief (discussed in more detail below) has been granted by the District Court. We have not received any of the amounts indicated by the District Court in its final judgment. The injunctive relief included:

(1) enjoining BD s use of World s Sharpest Needle or any similar assertion of superior sharpness;

(2) requiring notification to all customers who purchased BD syringe products from July 2, 2004 to date that BD wrongfully claimed that its syringe needles were sharper and that its statement that it had data on file was false and misleading;

(3) requiring notification to employees, customers, distributors, GPOs, and government agencies that the deadspace of the VanishPoint® has been within ISO standards since 2004 and that BD overstated the deadspace of the VanishPoint® to represent that it was higher than some of BD s syringes when it was actually less, and that BD s statement that it had data on file was false and misleading, and, in addition, posting this notice on its website for a period of three years;

(4) enjoining BD from advertising that its syringe products save medication as compared to VanishPoint® products for a period of three years;

(5) requiring notification to all employees, customers, distributors, GPOs, and government agencies that BD s website, cost calculator, printed materials, and oral representations alleging BD s syringes save medication as compared to the VanishPoint® were based on false and inaccurate measurement of the VanishPoint®, and, in addition, posting this notice on its website for a period of three years; and

(6) requiring the implementation of a comprehensive training program for BD employees and distributors that specifically instructs them not to use old marketing materials and not to make false representations regarding VanishPoint® syringes.

BD has appealed to the United States Court of Appeals for the Fifth Circuit. Oral argument was heard on February 29, 2016 and no order has issued.

On September 30, 2013, we received payment of $7,724,826 (the Judgment Amount) from BD pursuant to a stipulation in the patent infringement case *Retractable Technologies, Inc. and Thomas Shaw* v. *Becton Dickinson and Company*, Civil Action No. 2:07-cv-250, in the U.S. District Court for the Eastern District of Texas,

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Marshall Division. The Judgment Amount was included as income in the second quarter of 2015 due to the conclusion of the case and related appeals. Prior to the second quarter of 2015, the Judgment Amount had been shown as a liability on the balance sheet since we were paid the Judgment Amount and the litigation did not come to a final conclusion until the second quarter of 2015.

In 2014, we took steps to decrease our non-litigation legal costs by approximately $1.1 million. Additionally, effective May 9, 2014, we reduced our workforce by 13.7% in an effort to cut costs. In 2015, we further reduced our workforce, including our acceptance of the resignation of Steven R. Wisner, a former executive officer, on May 29, 2015. Mr. Wisner was granted a one-time payment in connection with his resignation. The net effect of the lower non-litigation costs and the reduced workforce, offset by the payment to Mr. Wisner, was approximately $450,000 in 2015. In the future, if such cost cutting measures prove insufficient, we may reduce the number of units being produced, further reduce the workforce, further reduce the salaries of officers as well as other employees, and/or defer royalty payments.

Section 4191 of the Internal Revenue Code, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act provides for an excise tax of 2.3% on medical devices. The excise tax was applicable to domestic sales of our products, except those which are sold to exempt organizations. The majority of our sales are domestic and not in the retail market. The tax was imposed on sales, not profits. We have not passed this tax along to our customers. The impact of this tax was $360,000 in 2015, $856,000 in 2014, and $758,000 in 2013, and is net of expected refunds attributable to rebate credits. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on December 18, 2015, includes a two year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017.

We exchanged 728,000 shares of Common Stock for 200,000 shares of our Series IV Class B Convertible Preferred Stock as of November 30, 2015 pursuant to an agreement with a shareholder. Such shareholder agreed to waive all unpaid dividends in arrears associated with the tendered preferred stock, equaling $3,094,795. Future dividend requirements of $200,000 per year are avoided as a result of this transaction.

Product purchases from our primary Chinese manufacturer have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufacturing cost. In 2015, our Chinese manufacturer produced approximately 77.7% of our VanishPoint® finished products. In the event that we become unable to purchase products from our primary Chinese manufacturer, we would need to find an alternate manufacturer for the 0.5mL insulin syringe, the 0.5mL autodisable syringe, and the 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes.

