

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)

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

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)

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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
Common

Name of each exchange on which registered
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 No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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.

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. The aggregate market value of the common equity held by non-affiliates as of June 30, 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 No

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of March 1, 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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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 similar words constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, our ability to maintain liquidity, our maintenance of patent protection, the impact of current and future Court decisions regarding current litigation, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, 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.

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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 our current product line offering. These products include: retractable needles and syringes, glass syringes, dental syringes, IV catheter introducers, and blood collection sets.

Our products 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 tradeshow, 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

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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

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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.

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| | 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

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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

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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

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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 |

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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 similar words constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, our ability to maintain liquidity, our maintenance of patent protection, the impact of current and future Court decisions regarding current litigation, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, 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;

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(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

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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:

| | Total | Payments Due by Period | | | |
|--------------------------------|--------------|------------------------|------------|--------------|-------------------|
| | | 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.

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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.

Dallas, Texas
March 30, 2016

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

Table of Contents**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 |

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| | | | | |
|--|----|------------|----|------------|
| Total liabilities and stockholders' equity | \$ | 42,540,864 | \$ | 45,353,114 |
|--|----|------------|----|------------|

See accompanying notes to financial statements

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Table of Contents**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

Table of Contents**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 | | | | | | | | | | | | |

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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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Table of Contents**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 |
| Balance as of December 31, 2015 | \$ 58,268,036 | \$ (28,021,801) | \$ | \$ 31,027,680 |

See accompanying notes to financial statements

Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****STATEMENTS OF CASH FLOWS**

| | Years Ended December 31, | | |
|---|--------------------------|----------------|----------------|
| | 2015 | 2014 | 2013 |
| Cash flows from operating activities: | | | |
| Net income (loss) | \$ 4,314,318 | \$ (2,354,605) | \$ (6,213,852) |
| Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities: | | | |
| Depreciation and amortization | 858,391 | 1,074,520 | 1,284,249 |
| Share based compensation | | | 52,775 |
| Provision for doubtful accounts | 116,395 | 27,300 | 50,000 |
| Provision for inventory valuation | | | 530,000 |
| Gain on disposal of assets | | | (1,000) |
| (Increase) decrease in assets: | | | |
| Inventories | (1,633,077) | 1,072,041 | (1,275,336) |
| Accounts receivable | 624,699 | (2,192,673) | 167,589 |
| Income taxes receivable | | | 9,431 |
| Other current assets | (373,977) | (128,414) | (281,881) |
| Increase (decrease) in liabilities: | | | |
| Accounts payable | 554,722 | 35,018 | 7,895 |
| Litigation proceeds subject to stipulation | (7,724,826) | | 7,724,826 |
| Other accrued liabilities | 11,312 | (1,318,327) | 787,902 |
| Income taxes payable | (114) | (82,682) | 90,971 |
| Net cash provided (used) by operating activities | (3,252,157) | (3,867,822) | 2,933,569 |
| Cash flows from investing activities: | | | |
| Purchase of property, plant, and equipment | (1,465,010) | (1,007,933) | (283,289) |
| Changes in restricted cash | 600,897 | (600,897) | |
| Proceeds from sale of assets | | | 1,000 |
| Net cash used by investing activities | (864,113) | (1,608,830) | (282,289) |
| Cash flows from financing activities: | | | |
| Repayments of long-term debt and notes payable | (184,447) | (249,220) | (317,303) |
| Proceeds from long-term debt | 276,495 | | |
| Proceeds from the exercise of stock options | 283,933 | 398,328 | 536,925 |
| Repurchase of Common Stock | | | (974,407) |
| Stock registration fees | (60,101) | | |
| Payment of Preferred Stock dividends | (283,543) | (172,838) | (230,449) |
| Net cash provided (used) by financing activities | 32,337 | (23,730) | (985,234) |
| Net increase (decrease) in cash and cash equivalents | (4,083,933) | (5,500,382) | 1,666,046 |
| Cash and cash equivalents at: | | | |
| Beginning of period | 22,128,977 | 27,629,359 | 25,963,313 |
| End of period | \$ 18,045,044 | \$ 22,128,977 | \$ 27,629,359 |
| Supplemental schedule of cash flow information: | | | |
| Interest paid | \$ 219,672 | \$ 222,808 | \$ 241,052 |
| Income taxes paid | \$ 3,700 | \$ 94,332 | \$ 7,988 |
| Supplemental schedule of noncash investing and financing activities: | | | |
| Preferred dividends declared, not paid | \$ 55,414 | \$ | \$ 57,613 |

See accompanying notes to financial statements

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NOTES TO FINANCIAL STATEMENTS

1. BUSINESS OF THE COMPANY AND BASIS OF PRESENTATION

Business of the Company

Retractable Technologies, Inc. (the Company) was incorporated in Texas on May 9, 1994, and designs, develops, manufactures, and markets safety syringes and other safety medical products for the healthcare profession. The Company began to develop its manufacturing operations in 1995. The Company's manufacturing and administrative facilities are located in Little Elm, Texas. The Company's commercially available products are the VanishPoint® 0.5mL insulin syringe; 1mL tuberculin, insulin, and allergy antigen syringes; 0.5mL, 1mL, 2mL, 3mL, 5mL, and 10mL syringes; the small diameter tube adapter; the blood collection tube holder; the allergy tray; the IV safety catheter; the Patient Safe® syringes; the Patient Safe® Luer Cap; and the VanishPoint® Blood Collection Set. The Company also sells VanishPoint® autodisable syringes in the international market in addition to our other products.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Accounting estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires Management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

Cash and cash equivalents

For purposes of reporting cash flows, cash and cash equivalents include unrestricted cash, money market accounts, and investments with original maturities of three months or less.

Restricted cash

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Amounts pledged as collateral for an underlying letter of credit for equipment is classified as restricted cash. Changes in restricted cash have been presented as investing activities in the Statements of Cash Flows.

Accounts receivable

The Company records trade receivables when revenue is recognized. No product has been consigned to customers. The Company's 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.

The Company requires certain customers to make a prepayment prior to beginning production or shipment of their order. Customers may apply such prepayments to their outstanding invoices or pay the invoice and continue to carry forward the deposit for future orders. Such amounts are included in Other accrued liabilities on the Balance Sheets and are shown in Note 6, Other Accrued Liabilities.

The Company records an allowance for estimated returns as a reduction to Accounts receivable and Gross sales. Historically, returns have been immaterial.

Table of Contents**Inventories**

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.

Property, plant, and equipment

Property, plant, and equipment are stated at cost. Expenditures for maintenance and repairs are charged to operations as incurred. Cost includes major expenditures for improvements and replacements which extend useful lives or increase capacity and interest cost associated with significant capital additions. Gains or losses from property disposals are included in income.

Depreciation and amortization are calculated using the straight-line method over the following useful lives:

| | |
|--------------------------------|---------------|
| Production equipment | 3 to 13 years |
| Office furniture and equipment | 3 to 10 years |
| Buildings | 39 years |
| Building improvements | 15 years |
| Automobiles | 7 years |

Long-lived assets

The Company assesses the recoverability of long-lived assets using an assessment of the estimated undiscounted future cash flows related to such assets. In the event that assets are found to be carried at amounts which are in excess of estimated gross future cash flows, the assets will be adjusted for impairment to a level commensurate with fair value determined using a discounted cash flow analysis of the underlying assets.

The Company's property, plant, and equipment primarily consist of buildings, land, assembly equipment for syringes, molding machines, molds, office equipment, furniture, and fixtures.

Intangible assets

Intangible assets are stated at cost and consist primarily of intellectual property which is amortized using the straight-line method over 17 years.

Financial instruments

The Company estimates the fair market value of financial instruments through the use of public market prices, quotes from financial institutions, and other available information. Judgment is required in interpreting data to develop estimates of market value and, accordingly, amounts are not necessarily indicative of the amounts that could be realized in a current market exchange. Short-term financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and other liabilities, consist primarily of instruments without extended maturities, the fair value of which, based on Management's estimates, equals their recorded values. The fair value of long-term liabilities, based on Management's estimates, approximates their reported values.

Table of Contents**Concentration risks**

The Company's financial instruments exposed to concentrations of credit risk consist primarily of cash, cash equivalents, and accounts receivable. Cash balances, some of which exceed federally insured limits, are maintained in financial institutions; however, Management believes the institutions are of high credit quality. The majority of accounts receivable are due from companies which are well-established entities. As a consequence, Management considers any exposure from concentrations of credit risks to be limited.

The following table reflects our significant customers in 2015, 2014, and 2013:

| | Years Ended December 31, | | |
|---|--------------------------|-----------------|----------------|
| | 2015 | 2014 | 2013 |
| Number of significant customers | 2 | 3 | 2 |
| Aggregate dollar amount of net sales to significant customers | \$ 13.5 million | \$ 16.5 million | \$ 9.3 million |
| Percentage of net sales to significant customers | 45.7% | 47.9% | 30.2% |

Considering the current economic climate, the Company increased its allowance for doubtful accounts by approximately \$70,000 this year.

The Company manufactures syringes in Little Elm, Texas as well as utilizing manufacturers in China. The Company purchases most of its product components from single suppliers, including needle adhesives and packaging materials. There are multiple sources of these materials. The Company obtained roughly 77.7% of its VanishPoint® finished products in 2015 from its primary Chinese manufacturer. Purchases from this Chinese manufacturer aggregated 73.1% and 72.9% of VanishPoint® finished products in 2014 and 2013, respectively. In the event that the Company becomes unable to purchase products from its primary Chinese manufacturer, the Company would need to find an alternate manufacturer for its 0.5mL insulin syringe, its 2mL, 5mL, and 10mL syringes and its autodisable syringe and increase domestic production for 1mL and 3mL syringes.

Revenue recognition

Revenue is recognized for sales when title and risk of ownership passes to the customer, generally upon shipment. Under certain contracts, revenue is recorded on the basis of sales price to distributors, less contractual pricing allowances. Contractual pricing allowances consist of: (i) rebates granted to distributors who provide tracking reports which show, among other things, the facility that purchased the products, and (ii) a provision for estimated contractual pricing allowances for products for which the Company has not received tracking reports. Rebates are recorded when issued and are applied against the customer's receivable balance. Distributors receive a rebate for the difference between the Wholesale Acquisition Cost and the appropriate contract price as reflected on a tracking report provided by the distributor to the Company. If product is sold by a distributor to an entity that has no contract, there is a standard rebate (lower than a contracted rebate) given to the distributor. One of the purposes of the rebate is to encourage distributors to submit tracking reports to the Company. The provision for contractual pricing allowances is reviewed at the end of each quarter and adjusted for changes in levels of products for which there is no tracking

report. Additionally, if it becomes clear that tracking reports will not be provided by individual distributors, the provision is further adjusted. The estimated contractual allowance is included in Accounts payable in the Balance Sheets and deducted from revenues in the Statements of Operations. Accounts payable included estimated contractual allowances for \$3,733,199 and \$4,160,099 for 2015 and 2014, respectively. The terms and conditions of contractual pricing allowances are governed by contracts between the Company and its distributors. Revenue for shipments directly to end-users is recognized when title and risk of ownership pass from the Company. Any product shipped or distributed for evaluation purposes is expensed.

Certain distributors have taken rebates to which they are not entitled, such as utilizing a rebate for products not purchased directly from the Company. Major customers said they have ceased the practices resulting in

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claiming non-contractual rebates. Rebates can only be claimed on purchases made directly from the Company. The Company has established a reserve for the collectability of these non-contractual rebate amounts. The expense for the reserve is recorded in Operating expense, General and administrative. The reserve for such non-contractual deductions is included in the allowance for doubtful accounts. There has been no change to the reserve for contractual rebates in the periods currently presented.

The Company's domestic return policy is set forth in its 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 the Company and affix the code to the returned product. The Company will not accept returned goods without a returned goods authorization number. The Company may refund the customer's money or replace the product.

The Company's 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. All product overstocks and returns are subject to inspection and acceptance by the Company.

The Company's international distribution agreements generally do not provide for any returns.

Litigation proceeds

Proceeds from litigation are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected.

On September 30, 2013, the Company received payment of \$7,724,826 (the Judgment Amount) from Becton, Dickinson and Company (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 the Company was paid the Judgment Amount and the litigation did not come to a final conclusion until the second quarter of 2015.

Income taxes

The Company evaluates tax positions taken or expected to be taken in a tax return for recognition in the financial statements based on whether it is more-likely-than-not that a tax position will be sustained based upon the technical merits of the position. Measurement of the tax position is based upon the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement.

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The Company provides for deferred income taxes through utilizing an asset and liability approach for financial accounting and reporting based on the tax effects of differences between the financial statement and tax bases of assets and liabilities, based on enacted rates expected to be in effect when such differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. The Company utilized some of its net operating loss carry forwards in 2013 and paid Alternative Minimum Tax on its taxable income. The Company has established a valuation allowance for its net deferred tax asset as future taxable income cannot be reasonably assured. Penalties and interest related to income tax are classified as General and administrative expense and Interest expense, respectively, in the Statements of Operations.

Earnings per share

The Company computes basic earnings per share (EPS) by dividing net earnings for the period (adjusted for any cumulative dividends for the period) by the weighted average number of common shares outstanding during the period. Diluted EPS includes the determinants of basic EPS and, in addition, reflects the dilutive effect, if any, of the common stock deliverable pursuant to stock options or common stock issuable upon the conversion of convertible preferred stock. The calculation of diluted EPS excluded 1,774,520 and 1,305,847

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shares of Common Stock underlying issued and outstanding stock options at December 31, 2014 and 2013, respectively, as their effect was antidilutive. The potential dilution, if any, is shown on the following schedule:

| | Years Ended December 31, | | |
|---|--------------------------|----------------|----------------|
| | 2015 | 2014 | 2013 |
| Net income (loss) | \$ 4,314,318 | \$ (2,354,605) | \$ (6,213,852) |
| Preferred 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 after assumed conversions | \$ 5,910,645 | \$ (3,269,830) | \$ (7,129,917) |
| Average common shares outstanding | 27,822,593 | 27,375,450 | 26,999,698 |
| Average common and common equivalent shares outstanding - assuming dilution | 29,481,294 | 27,375,450 | 26,999,698 |
| Basic earnings (loss) per share | \$ 0.21 | \$ (0.12) | \$ (0.26) |
| Diluted earnings (loss) per share | \$ 0.20 | \$ (0.12) | \$ (0.26) |

The Financial Accounting Standards Board Accounting Standards Codification 260-10-S99-2, Effect on the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock, requires the gain or loss on extinguishment of equity-classified preferred stock to be included in net income per common stockholder used to calculate earnings per share (similar to the treatment of dividends paid on preferred stock). The difference between (1) the fair value of the consideration transferred to the holders of the preferred stock and (2) the carrying amount of the preferred stock (net of issuance costs) is subtracted from (or added to) net income to arrive at income available to common stockholders in the calculation of earnings per share.

The Company has determined to apply this guidance to its accounting treatment of the preferred stock transaction described in note 20. From a legal standpoint, the transaction was neither a redemption nor conversion pursuant of the terms of the Certificate of Designation, Preferences, Rights and Limitations of the Series IV Class B Convertible Preferred Stock.

Shipping and handling costs

The Company classifies shipping and handling costs as part of Cost of sales in the Statements of Operations.

Research and development costs

Research and development costs are expensed as incurred.

Share-based compensation

The Company's share-based payments are accounted for using the fair value method. The Company records share-based compensation expense on a straight-line basis over the requisite service period. The Company incurred \$52,775 in General and administrative cost related to share-based compensation in 2013. No share-based compensation costs were incurred in 2015 or 2014.

All stock options are fully vested; therefore, all stock option expense has been fully recognized.

Recent Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, Leases (topic 842). Under the new ASU, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Under the new guidance lessor accounting is largely unchanged. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. This ASU is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of this standard.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes. This ASU amends Topic 740, Income Taxes, requiring deferred tax assets and liabilities to be classified as non-current in the statement of financial position. As required by ASU No. 2015-17, all deferred tax assets and liabilities will be classified as non-current in the Company's consolidated balance sheets. Effective for public business entities for financial statements issued for annual periods beginning after December 15, 2016,

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and interim periods within those annual periods. The amendments may be applied prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company is currently evaluating the impact of this standard.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330) Simplifying the Measurement of Inventory, which is part of the FASB's Simplification Initiative. Inventory, including inventory measured at average cost, would be valued at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for the Company's annual periods and interim periods within those annual periods beginning January 1, 2017. Amendments in this ASU should be applied prospectively with earlier application permitted at the beginning of an interim or annual reporting period. The Company is currently assessing the potential impact of this ASU on its financial statements.

In May 2014, FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which provides guidance for revenue recognition. This ASU's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects consideration to which the company expects to be entitled in exchange for those goods or services. This ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU No. 2014-09 allows for either full retrospective or modified retrospective adoption. In July 2015, the FASB voted to delay the effective date of this ASU by one year. The ASU will now be effective commencing with the Company's quarter ending March 31, 2018. Early adoption of this ASU is allowed no sooner than the original effective date. The Company is currently assessing the potential impact of this ASU on its financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Currently there is no guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern. This ASU requires management to assess the entity's ability to continue as a going concern. This guidance is effective for the Company's annual reporting period ending December 31, 2016 and for subsequent interim periods. Early adoption is permitted. The Company expects to adopt this guidance when effective, and upon adoption, will evaluate going concern based on this guidance.

In April 2015, the FASB issued ASU 2015-03, Interest Imputation of Interest. To simplify presentation of debt issuance costs, the amendments in this ASU would require that debt issuance costs be presented in the balance sheet as a direct deduction from the carrying amount of debt liability, consistent with debt discounts or premiums. The recognition and measurement guidance for debt issuance costs would not be affected by the amendments in this ASU. This ASU is the final version of Proposed Accounting Standards Update 2014-250 Interest Imputation of Interest (Subtopic 835-30), which has been deleted. The amendments in this ASU are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company has no unamortized debt issuance costs.

3. INVENTORIES

Inventories consist of the following:

| Year Ended December 31, | |
|-------------------------|------|
| 2015 | 2014 |

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| | | | | |
|-------------------|----|-----------|----|-----------|
| Raw materials | \$ | 1,664,241 | \$ | 1,510,225 |
| Finished goods | | 5,313,778 | | 3,834,717 |
| | | 6,978,019 | | 5,344,942 |
| Inventory reserve | | (681,394) | | (681,394) |
| | \$ | 6,296,625 | \$ | 4,663,548 |

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Table of Contents**4. PROPERTY, PLANT, AND EQUIPMENT**

Property, plant, and equipment consist of the following:

| | December 31, | |
|-------------------------------------|---------------|---------------|
| | 2015 | 2014 |
| Land | \$ 261,893 | \$ 261,893 |
| Buildings and building improvements | 11,485,797 | 11,414,961 |
| Production equipment | 15,648,515 | 15,609,824 |
| Office furniture and equipment | 3,316,390 | 3,147,786 |
| Construction in progress | 2,739,260 | 1,552,379 |
| Automobiles | 102,321 | 102,321 |
| | 33,554,176 | 32,089,164 |
| Accumulated depreciation | (22,086,115) | (21,236,311) |
| | \$ 11,468,061 | \$ 10,852,853 |

Depreciation expense for the years ended December 31, 2015, 2014, and 2013 was \$849,804; \$1,065,248; and \$1,272,770, respectively.

5. INTANGIBLE ASSETS

Intangible assets consist of the following:

| | December 31, | |
|--------------------------|--------------|------------|
| | 2015 | 2014 |
| Intellectual property | \$ 494,399 | \$ 494,399 |
| Accumulated amortization | (237,218) | (228,631) |
| | \$ 257,181 | \$ 265,768 |

In 1995, the Company entered into a license agreement with the Chief Executive Officer of the Company for the exclusive right to manufacture, market, and distribute products utilizing automated retraction technology, which agreement has been amended twice. This technology is the subject of various patents and patent applications owned by such officer of the Company. The initial licensing fee of \$500,000 was amortized over 17 years. The license agreement also provides for quarterly payments of a 5% royalty fee on gross sales. The royalty fee expense is recognized in the period in which it is earned. Royalty fees of \$2,477,583; \$2,728,701; and \$2,474,762 are included in Cost of sales for the years ended December 31, 2015, 2014, and 2013, respectively. Royalties payable under this agreement aggregated \$631,145 and \$787,434 at December 31, 2015 and 2014, respectively. Gross sales upon which royalties are based were \$49,551,660; \$54,574,020; and \$49,495,232 for 2015, 2014, and 2013, respectively.

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Amortization expense for the years ended December 31, 2015, 2014, and 2013, was \$8,587; \$9,272; and \$11,479, respectively.

6. OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

| | December 31, | |
|----------------------------|--------------|------------|
| | 2015 | 2014 |
| Prepayments from customers | \$ 395,396 | \$ 435,821 |
| Accrued property taxes | | 7,554 |
| Accrued professional fees | 274,252 | 201,866 |
| Other accrued expenses | 20,887 | 137,081 |
| | \$ 690,535 | \$ 782,322 |

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Table of Contents**7. LONG-TERM DEBT**

Long-term debt consists of the following:

| | December 31, | |
|---|--------------|--------------|
| | 2015 | 2014 |
| Loan from American First National Bank. It has a 20 year amortization and 10 year maturity from December 10, 2009. The loan provided funding for the expansion of the warehouse, additional office space, and a new Controlled Environment. The loan is secured by the Company's land and buildings. The interest rate is 5.968%. | \$ 3,426,926 | \$ 3,574,772 |
| Note payable to Deutsche Leasing USA, Inc. The interest rate is 3.69%. The original amount of the note was \$276,495 with a 36 month maturity ending in July 2018. Beginning August 2015, the loan became payable in equal installments of principal and interest of approximately \$8,100. Collateralized by molding machines and ancillary equipment. | 239,894 | |
| | 3,666,820 | 3,574,772 |
| Less: current portion | (249,349) | (149,744) |
| | \$ 3,417,471 | \$ 3,425,028 |

The fair value of long-term liabilities, based on Management's estimates, approximates their reported values.

The aggregate maturities of long-term debt as of December 31, 2015, are as follows:

| | |
|------------|--------------|
| 2016 | \$ 249,349 |
| 2017 | 262,758 |
| 2018 | 236,048 |
| 2019 | 2,918,665 |
| Thereafter | \$ 3,666,820 |

8. COMMITMENTS AND CONTINGENCIES

In May 2010, the Company and an officer'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 the Company \$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 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

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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 the Company \$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 the Company 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. The Company filed its 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 the Company in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that the Company is 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. The Company 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 the Company subsequently dropped its 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 first paragraph of this Note 8.

Operating Leases

In 2010, the Company entered into a non-cancellable operating lease for additional office space. Rent expense under this lease for the years ended December 31, 2015, 2014, and 2013 was \$64,683; \$62,813; and \$61,607, respectively. The Company renewed the lease in 2015. Future annual minimum rental payments as of December 31, 2015 are presented below:

| | | |
|-------|----|---------|
| 2016 | \$ | 74,772 |
| 2017 | | 77,015 |
| 2018 | | 79,331 |
| 2019 | | 81,694 |
| 2020 | | 84,155 |
| Total | \$ | 396,967 |

9. INCOME TAXES

The provision for income taxes consists of the following:

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| | For the Years Ended December 31, | | | |
|-------------------------------------|----------------------------------|-----------------|-----------|---------------|
| | 2015 | 2014 | | 2013 |
| Current tax provision | | | | |
| Federal | \$ | \$ | \$ | 83,470 |
| State | 7,877 | 8,177 | | 7,502 |
| Total current provision | 7,877 | 8,177 | | 90,972 |
| Deferred tax provision | | | | |
| Federal | | | | |
| State | | | | |
| Total deferred tax provision | | | | |
| Total income tax provision | \$ 7,877 | \$ 8,177 | \$ | 90,972 |

The Company has \$15.8 million in tax benefits attributable to carry back losses for federal tax purposes. The loss carry forwards will begin to expire in 2028 for federal tax purposes and began to expire for state tax purposes in 2013. The Company also has credits for alternative minimum taxes (AMT) paid of \$202 thousand that are available to offset future federal income taxes, excluding AMT. Such credits do not expire.