In 1995, we entered into a license agreement with Thomas J. Shaw for the exclusive right to manufacture, market, and distribute products utilizing automated retraction technology. This technology is the subject of various patents and patent applications owned by Mr. Shaw. The license agreement generally provides for quarterly payments of a 5% royalty fee on gross sales.

With increased volumes, our manufacturing unit costs have generally tended to decline. Factors that could affect our unit costs include increases in costs by third party manufacturers, changing production volumes, costs of petroleum products, and transportation costs. Increases in such costs may not be recoverable through price increases of our products.

RESULTS OF OPERATIONS

The following discussion contains trend information and other forward-looking statements that involve a number of risks and uncertainties. Our actual future results could differ materially from our historical results of operations and those discussed in the forward-looking statements. All period references are to our fiscal years ended December 2015, 2014, or 2013. Dollar amounts have been rounded for ease of reading.

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Comparison of Year Ended

December 31, 2015 and Year Ended December 31, 2014

Domestic sales accounted for 77.9% and 80.1% of the revenues in 2015 and 2014, respectively. Domestic revenues decreased 16.7% principally due to reduced flu demand. Domestic unit sales decreased 17.6%. Domestic unit sales were 67.0% of total unit sales for 2015. International revenues decreased from $6.9 million in 2014 to $6.5 million in 2015, primarily due to more restrictive qualification requirements by the Company. Overall unit sales decreased 11.9%. Our international orders may be subject to significant fluctuation over time. Such orders may fluctuate due to health initiatives at various times as well as economic conditions.

Cost of sales decreased $3.3 million principally due to lower volumes. Royalty expense decreased $251 thousand due to decreased gross sales. Gross profit margins increased from 34.8% in 2014 to 35.8% in 2015.

Operating expenses decreased 2.9% from the prior year due to decreased Medical Device Excise Taxes attributable to refunds, lower compensation costs, and lower travel and entertainment costs.

A non-recurring recognition of $7,724,826 received from BD in the second quarter of 2015 pursuant to a patent infringement case had a significant impact on 2015 income. Recognizing this payment also significantly decreased 2015 current liabilities on the Balance Sheets.

The loss from operations was $3.2 million in 2015 compared to an operating loss of $2.2 million in 2014.

Earnings per share were positively affected by our acquisition of 200,000 shares of Series IV Class B Convertible Preferred Stock. Under the guidelines of ASC 260-10-S99-2, *Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock*, we reflected the gain on extinguishment of this preferred stock in net income per common stockholder used to calculate earnings per share.

Cash flow from operations was a negative $3.3 million for 2015 due primarily to the loss from operations and changes in working capital, namely increased inventories and other current assets, mitigated by a decrease in Accounts receivable and an increase in Accounts payable.

Comparison of Year Ended

December 31, 2014 and Year Ended December 31, 2013

Domestic sales accounted for 80.1% and 80.7% of the revenues in 2014 and 2013, respectively. Domestic revenues increased 11.3% principally due to increased unit sales. Domestic unit sales increased 11.8%. Domestic unit sales were 71.6% of total unit sales for 2014. International

revenues increased from $5.9 million in 2013 to $6.9 million in 2014, primarily due to increased unit sales and an increase in average price. Overall unit sales increased 12.0%. Our international orders may be subject to significant fluctuation over time. Such orders may fluctuate due to health initiatives at various times as well as economic conditions.

Cost of sales increased $2.0 million due to an increase in units sold mitigated by a slightly lower unit cost of manufacture. Royalty expense increased $254 thousand due to increased gross sales. Gross profit margins increased from 33.5% in 2013 to 34.8% in 2014.

Operating expenses decreased 12.7% from the prior year due to decreased cost of non-litigation legal expense, lower compensation cost, and decreased office expenses which is the result of cost-cutting measures implemented in 2014.

The loss from operations was $2.2 million in 2014 compared to an operating loss of $5.9 million in 2013, a 63.6% decrease.

Cash flow from operations was a negative $3.9 million for 2014 due primarily to our increase in accounts receivable, decrease in current liabilities, and our loss from operations, mitigated by a decrease in inventory and depreciation.