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Deferred taxes are provided for those items reported in different periods for income tax and financial reporting purposes. The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities are presented below:

| | December 31, | |
|--|--------------|--------------|
| | 2015 | 2014 |
| Deferred tax assets | | |
| Net operating loss carry forwards | \$ 5,979,717 | \$ 4,704,612 |
| Credit for alternative minimum tax paid | 201,773 | 201,773 |
| Accrued expenses and reserves | 1,383,461 | 1,424,969 |
| Employee stock option expense | 303,465 | 315,711 |
| Nonemployee stock option expense | 12,770 | 15,546 |
| Inventory | 356,170 | 287,190 |
| Litigation proceeds subject to stipulation | | 2,929,640 |
| Deferred tax assets | 8,237,356 | 9,879,441 |
| Deferred tax liabilities | | |
| Property and equipment | (485,384) | (493,985) |
| Deferred tax liabilities | (485,384) | (493,985) |
| Net deferred assets | 7,751,972 | 9,385,456 |
| Valuation allowance | (7,751,972) | (9,385,456) |
| Net deferred tax assets | \$ | \$ |

The valuation allowance decreased \$1,633,485 for 2015. The valuation allowance increased \$807,790 for 2014.

A reconciliation of income taxes based on the federal statutory rate and the effective income tax rate is summarized as follows:

| | 2015 | December 31, | |
|--|--------|--------------|--------|
| | | 2014 | 2013 |
| Income tax at the federal statutory rate | 35.0% | 35.0% | 35.0% |
| State tax, net of federal tax | 2.9 | 2.9 | 2.9 |
| Change in valuation allowance | (37.8) | (34.3) | (39.3) |
| Permanent differences | 0.7 | (0.7) | (0.3) |
| Alternative minimum tax | | | (1.4) |
| Other | (0.6) | (3.2) | 1.6 |
| Effective tax rate | 0.2% | (0.3)% | (1.5)% |

The Company files income tax returns in the U.S. federal jurisdiction and in various state and local jurisdictions. The Company's federal income tax returns for all tax years ended on or after December 31, 2012, remain subject to examination by the Internal Revenue Service. The Company's state and local income tax returns are subject to examination by the respective state and local authorities over various statutes of limitations, most ranging from three to five years from the date of filing.

10. STOCK REPURCHASE PROGRAM

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On July 10, 2012, the Company authorized a Common Stock repurchase plan structured to comply with Rules 10b5-1 and 10b-18 under the Securities Exchange Act of 1934. Under the plan, the Company purchased 655,818 shares in 2013. The plan was terminated effective August 30, 2013.

Pursuant to the Certificates of Designation, Preferences, Rights And Limitations of the Series I Class B and Series II Class B Convertible Preferred Stock, the Company would have been prohibited from purchasing its Common Stock while dividends were in arrears. Therefore, to facilitate the Common Stock repurchase plan, the Company paid dividends on the Series I Class B Preferred Stock in the amount of \$12,938 at each date on

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January 21, 2013, April 22, 2013, and July 22, 2013. The Company paid dividends to Series II Class B Preferred Stockholders in the amount of \$44,675 on each of the same three dates listed in the preceding sentence.

11. STOCK OPTION GRANT

The Compensation and Benefits Committee approved a grant of a non-qualified stock option pursuant to the 2008 Stock Option Plan to Walter O. Bigby, Jr., a Director, for the purchase of 50,000 shares of Common Stock on May 14, 2013. Related share based compensation of \$52,775 is included in general and administrative expense in the accompanying Statements of Operations for 2013.

12. DIVIDENDS

The Board declared and the Company paid dividends to Series I and Series II Class B Preferred Stockholders in the amounts of \$12,938 and \$44,675, respectively, in each of the four quarters of 2013. The Board declared and the Company paid the same amounts to the Series I and Series II Class B Preferred Stockholders in only the first two quarters of 2014. See Note 10 for information about dividends paid during the term of the Stock Repurchase Program. In 2015, the Board declared and the Company paid dividends to Series I and Series II Class B Preferred Shareholders in the following amounts: \$37,891 and \$132,926 paid to Series I Class B and Series II Class B Preferred Stockholders, respectively, on April 30, 2015; \$12,313 and \$44,050 paid to Series I Class B and Series II Class B Preferred Stockholders, respectively, on July 20, 2015; \$12,313 and \$44,050 paid to Series I Class B and Series II Class B Preferred Stockholders, respectively, on October 22, 2015; and \$12,313 and \$43,101 paid to Series I Class B and Series II Class B Preferred Stockholders, respectively, on February 1, 2016.

13. STOCK OPTION EXERCISES

Stock options were exercised at various dates in 2015, 2014, and 2013 and, consequently, a total of 272,477 shares of Common Stock were issued in 2015, 418,195 shares of Common Stock in 2014, and a total of 584,450 shares of Common Stock in 2013 for an aggregate payment of \$283,933 in 2015, \$398,328 in 2014, and \$536,925 in 2013 to exercise such options. These options were granted in 2008 and 2009 at exercise prices of \$0.81 and \$1.30.

14. STOCKHOLDERS EQUITY

Preferred Stock

The Company is authorized to issue 5,000,000 shares of Preferred Stock Class A with a par value of One Dollar (\$1.00) per share; 5,000,000 shares of Preferred Stock Class B with a par value of One Dollar (\$1.00) per share; and 5,000,000 shares of Preferred Stock Class C with a par value of One Dollar (\$1.00) per share.

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The Company has one class of Preferred Stock outstanding: Class B Convertible Preferred Stock (Class B Stock). The Class B Stock has five series: Series I, Series II, Series III, Series IV, and Series V.

The Class B Stock has been allocated among Series I, II, III, IV, and V in the amounts of 98,500; 171,200; 129,245; 342,500; and 40,000 shares, respectively as of December 31, 2015. The remaining 4,218,555 authorized shares have not been assigned a series.

Series I Class B Stock

There were 98,500 shares of \$1 par value Series I Class B Stock outstanding at December 31, 2015 and 2014. Holders of Series I Class B Stock are entitled to receive a cumulative annual dividend of \$0.50 per share, payable quarterly if declared by the Board of Directors. The Company paid dividends of \$62,516; \$38,814; and \$38,814 in 2015, 2014, and 2013, respectively. At December 31, 2015, no dividends were in arrears.

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Series I Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$7.50 per share, plus all unpaid dividends. Each share of Series I Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, 5,000 shares of Series I Class B Stock were converted into Common Stock in 2014. No shares were converted in 2015. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series I Class B Stock then outstanding are entitled to \$6.25 per share, plus all unpaid dividends prior to any distributions to holders of Series II Class B Stock, Series III Class B Stock, Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series II Class B Stock

There were 171,200 and 176,200 shares of \$1 par value Series II Class B Stock outstanding at December 31, 2015 and 2014, respectively. Holders of Series II Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the Board of Directors. Holders of Series II Class B Stock generally have no voting rights until dividends are in arrears and unpaid for twelve consecutive quarters. In such case, the holders of Series II Class B Stock have the right to elect one-third of the Board of Directors of the Company. The Company paid dividends of \$221,026; \$134,025; and \$134,025 in 2015, 2014, and 2013, respectively. At December 31, 2015, no dividends were in arrears.

Series II Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share plus all unpaid dividends. Each share of Series II Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, 5,000 shares of Series II Class B Stock were converted into Common Stock in 2015. 2,500 shares were converted in 2014. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series II Class B Stock then outstanding are entitled to \$12.50 per share, plus all unpaid dividends, after distribution obligations to holders of Series I Class B Stock have been satisfied and prior to any distributions to holders of Series III Class B Stock, Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series III Class B Stock

There were 129,245 and 130,245 shares of \$1 par value Series III Class B Stock outstanding at December 31, 2015 and 2014. Holders of Series III Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the Board of Directors. At December 31, 2015, approximately \$3,887,000 of dividends which have not been declared were in arrears.

Series III Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share, plus all unpaid dividends. Each share of Series III Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, 1,000 shares of Series III Class B Stock were converted into Common Stock in 2015. No shares were converted in 2014. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series III Class B Stock then outstanding are entitled to \$12.50 per share, plus all unpaid dividends, after distribution obligations to Series I Class B Stock and Series II Class B Stock have been satisfied and prior to any distributions to holders of Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series IV Class B Stock

There were 342,500 and 542,500 shares of \$1 par value Series IV Class B Stock outstanding at December 31, 2015 and 2014. Holders of Series IV Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly, if declared by the Board of Directors. At December 31, 2015, approximately \$5,456,000 of dividends which have not been declared were in arrears.

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Series IV Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$11.00 per share plus all unpaid dividends. Each share of Series IV Class B Stock may, at the option of the stockholder any time subsequent to three years from date of issuance, be converted into one share of Common Stock, or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series IV Class B Stock were converted into Common Stock in 2015 or 2014. However, the Company did enter into an agreement which had the effect of cancelling 200,000 shares in 2015. See Note 20. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series IV Class B Stock then outstanding are entitled to receive liquidating distributions of \$11.00 per share, unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, and Series III Class B Stock have been satisfied and prior to any distribution to holders of Series V Class B Stock or Common Stock.

Series V Class B Stock

There were 40,000 shares of \$1 par value Series V Class B Stock outstanding at December 31, 2015 and 2014. Holders of Series V Class B Stock are entitled to receive a cumulative annual dividend of \$0.32 per share, payable quarterly, if declared by the Board of Directors. At December 31, 2015, approximately \$970,000 of dividends which have not been declared were in arrears.

Series V Class B Stock is redeemable after two years from the date of issuance at the option of the Company at a price of \$4.40 per share plus all unpaid dividends. Each share of Series V Class B Stock may, at the option of the stockholder any time subsequent to the date of issuance, be converted into Common Stock. Pursuant to these terms, no shares of Series V Class B Stock were converted into Common Stock in 2015 or 2014. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series V Class B Stock then outstanding are entitled to receive liquidating distributions of \$4.40 per share, plus unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, Series III Class B Stock, and Series IV Class B Stock have been satisfied and prior to any distribution to the holders of the Common Stock.

Common stock

The Company is authorized to issue 100,000,000 shares of no par value Common Stock, of which 28,619,874 and 27,613,397 shares were outstanding at December 31, 2015 and 2014, respectively.

15. RELATED PARTY TRANSACTIONS

The Company has a license agreement with the Chief Executive Officer of the Company. See Note 5.

During the years ended December 31, 2014 and 2013, the Company paid \$38,693 and \$93,939, respectively, to a family member of its Chief Executive Officer as an employee and/or consultant.

16. STOCK OPTIONS

Stock options

The Company has approved stock option plans for the granting of stock options to employees, Directors, and consultants. Options for the purchase of 2,899,108 shares of Common Stock have been issued under the 2008 Stock Option Plan, which, pursuant to a 2014 amendment, authorizes a total of 6,000,000 shares of Common Stock upon the exercise of stock options. Options for the purchase of 2,182,569 shares under the 2008 Stock Option Plan were outstanding as of December 31, 2015. Options for the purchase of 1,000,000 shares of Common Stock remain outstanding under an option granted to Mr. Thomas J. Shaw.

The Compensation and Benefits Committee administers all plans and determines and/or recommends to the Board exercise prices at which options are granted. All executive compensation, including the granting of stock options, is determined by the Compensation and Benefits Committee. Shares issued upon exercise of options come from the Company's authorized but unissued Common Stock. The options vested over periods up to three

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years from the date of grant and generally expire ten years after the date of grant. Unvested options issued under the 2008 Stock Option Plan expire immediately after termination of employment.

Employee options

A summary of Director, officer, and employee options granted and outstanding under the Plans is presented below:

| | 2015 | | Years Ended December 31, 2014 | | 2013 | |
|------------------------------------|-----------|--|----------------------------------|--|-----------|--|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at beginning of period | 2,386,736 | \$ 0.95 | 2,820,631 | \$ 0.95 | 3,367,081 | \$ 0.95 |
| Granted | | \$ | | \$ | 50,000 | \$ 1.46 |
| Exercised | (259,977) | \$ (1.05) | (418,195) | \$ (0.95) | (584,450) | \$ (0.92) |
| Forfeited | (1,690) | \$ (1.30) | (15,700) | \$ (1.37) | (12,000) | \$ (2.38) |
| Outstanding at end of period | 2,125,069 | \$ 0.94 | 2,386,736 | \$ 0.95 | 2,820,631 | \$ 0.95 |
| Exercisable at end of period | 2,125,069 | \$ 0.94 | 2,386,736 | \$ 0.95 | 2,820,631 | \$ 0.95 |

No employee options were issued in 2015 or 2014. The fair value of the 2013 grant is \$1.06 per share of underlying Common Stock and is estimated on the date of the grant using the Black Scholes pricing model with the following assumptions: expected volatility of 67.53%, risk free interest rate of 3.35%, and an expected life of 8.61 years. This option was issued under the 2008 Stock Option Plan.

The following table summarizes information about Director, officer, and employee options outstanding under the aforementioned plans at December 31, 2015:

| Exercise Prices | Shares Outstanding | Weighted Average Remaining Contractual Life | Shares Exercisable |
|-----------------|--------------------|---|--------------------|
| \$ 1.30 | 495,366 | 2.88 | 495,366 |
| \$ 1.46 | 50,000 | 7.37 | 50,000 |
| \$ 0.81 | 1,579,703 | 3.54 | 1,579,703 |

Non-employee options

A summary of options outstanding during the years ended December 31 and held by non-employees is as follows:

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| | 2015 | | Years Ended December 31, 2014 | | 2013 | |
|------------------------------------|----------|---------------------------------|----------------------------------|---------------------------------|--------|---------------------------------|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at beginning of period | 70,000 | \$ 0.81 | 70,000 | \$ 0.81 | 70,000 | \$ 0.81 |
| Granted | | | | | | |
| Exercised | (12,500) | (0.81) | | | | |
| Forfeited | | \$ | | | | \$ |
| Outstanding at end of period | 57,500 | \$ 0.81 | 70,000 | \$ 0.81 | 70,000 | \$ 0.81 |
| Exercisable at end of period | 57,500 | \$ 0.81 | 70,000 | \$ 0.81 | 70,000 | \$ 0.81 |

No non-employee options were issued in 2015, 2014, or 2013.

The following table summarizes information about non-employee options outstanding under the aforementioned plans at December 31, 2015:

| | Exercise Price | Shares Outstanding | Weighted Average Remaining Contractual Life | Shares Exercisable |
|----|----------------|--------------------|---|--------------------|
| \$ | 0.81 | 57,500 | 3.54 | 57,500 |

The Company recorded no stock-based compensation expense in 2015 or 2014. The Company recorded \$52,775 of stock-based compensation expense in 2013. The total intrinsic value of options exercised was \$856,269; \$1,157,615; and \$1,210,135 in 2015, 2014, and 2013, respectively. The aggregate intrinsic value of options outstanding and exercisable with exercise prices lower than market price at December 31, 2015 was approximately \$4,722,854. There is no compensation cost related to non-vested stock options to be recognized in the future.

Options Pricing Models Assumptions

The expected life and forfeiture rate assumptions are based on the vesting period for each option grant and expected exercise behavior. The assumptions for expected volatility and dividend yield are based on recent historical experience. Risk-free interest rates are set using grant-date U.S. Treasury yield curves for the same periods as the expected term.

17. 401(k) PLAN

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The Company implemented an employee savings and retirement plan (the 401(k) Plan) in 2005 that is intended to be a tax-qualified plan covering substantially all employees. Under the terms of the 401(k) Plan, employees may elect to contribute up to 88% of their compensation, or the statutory prescribed limit, if less. The Company may, at its discretion, match employee contributions. In the third quarter of 2009, the Company discontinued its matching contributions until further notice.

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Table of Contents**18. BUSINESS SEGMENTS**

| | 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 |

The Company does not operate in separate reportable segments. The Company has 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. The Company does 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.

19. TREASURY SHARES

The Board of Directors of the Company cancelled all treasury shares effective August 11, 2015.

20. PREFERRED STOCK TRANSACTION

The Company 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. The fair value of the common stock issued (\$2,606,240) over the carrying value of the preferred stock extinguished (\$2,000,000) was \$606,240. The excess of the dividend arrearage waived less the excess value of common stock issued, less the preferred dividend requirements for 2015 through the extinguishment date (\$182,877) resulted in a deemed capital contribution of \$2,305,678 for purposes of computing net income available to common shareholders. Future dividend requirements of \$200,000 per year are avoided as a result of this transaction.

SELECTED QUARTERLY FINANCIAL DATA - UNAUDITED

The selected quarterly financial data for the periods ended December 31, 2015 and 2014, have been derived from the Company's unaudited financial statements and include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the results of the interim periods.

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(In thousands, except for per share and outstanding stock amounts)

| | 2015 | | | |
|--|------------|------------|------------|------------|
| | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 |
| Sales, net | \$ 6,179 | \$ 6,715 | \$ 9,483 | \$ 7,175 |
| Cost of sales | 3,781 | 4,114 | 6,259 | 4,833 |
| Gross profit | 2,398 | 2,601 | 3,224 | 2,342 |
| Total operating expenses | 3,293 | 3,841 | 3,423 | 3,215 |
| Loss from operations | (895) | (1,240) | (199) | (873) |
| Litigation proceeds | | 7,725 | | |
| Interest and other income | 7 | 9 | 5 | 4 |
| Interest expense, net | (54) | (53) | (59) | (54) |
| Provision for income taxes | 2 | 2 | 2 | 2 |
| Net income (loss) | (944) | 6,439 | (255) | (925) |
| Preferred stock dividend requirements | (228) | (228) | (227) | (176) |
| Deemed capital contribution on extinguishment of preferred stock | | | | 2,455 |
| Income (loss) applicable to common shareholders | \$ (1,172) | \$ 6,211 | \$ (482) | \$ 1,354 |
| Basic earnings (loss) per share | \$ (0.04) | \$ 0.22 | \$ (0.02) | \$ 0.05 |
| Diluted earnings (loss) per share | \$ (0.04) | \$ 0.21 | \$ (0.02) | \$ 0.05 |
| Weighted average shares outstanding - basic | 27,663,500 | 27,741,052 | 27,873,447 | 28,012,374 |
| Weighted average shares outstanding - diluted | 27,663,500 | 29,432,468 | 27,873,447 | 29,605,874 |
| Gross profit margin | 38.8% | 38.7% | 34.0% | 32.6% |

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(In thousands, except for per share and outstanding stock amounts)

| | 2014 | | | |
|---|------------|------------|------------|------------|
| | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 |
| Sales, net | \$ 6,040 | \$ 6,876 | \$ 10,887 | \$ 10,717 |
| Cost of sales | 4,317 | 4,698 | 7,035 | 6,449 |
| Gross profit | 1,723 | 2,178 | 3,852 | 4,268 |
| Total operating expenses | 3,713 | 3,518 | 3,431 | 3,517 |
| Income (loss) from operations | (1,990) | (1,340) | 421 | 751 |
| Interest and other income | 10 | 8 | 8 | 8 |
| Interest expense, net | (57) | (56) | (55) | (54) |
| Provision for income taxes | 2 | 2 | 2 | 3 |
| Net income (loss) | (2,038) | (1,390) | 371 | 702 |
| Preferred stock dividend requirements | (229) | (229) | (229) | (229) |
| Income (loss) applicable to common shareholders | \$ (2,267) | \$ (1,619) | \$ 142 | \$ 473 |
| Basic earnings (loss) per share | \$ (0.08) | \$ (0.06) | \$ 0.01 | \$ 0.02 |
| Diluted earnings (loss) per share | \$ (0.08) | \$ (0.06) | \$ 0.00 | \$ 0.02 |
| Weighted average shares outstanding - basic | 27,258,689 | 27,332,483 | 27,394,061 | 27,520,900 |
| Weighted average shares outstanding - diluted | 27,258,689 | 27,332,483 | 29,173,359 | 29,405,819 |
| Gross profit margin | 28.5% | 31.7% | 35.4% | 39.8% |

Certain quarterly amounts may not add to the annual totals due to rounding. 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.

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 (the Exchange Act), Management, with the participation of our President, Chairman, and Chief Executive Officer, Thomas J. Shaw (the CEO), and our Vice President and Chief Financial Officer, Douglas W. Cowan (the CFO), acting in their capacities as our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act. The term disclosure controls and procedures means controls and other procedures that are designed to ensure that information required to be disclosed by us in our periodic reports is: i) recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's (the SEC) rules and forms; and ii) accumulated and communicated to our Management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based upon this evaluation, the CEO and CFO concluded that, as of December 31, 2015, our disclosure controls and procedures were not effective, as discussed below.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The term internal control over financial reporting means a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, Management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets; (ii) provide reasonable assurance that our transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of Management and Directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements. Management used the *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting as required by paragraph (c) of Rule 13a-15 under the Exchange Act.

During the preparation of this annual report, our auditors brought errors in the total amount of raw materials to the attention of Management. The errors resulted from an incorrect pricing of two individual inventory amounts in our detailed raw materials ledger, which is currently maintained in a spreadsheet. The errors arising from the underlying deficiency did not result in a revision to previously filed financial statements. However, in the absence of remedial efforts, this control deficiency could have resulted in future misstatements that would not be prevented or detected in a timely manner. Accordingly, Management, with the participation of our CEO and CFO, concluded that there was a material weakness in our internal control over financial reporting and that our disclosure controls and procedures and our internal control over

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financial reporting were not effective as of December 31, 2015. In light of the material weakness in internal control over financial reporting, we plan to transition to an Oracle inventory accounting system, which we expect to implement by the third quarter of 2016. Such a system would help to remedy the weakness discovered in connection with this annual report as well as errors of the type indicated in our quarterly report on Form 10-Q for the period ended September 30, 2015. Also, additional senior members of the accounting team, including the CFO, will provide more oversight and analyze critical accounting procedures and related calculations for completeness and accuracy.