LIQUIDITY AND CAPITAL RESOURCES

At the present time, Management does not intend to raise equity capital. Due to the funds received from prior litigation, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing, when available, as the primary ongoing sources of cash. Our ability to obtain additional funds through loans is

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uncertain. Our financial statements do not reflect a 2015 judgment in our favor for $352 million plus post-judgment interest.

Historical Sources of Liquidity

We have historically funded operations primarily from the proceeds from revenues, private placements, litigation settlements, and loans.

Internal Sources of Liquidity

Margins and Market Access

To routinely achieve positive or break even quarters, we need increased access to hospital markets which has been difficult to obtain. We will continue to attempt to gain access to the market through our sales efforts, innovative technology, the introduction of new products, and, when necessary, litigation.

We continue to focus on methods of upgrading our manufacturing capability and efficiency in order to reduce costs.

Fluctuations in the cost and availability of raw materials and inventory and our ability to maintain favorable manufacturing arrangements and relationships could result in the need to manufacture all (as opposed to 78.2%) of our products in the U.S. This could temporarily increase unit costs as we ramp up domestic production.

The mix of domestic and international sales affects the average sales price of our products. Generally, the higher the ratio of domestic sales to international sales, the higher the average sales price will be. Typically, large international sales of VanishPoint® syringes are shipped directly from China to the customer. Purchases of product manufactured in China usually decrease the average cost of manufacture for all units. The number of units produced by us versus manufactured in China can have a significant effect on the carrying costs of inventory as well as Cost of sales. We will continue to evaluate the appropriate mix of products manufactured domestically and those manufactured in China to achieve economic benefits as well as to maintain our domestic manufacturing capability.

Fluctuations in the cost of oil (since our products are petroleum based) and transportation and the volume of units purchased from our Chinese manufacturers may have an impact on the unit costs of our product. Increases in such costs may not be recoverable through price increases of our products. Reductions in oil prices may not quickly affect petroleum product prices.

Seasonality

Historically, unit sales have increased during the flu season.

Cash Requirements

Due to funds received from prior litigation, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing, when available, as the primary ongoing sources of cash. We have taken steps to decrease our non-litigation legal costs and we continue to evaluate these costs. Additionally, since the beginning of 2014, we have reduced our workforce. In the future, if such cost cutting measures prove insufficient, we may reduce the number of units being produced, further reduce the workforce, further reduce the salaries of officers and other employees, and/or defer royalty payments.

External Sources of Liquidity

We have obtained several loans from our inception, which have, together with the proceeds from the sales of equities and litigation efforts, enabled us to pursue development and production of our products. Our ability to obtain additional funds through loans is uncertain. Due to the current market price of our Common Stock, it is unlikely we would choose to raise funds by the sale of equity.

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On September 30, 2013, we received payment of $7,724,826 (the Judgment Amount) from BD pursuant to a stipulation in the patent infringement case *Retractable Technologies, Inc. and Thomas Shaw* v. *Becton Dickinson and Company*, Civil Action No. 2:07-cv-250, in the U.S. District Court for the Eastern District of Texas, Marshall Division. The Judgment Amount was included as income in the second quarter of 2015 due to the conclusion of the case and related appeals. Prior to the second quarter of 2015, the Judgment Amount had been shown as a liability on the balance sheet since we were paid the Judgment Amount and the litigation did not come to a final conclusion until the second quarter of 2015. After the matter was concluded, we recognized the proceeds as income.

In our litigation against BD alleging anticompetitive conduct and false advertising, a final judgment for $352 million plus post-judgment interest and costs as well as some injunctive relief has been granted by the District Court. We have not received any of the amounts indicated by the District Court in its final judgment. BD is currently under court order to make certain disclosures regarding its exclusionary conduct to a specified class of distributors and customers. BD has appealed to the United States Court of Appeals for the Fifth Circuit. Oral argument was heard on February 29, 2016 and no order has issued.

OFF-BALANCE SHEET ARRANGEMENTS

None.