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Except as noted above, there has been no change in our internal control over financial reporting during the fourth quarter of 2015 or subsequent to December 31, 2015 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III**Item 10. Directors, Executive Officers and Corporate Governance.**

The following table sets forth information concerning our Directors, executives, and certain of our significant employees as of the date of this report. Our Board of Directors currently consists of a total of five (5) members, three (3) members of which are Class 1 Directors and two (2) of which are Class 2 Directors which serve for two-year terms.

| Name | Age | Position | Term as Director Expires |
|------------------------------|-----|--|--------------------------|
| EXECUTIVES | | | |
| Thomas J. Shaw | 65 | Chairman, President, Chief Executive Officer, and Class 2 Director | 2016 |
| Douglas W. Cowan | 72 | Vice President, Chief Financial Officer, Treasurer, Principal Accounting Officer, and Class 2 Director | 2016 |
| Russell B. Kuhlman | 62 | Vice President, Sales Development | N/A |
| Michele M. Larios | 49 | Vice President, General Counsel, and Secretary | N/A |
| INDEPENDENT DIRECTORS | | | |
| Marco Laterza | 68 | Class 1 Director | 2017 |
| Amy Mack | 48 | Class 1 Director | 2017 |
| Walter O. Bigby, Jr. | 51 | Class 2 Director | 2016 |
| SIGNIFICANT EMPLOYEES | | | |
| Kathryn M. Duesman | 53 | Executive Director, Global Health | N/A |
| Lawrence G. Salerno | 55 | Director of Operations | N/A |
| Shayne Blythe | 47 | Director of Sales and Marketing Logistics | N/A |
| John W. Fort III | 47 | Director of Accounting | N/A |
| James A. Hoover | 68 | Director of Quality Assurance | N/A |
| R. John Maday | 55 | Production Manager | N/A |

| | | | |
|-------------|----|----------------------------------|-----|
| Judy Ni Zhu | 57 | Research and Development Manager | N/A |
| Patti King | 58 | Director of National Accounts | N/A |

Executives

Thomas J. Shaw, our Founder, has served as Chairman of the Board, President, Chief Executive Officer, and Director since our inception. We believe it is appropriate for Mr. Shaw to continue to serve as a Director and as the Chairman of the Board because of his deep knowledge of the strengths and weaknesses of our products (as their primary inventor) and of the Company (as its Founder). Further, his strategic knowledge of the Company and its competitive environment arising from his ongoing services as its CEO is vital to the successful supervision of the Company by the Board of Directors. Finally, Mr. Shaw's educational background in both Engineering and Accounting is helpful to Board deliberations. In addition to his duties overseeing our Management, he continues to lead our design team in product development of other medical safety devices that utilize, among other things, his

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unique patented friction ring technology. Mr. Shaw has extensive experience in industrial product design and has developed several solutions to complicated mechanical engineering challenges.

Douglas W. Cowan is a Vice President and our Chief Financial Officer, Treasurer, Principal Accounting Officer, and a Director. Mr. Cowan joined us as Chief Financial Officer and was elected to the Board of Directors in 1999. We believe it is appropriate Mr. Cowan continue to serve as a Director due to his level of involvement in the financial state of the Company (as its CFO) as well as his lead role in supervising all internal control and disclosure control procedures and statements. He also serves as the primary contact for investors which enables him to bring their concerns to the Board on appropriate topics as they arise. His expertise as a CPA and experience as the Company's CFO allow him to guide the Board, upon request, with regard to financial matters. He is responsible for our financial, accounting, investor relations, information technology, risk management, and forecasting functions.

Russell B. Kuhlman joined us in February 1997 and is our Vice President, Sales Development. Mr. Kuhlman is responsible for development of national customers and liaison with GPOs and product training for our sales organization, as well as distribution. Mr. Kuhlman's efforts with us have resulted in bringing onboard Specialty Distributors, influencing legislation, and educating influential healthcare representatives about the benefits of our product line. Mr. Kuhlman is respected throughout the industry and is a main contributor to the safety effort in this country.

Michele M. Larios joined us in February 1998 and currently serves as our Vice President, General Counsel, and Secretary. Ms. Larios is responsible for our legal and legislative, human resource, and regulatory functions. In addition to working on all legal matters, both internally and with outside counsel, Ms. Larios oversees work on any pertinent legislative issues and all relevant regulatory matters.

Independent Directors

Marco Laterza joined us as a Director effective as of March 22, 2005. We believe it is appropriate Mr. Laterza continue to serve as a Director because of his skills as a CPA as well as his decades of experience in advising individuals and entities with regard to corporate planning and financial issues. Such skills and experience provide a valuable contribution in his role as the designated financial expert on the Audit Committee as well as provide valuable independent accounting advice to the Board. Since 2015, Mr. Laterza has owned and operated an accounting practice and income tax consulting practice. From 1988 through 2014, Mr. Laterza owned and operated a public accounting practice. His practice included corporate, partnership and individual taxation, compilation/review of financial statements, financial planning, business consulting, and trusts and estates. Formerly, Mr. Laterza was employed in a number of positions from 1977 to 1985 with El Paso Natural Gas Company eventually serving as its Director of Accounting.

Amy Mack joined us as a Director on November 19, 2007. We believe it is appropriate that Ms. Mack continue as a Board member due both to her experience as a nurse (the primary retail user of our products) as well as her experience in running her own company. Since April of 2000, she has been the Secretary of EmergiStaff & Associates, a nursing agency, and she served as the Chief Nursing Officer of EmergiStaff & Associates from 2000 to 2010. From 2003 to 2010, she was the owner and Aesthetics Nurse Specialist for Spa O2 & Medical Aesthetics. Ms. Mack has served as an emergency room nurse in various emergency rooms throughout her career as a nurse. Currently, Ms. Mack is the administrator of a free-standing emergency room.

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Walter O. Bigby, Jr. has served on our Board of Directors since July 2012. We believe it is appropriate for Mr. Bigby to continue to serve as a Director due to his experience in owning and operating healthcare-related businesses. Mr. Bigby's experience includes ownership of several small businesses, including hospitals, nursing homes, commercial real estate, and office equipment providers. Mr. Bigby has owned and operated Bastrop Rehabilitation Hospital, a rehabilitation hospital in Louisiana, since 2001. He is currently a minority interest owner in a nursing home in Louisiana. In 1995, Mr. Bigby sold his home health agency to Columbia HCA and remained a contract employee of the company (Hayden Health, Inc.) for three years developing other home health markets. Mr. Bigby has over a decade of experience operating healthcare businesses heavily regulated by Federal agencies and has experience with Medicare and Medicaid.

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Significant Employees

Kathryn M. Duesman, RN, joined us in 1996 and currently serves as the Executive Director, Global Health. She provides clinical expertise on existing products as well as those in development. She has been instrumental in developing training and marketing materials and has spoken and been published on safety sharps issues. Ms. Duesman works with international agencies to promote the use of safe technologies in developing countries.

Lawrence G. Salerno has been employed with us since 1995 and has served as Director of Operations for us since 1998. He is responsible for the manufacture of all our products, as well as all product development and process development projects. In addition, he supervises all aspects of the construction and expansion of our facilities in Little Elm, Texas. Mr. Salerno is the brother of a 5% shareholder who ceased to be a 10% shareholder in 2008.

Shayne Blythe has been with us since 2001 and is our Director of Sales and Marketing Logistics. She is responsible for developing and implementing strategic directions, objectives, comprehensive sales and marketing plans, and programs. In addition, she directs and oversees all aspects of the distribution process and customer service policies in order to monitor and maintain customer satisfaction.

John W. Fort III is our Director of Accounting. Mr. Fort joined us in March of 2000 as a Financial Analyst and has served as our Director of Accounting since October of 2002. His primary responsibilities include managing the day-to-day operations of the Accounting and Finance Department and coordination of the annual audits, and interim reviews by our independent accountants, as well as our cost accounting and forecasting functions.

James A. Hoover joined us in February 1996 and is our Director of Quality Assurance. Prior to his becoming Director of Quality Assurance he was Production Manager. He is responsible for our quality assurance functions. Mr. Hoover has also developed and implemented FDA required procedures and has been involved in the FDA inspection process.

R. John Maday joined us in July 1999 and is our Production Manager. He is responsible for supervision of the production of our products. Prior to becoming Production Manager on January 1, 2005, he served as our Production General Supervisor. Mr. Maday has extensive manufacturing experience in both class II and III medical devices.

Judy Ni Zhu joined us in 1995 and is our Research and Development Manager. Her primary focus is on new product development and improvement of current products. Prior to joining us, Ms. Zhu worked as a design engineer with Mr. Shaw on the original 3mL syringe and other SBIR grant projects.

Patti S. King joined us in 2006 and is our Director of National Accounts. Ms. King is responsible for managing all activities with healthcare group purchasing organizations (GPOs), which includes national contracting negotiations and contract implementation. She has over 30 years of healthcare experience, including patient care in respiratory therapy and cardiopulmonary technology, clinical data research, clinical software development, sales, sales and operations management, and national account (group purchasing) business development. In 2005 and 2006,

Ms. King served on our Board of Directors.

FAMILY RELATIONSHIPS

There are no family relationships among the above persons except as set forth above.

DIRECTORSHIPS IN OTHER COMPANIES

No Directors hold directorships in reporting companies.

INVOLVEMENT IN CERTAIN LEGAL PROCEEDINGS

None of the above persons or any business in which such person was an executive officer have been involved in a bankruptcy petition, been subject to a criminal proceeding (excluding traffic violations and other minor

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offenses), been subject to any order enjoining or suspending their involvement in any type of business, or been party to an alleged violation of a securities law, commodities law, law or regulation respecting financial institutions or insurance companies, law or regulation prohibiting mail or wire fraud, or rules of any organization that has disciplinary authority over its members.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16 of the Exchange Act requires our Directors, executive officers, and persons who own more than 10% of a registered class of our equity securities to file with the SEC initial reports of beneficial ownership (Form 3) and reports of changes in beneficial ownership (Forms 4 and 5) of our Common Stock and our other equity securities. Officers, Directors, and greater than 10% shareholders are required by the SEC's regulations to furnish us with copies of all Section 16(a) reports they file. Based on our review of the forms submitted to us during and with respect to its most recent fiscal year, all of our Directors, executive officers, and 10% shareholders filed all reports timely.

CODE OF ETHICS

Effective as of March 9, 2004, we adopted a code of ethics that applies to all employees, including, but not limited to, our principal executive and financial officers. Our Code of Business Conduct and Ethics is designed to deter wrongdoing and to promote:

1. Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interests between personal and professional relationships;
2. Full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in our other public communications;
3. Compliance with applicable governmental laws, rules, and regulations;
4. The prompt, internal reporting of violations of the code to an appropriate person or persons identified in the code; and
5. Accountability for adherence to the code.

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A copy of the code is incorporated herein as Exhibit No. 14. We have posted a copy of the code on our website at www.vanishpoint.com/investor.htm. Please follow the link to Governance then follow the link to Charters, then click on Code of Business Conduct and Ethics. Any amendment to this code or waiver of its application to the principal executive officer, principal financial officer, principal accounting officer, or controller or similar person shall be disclosed to investors by means of a Form 8-K filing with the SEC. We will provide to any person without charge, upon request, a copy of such code of ethics. Such requests should be submitted in writing to Mr. Douglas W. Cowan at 511 Lobo Lane, P.O. Box 9, Little Elm, Texas 75068-0009.

AUDIT COMMITTEE

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act consisting of Marco Laterza and Walter O. Bigby, Jr. Each of the members of the Audit Committee is independent as determined by the NYSE MKT rules. Since February 2, 2015, the Company has relied on a provision of Section 801(h) allowing the Audit Committee to consist of only two members. Section 801(h) is applicable to the Company because it is a Smaller Reporting Company.

Audit Committee Financial Expert

The Board of Directors has determined that we have at least one financial expert serving on the Audit Committee. Mr. Marco Laterza serves as our designated Audit Committee Financial Expert. Mr. Laterza is independent as defined for Audit Committee members by the listing standards of the NYSE MKT.

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Item 11. Executive Compensation.

COMPENSATION DISCUSSION AND ANALYSIS

The Objectives of Our Compensation Plan

Our executive officer compensation program (the Compensation Program) is based on the belief that competitive compensation is essential to attract, retain, motivate, and reward highly qualified and industrious executive officers. Our Compensation Program is intended to accomplish the following:

attract and retain highly talented and productive executive officers;

provide incentives and rewards for superior performance by the executive officers; and

align the interests of executive officers with the interests of our stockholders.

What the Compensation Program Is Designed to Award

Our Compensation Program is designed to award both superior long-term performance by our executive officers and their loyalty.

Summary of Each Element of Compensation

To achieve these objectives, the Compensation and Benefits Committee has approved an executive officer compensation program that consists of four basic components:

base salary;

short-term incentive compensation in the form of cash bonuses;

periodic long-term incentive compensation in the form of stock options; and

medical, life, and benefit programs (which are generally available to all employees).

Why We Choose to Pay Each Element of Our Compensation Program

Base Salary

We choose to pay a significant component of our compensation in base salary due to the fact that our financial performance is constrained by the anticompetitive activities of BD. Until such time as we believe that we have access to the market, we believe that it is appropriate to weigh our Compensation Program heavily in favor of base salaries rather than incentive compensation.

Cash Bonuses

From time to time and when our cash reserves allow, we grant cash bonuses in order to reward significant efforts or the accomplishment of short term goals. The Compensation and Benefits Committee last granted such bonuses in 2010. Prior to 2010, the last bonuses were granted in 2003.

Long-Term Incentives: Stock Options

Long-term incentives are provided through grants of stock options. The grants are designed to align the interests of executive officers with those of stockholders and to provide each executive officer with a significant incentive to manage from the perspective of an owner with an equity stake in the Company.

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How We Determine the Amount or Formula for Payment in Light of Our Objectives

Executive compensation remains the same until there is a review of such compensation by the Compensation and Benefits Committee. Compensation, other than that of the Chief Executive Officer, has generally not been reviewed annually. Under the terms of Mr. Shaw's employment agreement, his compensation is reviewed annually.

Base Salary

The base salary for each of our executive officers is subjectively determined primarily on the basis of the following factors: experience, individual performance, contribution to our performance, level of responsibility, duties and functions, salary levels in effect for comparable positions within and without our industry, and internal base salary comparability considerations. However, salaries can also be affected by our long-term needs.

These base salaries are reviewed periodically and may be adjusted based upon the factors discussed in the previous paragraph, as well as upon individual performance during the previous fiscal year, changes in the duties, responsibilities and functions of the executive officer, and general changes in the compensation peer group in which we compete for executive talent. The relative weight given to each of these factors in the Compensation and Benefits Committee's recommendation differs from individual to individual, as the Compensation and Benefits Committee deems appropriate.

Executive officer salaries were cut by 10% in 2009, then restored in 2013. Another 10% reduction occurred in July 2014, but the salaries were generally restored in January 2015. Executive officers were generally given a one-time payment in December 2014 to offset the 2014 reductions. However, Steven R. Wisner's salary was reduced in 2014 by 25% and was not restored and he did not receive an offsetting payment. Mr. Wisner resigned on May 29, 2015 and was granted a one-time payment in connection therewith.

Mr. Shaw's Employment Agreement provides that his salary is automatically increased by the percentage increase in the consumer price index (CPI) from the previous year. The Compensation and Benefits Committee decided to increase Mr. Shaw's salary by the CPI percentage increase (\$3,266 or 0.7%) over his 2015 salary for 2016.

Cash Bonuses

The bonuses, when paid, are paid on a discretionary basis as determined by the Compensation and Benefits Committee. Factors considered by the Compensation and Benefits Committee include personal performance, level of responsibility, and the factors used in determination of base salary as stated above, except with a greater focus on the prior fiscal year. The Compensation and Benefits Committee also considers our need to retain cash in deciding whether to grant cash bonuses.

Long-Term Incentive: Stock Options

We have issued stock options to our employees from time to time and may do so in the future. Options are generally granted to regular full-time employees and officers. Additionally, options are sometimes granted to non-employee Directors and independent contractors.

If stock options are to be issued, Management prepares a proposal to the Compensation and Benefits Committee. Considerations by Management in its initial proposal in determining a suitable aggregate fair market value of options to be granted include our financial condition, the number of options already outstanding, and the benefit to the non-officer employees. The proposal includes information relating to the expected expense of such grants to be recognized by us, the approximate number of options to be issued, the number of options currently outstanding, the employees to be included, the amount of stock currently outstanding, and the method under which the options would be awarded.

Once the dollar amount of options to be granted is approved by the Compensation and Benefits Committee, Management begins determining the aggregate number of shares underlying options that can be granted under such

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approval (based on the fair value of an option for the purchase of one underlying share). Factors included in the determination of the value of an option grant for the purchase of one share include current market price of the Company's stock, the proposed exercise price, the proposed expiration date, the volatility of the Company's stock, and the risk free rate. We may retain an independent outside consultant to determine such value. In the past we have utilized the Black-Scholes model as well as the binomial model, but we may use other methods in the future as more appropriate methods are developed.

Management provides the Compensation and Benefits Committee with a proposal regarding option grants to executive officers. If the recommendation is acceptable, the committee grants the options. If the committee feels changes are merited, it grants options on its own terms.

With regard to many past grants, after the aggregate number of shares underlying the options to be granted was determined, we allocated the options to our various departments using a factor based on their annual compensation times their performance rating. The individual employee's allocation factor was the numerator of a fraction. The denominator was the department's sum of all factors (annual compensation times performance ratings of all the eligible employees). The resulting fraction was multiplied by the stock options to be awarded to determine the employee's individual portion of the aggregate approved options. Future grants may be based on the value of contributions to the Company and not necessarily pursuant to any formula.

The allocation may be further reviewed by each department's management if they believed certain employees were not awarded an appropriate number of options. Management would consider any suggestions.

Each stock option grant to employees allows the employee to acquire shares of Common Stock at a fixed price per share (never less than the closing stock price of the Common Stock on the date of grant) for a fixed period (usually ten years). With regard to grants prior to 2009, each option generally became exercisable after three years, contingent upon the employee's continued employment with us. However, options issued to Officers and Directors pursuant to the 2008 option exchange offer vested immediately for non-employee Directors and after one year for employees (including employee Directors). Options granted in 2009 and later vested in one year for executive officers and immediately for non-employee Directors. Accordingly, generally stock option grants will provide a return to the employee only if the employee remains employed by us during the vesting period, and then only if the market price of the underlying Common Stock appreciates. Future grants may vest over a shorter or longer period.

How Each Compensation Element and Decision Fits Into Overall Compensation Objectives

Our Compensation Program is intended to accomplish the following objectives: 1) attract and retain highly talented and productive executive officers; 2) provide incentives and rewards for superior performance by the executive officers; and 3) align the interests of executive officers with the interests of our stockholders.

We pay the bulk of our compensation in the form of cash compensation due to the fact that competing in an anticompetitive environment means that results will not always be commensurate with performance. We believe that the performance of our executives has been outstanding. We believe this is especially true given the anticompetitive environment in which we operate. Bonuses are granted occasionally to recognize extraordinary performance and/or extraordinary job requirements. We believe this approach and weighting of compensation elements is necessary to retain our executive talent due to the environment in which we operate.

Periodically, we grant stock options with the intent to provide both an incentive and reward to executive officers for long-term performance and to align the interests of our employees with that of the shareholders.

Shareholder Advisory Votes

At our 2013 annual meeting of shareholders, we provided our shareholders with the opportunity to cast an advisory vote on the compensation paid to our named executive officers (say-on-pay). An overwhelming majority of the votes cast on the say-on-pay proposal were voted in favor of the proposal. We believe that this is an overall endorsement by the shareholders of our past approach to executive compensation. See Base Salary above for a discussion of recent changes to named executive officer salaries. The Compensation and Benefits Committee will continue to take into account the outcome of future say-on-pay votes when making compensation decisions for the

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named executive officers in the future. We intend to hold the next say-on-pay vote at our 2016 annual meeting of shareholders.

Allocation Between Long-Term/Current and Between Cash/Non-Cash Compensation

All of our long-term compensation consists of non-cash compensation in the form of stock options. We believe that the granting of stock options incentivizes executives to maximize our long-term strengths as well as our stock price. However, because we are operating in an anticompetitive environment and our stock price has little relationship with our performance, the most significant component of compensation is base salary and not stock options. Management is incentivized to maximize shareholder value and will be rewarded if they do so.

How Determinations Are Made as to When Awards Are Granted

Generally, option awards to executive officers are granted by the Compensation and Benefits Committee and for others are granted at the discretion of the Board after recommendation of the Compensation and Benefits Committee or on the committee's own initiative. No awards are granted if the Compensation and Benefits Committee does not support a recommendation.

Unfortunately, our stock price does not always react as expected to our achievements. Accordingly, at times, options have been granted to aid in retaining competent and experienced executives without regard to the then current stock price. However, such options always have exercise prices that are at or above fair market value on the date of grant.

In addition, there is no relationship between the date of grant of options and our possession of material non-public information (i.e., we grant options without regard to whether or not we are in possession of material non-public information). Furthermore, it is our policy with regard to options that (although the options could be exercised) the underlying shares could not be sold into the market while the executive was in possession of material non-public information. Accordingly, we believe that there is minimal risk of the executive profiting from such material nonpublic information.

What Specific Items of Corporate Performance Are Taken Into Account in Setting Compensation Policies and Making Compensation Decisions

Cash reserves as well as trends in sales and costs are taken into account when considering the advisability of increasing base salaries or granting cash bonuses. However, no specific items of corporate performance are taken into account in setting executive compensation due to the fact that we compete in an anticompetitive environment and, therefore, significant achievement or performance is not always correlated with corporate results. At such times that any of these factors make it inadvisable to increase salaries or grant bonuses, then consideration is given to increasing option awards taking into account the value of prior option awards.

Awards are granted on the basis of historical performance. Accordingly, there is no discretion to change the awards once granted.

How Compensation Reflects Individual Performance

Executive compensation is not based on the individual's contribution to specific, quantitative corporate objectives due to the fact that we compete in an anticompetitive environment. However, the individual's contribution to our performance is determined pursuant to qualitative factors as discussed above under **How We Determine the Amount or Formula for Payment in Light of Our Objectives**.

Factors We Consider in Determining to Change Compensation Materially

We consider our cash position, current liquidity trends, and the short-term and long-term needs for cash reserves when evaluating whether we can change compensation materially at a given time.

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On an individual-by-individual basis, we also consider the value of past option compensation, the competitiveness of that individual's base salary, and that individual's contribution to our goals.

The Impact of the Accounting and Tax Treatments of Our Types of Compensation

Stock options granted to executives and other employees are expensed for accounting purposes under the Stock Compensation Topic of the Financial Accounting Standards Board Accounting Standards Codification. We expense all of our option costs as we do the costs of salaries and any periodic bonuses. Accordingly, the impact of tax treatment of various compensation forms does not impact our compensation decisions. Stock option expense is not recognized for tax purposes, except in the case of non-qualified stock options. For non-qualified stock options, the intrinsic value of the option is recognized when the option is exercised.

Our Policy Regarding Stock Ownership and Hedging

We do not have a policy regarding stock ownership by executive officers. We prohibit certain stock transactions by employees and Directors, including:

1. Purchases and sales of our stock within a six month period;
2. Short sales of our stock; and
3. Transactions in puts, calls, or other derivative securities involving our stock.

Furthermore, employees and Directors are required to pre-clear any hedging transactions.

Benchmarking of Our Compensation Program

In 2003, we hired Trinity Executive Recruiters, Inc. to assist us in providing benchmarks for the salary component of executive compensation by similarly sized companies in similar industries for persons that hold positions which are currently fulfilled by various members of our executive team. These benchmarks at least support existing executive compensation.

The Role of Our Executives and Directors in Determining Compensation

Management establishes the initial recommendations regarding compensation for all employees, including themselves. The Compensation and Benefits Committee reviews executive compensation changes.

Compensation Pursuant to Employment Agreement

We have an Employment Agreement with Mr. Thomas J. Shaw (the Employment Agreement) which was modified effective January 1, 2008 to avoid adverse tax consequences to Mr. Shaw created by the passage of the American Jobs Creation Act of 2004. No other executives or Directors are compensated pursuant to employment agreements.

The Employment Agreement provides for an initial period of three years which ended December 31, 2010 and automatically and continuously renews for consecutive two-year periods. The Employment Agreement is terminable either by us or Mr. Shaw upon 30 days written notice or upon Mr. Shaw's death.