CONTRACTUAL OBLIGATIONS

Contractual Obligations and Commercial Commitments

The following chart summarizes our material obligations and commitments to make future payments under contracts for long-term debt as of December 31, 2015:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Contractual Obligations					
Long-term debt	$ 3,666,820	$ 249,349	$ 498,806	$ 2,918,665	$
Operating leases	396,967	74,772	156,346	165,849	
Total	$ 4,063,787	$ 324,121	$ 655,152	$ 3,084,514	$

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We believe that our market risk exposures regarding our cash and cash equivalents are immaterial as we do not have instruments for trading purposes. Additionally, reasonable, possible near-term changes in market rates or prices will not result in material changes in near-term earnings.

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Item 8. Financial Statements and Supplementary Data.

RETRACTABLE TECHNOLOGIES, INC.

FINANCIAL STATEMENTS AND

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

DECEMBER 31, 2015 AND 2014

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RETRACTABLE TECHNOLOGIES, INC.

INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders

of Retractable Technologies, Inc.

We have audited the accompanying balance sheets of Retractable Technologies, Inc. as of December 31, 2015 and 2014, and the related statements of operations, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2015. Our audits also included the financial statement schedule of Retractable Technologies, Inc., listed in Item 15(a). These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Retractable Technologies, Inc. as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ CF & Co., L.L.P.
CF & Co., L.L.P.

Dallas, Texas
March 30, 2016

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RETRACTABLE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31,	
	2015	**2014**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,045,044	$ 22,128,977
Restricted cash		600,897
Accounts receivable, net of allowance for doubtful accounts of $1,795,481 and $1,725,806, respectively	4,900,997	5,642,091
Inventories, net	6,296,625	4,663,548
Other current assets	1,568,032	1,194,055
Total current assets	30,810,698	34,229,568
Property, plant, and equipment, net	11,468,061	10,852,853
Intangible and other assets, net	262,105	270,693
Total assets	$ 42,540,864	$ 45,353,114
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,697,518	$ 5,142,796
Litigation proceeds subject to stipulation		7,724,826
Current portion of long-term debt	249,349	149,744
Accrued compensation	763,576	504,188
Dividends payable	55,414	
Accrued royalties to shareholders	631,145	787,434
Other accrued liabilities	690,535	782,322
Income taxes payable	8,176	8,290
Total current liabilities	8,095,713	15,099,600
Long-term debt, net of current maturities	3,417,471	3,425,028
Total liabilities	11,513,184	18,524,628
Commitments and contingencies See Note 8		
Stockholders equity:		
Preferred Stock $1 par value:		
Class B; authorized: 5,000,000 shares		
Series I, Class B; outstanding: 98,500 shares (liquidation preference of $615,625)	98,500	98,500
Series II, Class B; outstanding 171,200 and 176,200 shares, respectively (liquidation preference of $2,140,000 and $2,202,500, respectively)	171,200	176,200
Series III, Class B; outstanding: 129,245 and 130,245 shares, respectively (liquidation preference of $1,615,563 and $1,628,063, respectively)	129,245	130,245
Series IV, Class B; outstanding: 342,500 and 542,500 shares, respectively (liquidation preference of $3,767,500 and $5,967,500, respectively)	342,500	542,500
Series V, Class B; outstanding: 40,000 (liquidation preference of $176,000)	40,000	40,000
Common Stock, no par value; authorized: 100,000,000 shares; outstanding: 28,619,874 and 27,613,397 shares, respectively		
Additional paid-in capital	58,268,036	59,273,769
Retained deficit	(28,021,801)	(32,336,119)
Common stock in treasury - at cost; 0 and 722,920 shares, respectively		(1,096,609)
Total stockholders equity	31,027,680	26,828,486