The Employment Agreement provides for an annual salary of at least \$416,400 with an annual salary increase equal to no less than the percentage increase in the CPI over the prior year. The Employment Agreement requires that Mr. Shaw's salary be reviewed by the Compensation and Benefits Committee annually, which shall make such increases as it considers appropriate. Accordingly, the Compensation and Benefits Committee increased his 2016 salary by \$3,266 (0.7%) over his 2015 salary in accordance with the percentage increase in the CPI over the prior year.

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Under the Employment Agreement, we are obligated to provide certain benefits, including, but not limited to, participation in qualified pension plan and profit-sharing plans, participation in the Company's Cafeteria Plan and other such insurance benefits provided to other executives, paid vacation, and sick leave. We are also obligated to furnish him with a cellular telephone and suitable office space as well as reimburse him for any reasonable and necessary out of pocket travel and entertainment expenses incurred by him in carrying out his duties and responsibilities, membership dues to professional organizations, and any business-related seminars and conferences.

Pursuant to the Employment Agreement, we are obligated to indemnify Mr. Shaw for all legal expenses, court costs, and all liabilities incurred in connection with any proceeding involving him by reason of his being an officer, employee, or agent of the Company. We are further obligated to pay reasonable attorney fees and expenses and court and other costs associated with his defense in the event that, in Mr. Shaw's sole judgment, he needs to retain counsel or otherwise expend his personal funds for his defense.

Upon his death, Mr. Shaw's estate shall be entitled to his salary through the date of death, applicable benefits, and reimbursement of expenses.

We have the right to terminate the Employment Agreement if Mr. Shaw incurs a permanent disability during the term of his employment. A permanent disability means that Mr. Shaw is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months or is, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, receiving income replacement benefits for a period of not less than 3 months under an accident and health plan covering employees of the Company. Mr. Shaw shall also be deemed to be disabled if he is determined to be totally disabled by the Social Security Administration. In such event, Mr. Shaw is entitled to his salary through the date of termination, reimbursement of expenses, and salary for a period of 24 months as well as applicable benefits.

Mr. Shaw's employment may be terminated for cause which is defined to be conviction of a felony which is materially detrimental to the Company, proof, as determined finally by a court of competent jurisdiction of the gross negligence or willful misconduct which is materially detrimental to the Company, or proof, as determined finally by a court of competent jurisdiction, of a breach of a fiduciary duty which is materially detrimental to the Company. In such event, he shall be entitled to his salary through the date of termination plus reimbursement of expenses.

If Mr. Shaw is terminated without cause and not at his implicit request, Mr. Shaw shall be entitled to his salary through the date of termination, reimbursement of expenses, his salary for 24 months, as well as applicable benefits.

If Mr. Shaw resigns (other than because of a change in control), he is entitled to his salary through the date of termination, reimbursement of expenses, salary for 90 days, and applicable benefits.

Mr. Shaw has the right under this agreement to resign in the event that there is a change in control. A Change of Control shall be deemed to have occurred on either of the following dates: (i) the date any one person (other than Mr. Shaw), or more than one person acting as a group, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) ownership of stock of the Company possessing 30% or more of the total possible voting power of the stock of the Company (assuming the immediate conversion of all then outstanding convertible preferred stock) or (ii) the date a majority of members of the Board of Directors is replaced during

any 12-month period by Directors whose appointment or election is not endorsed by a majority of the members of the Company's Board of Directors before the date of the appointment or election. Mr. Shaw further has the right to resign if there is a change in ownership. A change in ownership is defined to have occurred on the date that any one person (other than Mr. Shaw) or more than one person acting as a group acquires ownership of the Company's stock that, together with the stock previously held by such person or group, constitutes more than 50% of the total fair market value or total voting power (assuming the immediate conversion of all then outstanding convertible preferred stock) of the Company. In such event Mr. Shaw is entitled to salary through the date of termination, salary for 24 months, reimbursement of expenses, and applicable benefits.

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Mr. Shaw's commitment to the Company may not be construed as preventing him from participating in other businesses or from investing his personal assets as may require occasional or incidental time in the management, conservation, and protection of such investments provided such investments or businesses cannot be construed as being competitive or in conflict with the business of the Company.

Mr. Shaw has agreed to a one-year non-compete, not to hire or attempt to hire employees for one year, and not make known our customers or accounts or to call on or solicit our accounts or customers in the event of termination of his employment for one year unless the termination is without cause or pursuant to a change of control or ownership.

Compensation Committee Report

The Compensation and Benefits Committee has reviewed and discussed the COMPENSATION DISCUSSION AND ANALYSIS required by Item 402(b) of Regulation S-K with Management, and, based on the review and discussions referred to in paragraph (e)(5)(i)(A) of Item 407 of Regulation S-K, has recommended to the Board of Directors that the COMPENSATION DISCUSSION AND ANALYSIS be included in this report on Form 10-K.

WALTER O. BIGBY, JR.
AMY MACK
MARCO LATERZA

The following Summary Compensation Table sets forth the total compensation paid or accrued by us over the past three fiscal years to or for the account of the principal executive officer, the principal financial officer, and the three highest paid additional executive officers:

SUMMARY COMPENSATION TABLE FOR 2013-2015

| Name and Principal Position | Year | Salary (\$) | All Other Compensation (\$) | Total (\$) |
|---|-------------|------------------------|--|-----------------------|
| Thomas J. Shaw President and CEO (principal executive officer) | 2013 | 420,280 | | 420,280 |
| | 2014 | 464,454 ⁽¹⁾ | | 464,454 |
| | 2015 | 484,506 | | 484,506 |
| Michele M. Larios Vice President, General Counsel | 2013 | 320,683 | | 320,683 |
| | 2014 | 351,346 ⁽¹⁾ | | 351,346 |
| | 2015 | 363,462 | | 363,462 |
| Douglas W. Cowan Vice President, CFO (principal financial officer, principal accounting officer) | 2013 | 265,462 | | 265,462 |
| | 2014 | 291,115 ⁽¹⁾ | | 291,115 |
| | 2015 | 301,154 | | 301,154 |
| Russell B. Kuhlman | 2013 | 143,429 | | 143,429 |

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| | | | | |
|-----------------------------------|------|------------|------------|---------|
| Vice President, Sales Development | 2014 | 146,117(1) | 112,600(2) | 258,717 |
| | 2015 | 151,351 | | 151,351 |
| Steven R. Wisner(3) | 2013 | 265,462 | | 265,462 |
| Former Executive Vice President, | 2014 | 248,173 | | 248,173 |
| Engineering and Production | 2015 | 129,373 | 150,000(4) | 279,373 |

(1) The following amounts included in the Salary column for 2014 represent nonrecurring payments made to offset salary reductions: for Thomas J. Shaw, \$23,143; for Michele M. Larios, \$17,500; for Douglas W. Cowan, \$14,500; and for Russell B. Kuhlman, \$7,069.

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(2) This amount is the result of Mr. Kuhlman's gain on exercising a portion of his stock option for 45,000 shares of Common Stock. This gain had no effect on our financial statements. The expense related to the stock options was recognized in previous years.

(3) Mr. Wisner resigned on May 29, 2015 and was granted a one-time payment in connection therewith. Mr. Wisner qualifies as a named executive officer only by virtue of Item 402(a)(3)(iv) of Regulation S-K.

(4) This amount represents a one-time payment in connection with Mr. Wisner's resignation.

Narrative Disclosure to Summary Compensation Table

Please see **Compensation Pursuant to Employment Agreement** above and POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL below for terms of our only employment agreement in effect.

Salary represents 100% of total compensation for 2015 for all Named Executive Officers except Mr. Wisner. Mr. Wisner's salary was 46% of his total compensation for 2015.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following Outstanding Equity Awards at Fiscal Year-End Table sets forth information regarding unexercised options held by the principal executive officer, the principal financial officer, and the three highest paid additional executive officers as of December 31, 2015.

OUTSTANDING EQUITY AWARDS AT 2015 FISCAL YEAR END

| Name | Number of Securities Underlying Unexercised Options Exercisable | Option Awards | |
|---|---|----------------------------|------------------------|
| | | Option Exercise Price (\$) | Option Expiration Date |
| Thomas J. Shaw President, CEO (principal executive officer) | 1,000,000 | 0.81 | 7-15-19 |

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| | | | |
|---|-------------------|--------------|---------------------|
| Michele M. Larios Vice President, General Counsel | 97,050 152,950 | 1.30 0.81 | 11-18-18 7-15-19 |
| Douglas W. Cowan Vice President, CFO (principal financial officer, principal accounting officer) | 102,000 98,000 | 1.30 0.81 | 11-18-18 7-15-19 |
| Russell B. Kuhlman Vice President, Sales Development | 43,450 | 1.30 | 11-18-18 |
| Steven R. Wisner Former Executive Vice President, Engineering and Production | 9,791 | 1.30 | 11-18-18 |

OPTION EXERCISES

The following table sets forth information concerning the exercise of stock options during the last completed fiscal year for each of the named executive officers.

Table of Contents**OPTION EXERCISES FOR 2015**

| Name | Option awards | |
|--|---------------------------------------|----------------------------|
| | Number of shares acquired on exercise | Value realized on exercise |
| Steven R. Wisner | 23,500 | \$ 74,965 |
| Former Executive Vice President, Engineering and Production | 90,909 | \$ 232,727 |

Mr. Wisner exercised a stock option for the purchase of 23,500 shares with an exercise price of \$0.81 per shares on June 1, 2015, a date on which the Company's stock price closed at \$4.00 per share. Mr. Wisner exercised a stock option for the purchase of 90,909 shares with an exercise price of \$1.30 per shares on June 16, 2015, a date on which the Company's stock price closed at \$3.86 per share.

PENSION BENEFITS

We do not have a pension plan other than the 401(k) plan which is available to all employees on the first day of the month after 90 days of service.

401(k) Plan

We implemented an employee savings and retirement plan (the 401(k) Plan) in 2005 that is intended to be a tax-qualified plan covering substantially all employees. Under the terms of the 401(k) Plan, employees may elect to contribute up to 88% of their compensation, or the statutory prescribed limit, if less. We may, at our discretion, match employee contributions. We suspended matching contributions beginning August 1, 2009 until further notice.

POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL

Steven R. Wisner was granted a one-time payment of \$150,000 in connection with his resignation. This payment was negotiated contemporaneously with his resignation. Other than the information set forth below for Mr. Shaw, no other Named Executive Officer has a contract in place for termination or change in control payments.

The following table identifies the types and amounts of payments that shall be made to Thomas J. Shaw, our CEO, in the event of a termination of his employment or a change in control per his Employment Agreement. Such payments shall be made by us and shall be one-time, lump sum payments except as indicated below. In 2015, no other contract existed for payments upon termination or change in control.

SUMMARY OF PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL

ASSUMING OCCURRENCE AS OF DECEMBER 31, 2015(1)

| Payment Triggering Event | Salary Through Trigger Event Date(2) | Amounts Owed Under Benefit Plans(3) | Reimbursement of Expenses | Undiscounted Salary For a Period of 24 Months | Payment Equal to 90 Days Salary | Value of Payments(4) |
|--|---|--|----------------------------------|--|--|-----------------------------|
| Death | x | x | x | | | |
| Disability | x | x | x | 933,122 | | 933,122 |
| Termination With Cause | x | | x | | | |
| Termination Without Cause | x | x | x | 933,122 | | 933,122 |
| Resignation (Other Than After a Change in Control) | x | x | x | | 116,640 | 116,640 |
| Resignation (After a Change in Control) | x | x | x | 933,122 | | 933,122 |

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(1) The above payments would be paid under Mr. Shaw's agreement at certain times. Any payments arising as a result of disability or resignation would be paid not sooner than six months and one day from the termination date but not later than seven months from the termination date. Any payments arising as a result of death would be paid no later than the 90th day following the death. Payments arising as a result of termination with cause or termination without cause would be paid not later than the 30th day following the date of termination, except that any amount due in excess of an amount equal to the lesser of: i) two times annual compensation or ii) two times the limit on compensation under section 401(17) of the Internal Revenue Code of 1986 shall be paid no earlier than six months and one day after the date of termination but in no event later than seven months after the date of termination. Under Mr. Shaw's agreement, Mr. Shaw has agreed to a one-year non-compete, not to hire or attempt to hire employees for one year, and not make known our customers or accounts or to call on or solicit our accounts or customers in the event of termination of his employment for one year unless the termination is without cause or pursuant to a change of control. However, it is not clear that the above payments are conditioned on the performance of these contractual obligations.