Total liabilities and stockholders equity	$ 42,540,864	$ 45,353,114

See accompanying notes to financial statements

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RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2015	**2014**	**2013**
Sales, net	$ 29,552,200	$ 34,520,630	$ 30,785,127
Cost of Sales			
Costs of manufactured product	16,509,446	19,770,226	18,000,408
Royalty expense to shareholders	2,477,583	2,728,701	2,474,762
Total cost of sales	18,987,029	22,498,927	20,475,170
Gross profit	10,565,171	12,021,703	10,309,957
Operating expenses:			
Sales and marketing	3,837,491	3,967,081	4,414,339
Research and development	607,527	616,784	837,073
General and administrative	9,328,029	9,595,399	10,989,790
Total operating expenses	13,773,047	14,179,264	16,241,202
Loss from operations	(3,207,876)	(2,157,561)	(5,931,245)
Litigation proceeds	7,724,826		
Interest and other income	24,917	33,941	38,943
Interest expense, net	(219,672)	(222,808)	(230,578)
Income (loss) before income taxes	4,322,195	(2,346,428)	(6,122,880)
Provision for income taxes	7,877	8,177	90,972
Net income (loss)	4,314,318	(2,354,605)	(6,213,852)
Preferred Stock dividend requirements	(709,351)	(915,225)	(916,065)
Deemed capital contribution on extinguishment of preferred stock	2,305,678		
Income (loss) applicable to common shareholders	$ 5,910,645	$ (3,269,830)	$ (7,129,917)
Basic earnings (loss) per share	$ 0.21	$ (0.12)	$ (0.26)
Diluted earnings (loss) per share	$ 0.20	$ (0.12)	$ (0.26)
Weighted average common shares outstanding:			
Basic	27,822,593	27,375,450	26,999,698
Diluted	29,481,294	27,375,450	26,999,698

See accompanying notes to financial statements

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RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	Series I Class B		Series II Class B		Series III Class B		Series IV Class B		Series V Class B		Common	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance as of December 31, 2012	103,500	$ 103,500	178,700	$ 178,700	130,245	$ 130,245	542,500	$ 542,500	46,607	$ 46,607	27,252,463	$
Conversion of Preferred Stock into Common Stock									(6,607)	(6,607)	6,607	
Recognition of stock option compensation												
Recognition of stock option exercise											584,450	
Dividends												
Repurchase of Common Stock											(655,818)	
Net loss												
Balance as of December 31, 2013	103,500	103,500	178,700	178,700	130,245	130,245	542,500	542,500	40,000	40,000	27,187,702	
Conversion of Preferred Stock into Common Stock	(5,000)	(5,000)	(2,500)	(2,500)							7,500	
Recognition of stock option exercise											418,195	
Dividends												
Net loss												
Balance as of December 31, 2014	98,500	98,500	176,200	176,200	130,245	130,245	542,500	542,500	40,000	40,000	27,613,397	
Conversion of Preferred Stock into Common Stock			(5,000)	(5,000)	(1,000)	(1,000)	(200,000)	(200,000)			206,000	
Recognition of stock option exercise											272,477	
Issuance of new Common Stock											528,000	
Registration of new shares												

Retirement of treasury stock																				
Dividends																				
Net income																				
Balance as of December 31, 2015	98,500	$	98,500	171,200	$	171,200	129,245	$	129,245	342,500	$	342,500	40,000	$	40,000	28,619,874	$			

See accompanying notes to financial statements

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RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	Additional Paid-in Capital	Retained Deficit	Treasury Stock	Total
Balance as of December 31, 2012	$ 58,617,308	$ (23,767,662)	$ (122,202)	$ 35,728,996
Conversion of Preferred Stock into Common Stock	6,607			
Recognition of stock option compensation	52,775			52,775
Recognition of stock option exercise	536,925			536,925
Dividends	(230,449)			(230,449)
Repurchase of Common Stock			(974,407)	(974,407)
Net loss		(6,213,852)		(6,213,852)
Balance as of December 31, 2013	58,983,166	(29,981,514)	(1,096,609)	28,899,988
Conversion of Preferred Stock into Common Stock	7,500			
Recognition of stock option exercise	398,328			398,328
Dividends	(115,225)			(115,225)
Net loss		(2,354,605)		(2,354,605)
Balance as of December 31, 2014	59,273,769	(32,336,119)	(1,096,609)	26,828,486
Conversion of Preferred Stock into Common Stock	206,000			
Recognition of stock option exercise	283,933			283,933
Issuance of new Common Stock				
Registration of new shares	(60,101)			(60,101)
Retirement of treasury stock	(1,096,609)		1,096,609	
Dividends	(338,956)			(338,956)
Net income		4,314,318		4,314,318