(2) Mr. Shaw is paid every two weeks. Therefore, the maximum value for this column in the event the triggering event took place immediately prior to a scheduled payment date is two weeks' salary (\$17,945).

(3) Mr. Shaw participates in our benefit plans which do not discriminate in scope, terms, or operation in favor of executive officers. Such plans are generally available to all salaried employees. Accordingly, the value of such payments is not included in the "Value of Payments" column.

(4) This value does not include payments under our benefit plans for reasons set forth in footnote 3 above. In addition, this value assumes that the triggering event occurred on December 31, 2015. Authorized payments under the Employment Agreement are also capped to one dollar less than the amount that would cause Mr. Shaw to be the recipient of a parachute payment under Section 280G(b) of the Internal Revenue Code.

COMPENSATION OF DIRECTORS

The following table identifies the types and amounts of compensation earned by our current and former Directors (with the exception of those that are named Executive Officers as described in footnote 1 to the table) in the last Fiscal Year:

DIRECTOR COMPENSATION TABLE FOR 2015

Name(1)

| | Fees Earned or Paid in Cash (\$) | Total (\$) |
|-----------------------------------|---|-----------------------|
| Marco Laterza | \$ 2,500 | \$ 2,500 |
| Amy Mack | \$ 2,500 | \$ 2,500 |
| Clarence Zierhut, former Director | \$ | \$ |
| Walter O. Bigby, Jr. | \$ 2,500 | \$ 2,500 |

(1) Thomas J. Shaw, Douglas W. Cowan, and Steven Wisner are Named Executive Officers who were also Directors in 2015. Their compensation is reflected in the Summary Compensation and other tables presented earlier.

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Narrative Explanation of Director Compensation Table for 2015

In 2015, we paid each non-employee Director a fee of \$500 per meeting and reimbursed travel expenses, if airfare, hotel, and other reasonable travel-related expenses were incurred to attend Board meetings. We do not pay any additional amounts for committee participation or special assignment.

Generally, employee Directors are compensated on an at-will basis as discussed in the COMPENSATION DISCUSSION AND ANALYSIS. However, one employee, Mr. Thomas J. Shaw, our President and CEO, is compensated pursuant to an employment agreement. Please see Compensation Pursuant to Employment Agreement , set forth above for an in depth summary of the terms of such agreement.

Compensation Committee Interlocks and Insider Participation

The Compensation and Benefits Committee is currently composed of Walter O. Bigby, Jr., Amy Mack, and Marco Laterza. Each of these members of this committee is an independent Board member and none have ever been employees of the Company. Clarence Zierhut served on the Compensation and Benefits Committee until his resignation on February 2, 2015.

There are no interlocking Directors or executive officers between us and any other company. Accordingly, none of our executive officers or Directors served as a Director or executive officer for another entity whose executive officers or Directors served on our Board of Directors.

COMPENSATION POLICIES AND PRACTICES AS THEY RELATE TO RISK MANAGEMENT

We do not believe that risk-taking incentives are created by our compensation policies. We do not have business units. We believe that our compensation expense is a reasonable percentage of revenues overall. We have not set specific performance criteria for the award of bonuses. Salaries and bonuses, if any, are awarded based on skill, experience, and our overall revenues. Non-cash awards to employees are made periodically in the form of stock options, which we believe align the employees' interests with those of stockholders. We review our compensation policies and practices as they relate to risk management objectives if compensation amounts are materially amended or if our risk profile changes. No changes to our compensation policies and practices have been implemented as a result of changes to our risk profile.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

EQUITY COMPENSATION PLAN INFORMATION

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The following table sets forth information relating to our equity compensation plans as of December 31, 2015:

Equity Compensation Plan Information

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c) |
|--|--|--|---|
| Equity compensation plans approved by security holders | 1,182,569 | \$ 1.04 | 3,100,892 |
| Total | 1,182,569 | \$ 1.04 | 3,100,892 |

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The Compensation and Benefits Committee authorized (and the shareholders approved) a grant of an option for the purchase of 3,000,000 shares of Common Stock to our CEO, Thomas J. Shaw, of which 1,000,000 remains exercisable. The option is exercisable at a price of \$0.81 per share, the market price on the date of grant. The option will terminate in 2019.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The following table sets forth certain information regarding the beneficial ownership as of March 1, 2016, for each person known by us to own beneficially 5% or more of our Common Stock. Except pursuant to applicable community property laws, each shareholder identified in the table possesses sole voting and investment power with respect to his or her shares, except as noted below.

| Title of Class | Name and Address of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percent of Class (1) |
|-----------------------|--|--|-----------------------------|
| Common Stock | | | |
| | Thomas J. Shaw(2) 511 Lobo Lane Little Elm, TX 75068 | 14,655,642 | 49.5% |
| | Suzanne M. August(3) 340 North Julia Circle St. Pete Beach, FL 33706 | 3,800,000 | 13.3% |
| | Lillian E. Salerno(4) 777 7th Avenue 430 Washington DC 20001 | 1,746,000 | 6.1% |
| | Lloyd I. Miller, III(5) 222 Lakeview Avenue Suite 160-365 West Palm Beach, FL 33401 | 2,355,824 | 8.2% |

(1) The Percent of Class is calculated for the Common Stock class by dividing each beneficial owner's Amount of Beneficial Ownership, as shown in the table above, by the sum of the total outstanding Common Stock (28,619,874 shares) plus that beneficial owner's stock equivalents (options), if any.

(2) 1,000,000 of the shares identified as Common Stock are shares acquirable through the exercise of a stock option. 2,800,000 of the shares are owned by the August 2010 Family Trust (see footnote 3) but are controlled by Mr. Shaw pursuant to a Voting Agreement. These shares are permanently controlled by Mr. Shaw until such time as they are sold by the August 2010 Family Trust. These shares are included in the share amounts and percentages for both Mr. Shaw and Ms. August in the above table. Mr. Shaw has investment power over 1,000,000 shares of Common Stock as Trustee pursuant to trust agreements for the benefit of family members. Ms. August has voting control over such 1,000,000 shares as Special Trustee (see footnote 3). These shares are included in the share amounts and percentages for both Mr. Shaw and Ms. August in the above table.

(3) 2,800,000 shares of these shares are controlled by Mr. Thomas J. Shaw pursuant to a Voting Agreement and are held by the August 2010 Family Trust, for which Ms. August serves as Trustee. These shares are included in the share amounts and percentages for both Mr. Shaw and Ms. August in the above table. Ms. August has voting control over 1,000,000 shares of Common Stock as Special Trustee pursuant to trust agreements for the benefit of family members. Mr. Shaw has investment power over such 1,000,000 shares as Trustee. These shares are included in the share amounts and percentages for both Mr. Shaw and Ms. August in the above table.

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(4) 25,000 shares identified as Common Stock are shares which are obtainable by the exercise of a stock option. 500,000 shares identified as Common Stock are owned by a trust for which Ms. Salerno serves as trustee.

(5) The number of shares held by this person was obtained from a Schedule 13G filed on February 3, 2016. Pursuant to the Schedule 13G, Lloyd I. Miller, III has sole voting and dispositive power for 2,335,624 of the shares and shared voting and dispositive power for 20,200 of the shares.

SECURITY OWNERSHIP OF MANAGEMENT AND DIRECTORS

The following table sets forth certain information regarding the beneficial ownership of our Common Stock as of March 1, 2016, for each Named Executive Officer specified by Item 402 of Regulation S-K (i.e., our CEO, CFO, and three other highest paid executive officers) and each Director of the Company. Except pursuant to applicable community property laws or as otherwise discussed below, each shareholder identified in the table possesses sole voting and investment power with respect to his or her shares.

| Title of Class | Name of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percent of Class(1) |
|----------------|--|---|---------------------|
| Common Stock | | | |
| As a Group | Named Executive Officers and Directors | 15,364,920 | 51.9% |
| As Individuals | Thomas J. Shaw(2) | 14,655,642 | 49.5% |
| | Michele M. Larios(3) | 261,000 | <1% |
| | Douglas W. Cowan(4) | 200,000 | <1% |
| | Russell B. Kuhlman(5) | 89,450 | <1% |
| | Marco Laterza(6) | 60,000 | <1% |
| | Walter O. Bigby, Jr.(7) | 55,000 | <1% |
| | Amy Mack(8) | 43,828 | <1% |

(1) The Percent of Class is calculated for the individuals holding Common Stock by dividing each beneficial owner's Amount of Beneficial Ownership, as shown in the table above, by the sum of the total outstanding Common Stock (28,619,874 shares) plus that beneficial owner's stock equivalents (options), if any. The Percent of Class is calculated for the As a Group row by totaling all of the Percent of Class percentages appearing in the chart.

(2) 1,000,000 of these shares are acquirable through the exercise of a stock option. 2,800,000 of the shares are owned by the August 2010 Family Trust but are controlled by Mr. Shaw pursuant to a Voting Agreement. These shares are permanently controlled by Mr. Shaw until such time as they are sold by the August 2010 Family Trust. These shares are included in calculating Mr. Shaw's percentages in the above table. Mr. Shaw has investment power over 1,000,000 shares of Common Stock as Trustee pursuant to trust agreements for the benefit of family

members. These shares are included in calculating Mr. Shaw's percentages in the above table.

(3) 250,000 of these shares are acquirable by the exercise of stock options. 1,000 of these shares are owned by Ms. Larios' children.

(4) These shares are acquirable by the exercise of stock options.

(5) 43,450 of these shares are acquirable by the exercise of stock options.

(6) 35,000 of these shares are acquirable by the exercise of stock options.

(7) 50,000 of these shares are acquirable by the exercise of stock options.

(8) These shares are acquirable by the exercise of stock options.

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There are no arrangements, the operation of which would result in a change in control of the Company, other than:

1. Ms. August's shares (and those owned by the August 2010 Family Trust) shall cease to be controlled by Mr. Shaw under their Voting Agreement upon their sale to a third party; and

2. Mr. Shaw is able to control 49.5% of the currently outstanding shares of the Common Stock and would control 46.4% of the Common Stock assuming the exercise of all outstanding options and conversion of all outstanding preferred shares.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Party Transactions

We believe that all of the transactions set forth below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties. In accordance with our Audit Committee Charter, the Audit Committee has reviewed and approved all related party transactions. In particular, the Audit Committee reviews all proposed transactions where the amount involved meets or exceeds \$120,000.

A royalty of 5% of gross sales of all licensed products sold to customers over the life of the Technology Licensing Agreement is paid (See Item 1 - Patents, Trademarks, Licenses, and Proprietary Rights). Of this royalty, Ms. Suzanne August, the former spouse of Mr. Shaw, was entitled to \$100,000 per quarter until May 11, 2015 when such royalty payments ceased being paid to Ms. August. A royalty of \$2,388,817 and \$2,143,477 was paid to Thomas J. Shaw in 2015 and 2014, respectively. Ms. August received \$245,055 in 2015 and \$400,000 in 2014.

Director Independence

The Board of Directors has the responsibility for establishing corporate policies and for our overall performance, although it is not involved in day-to-day operations. Currently, a majority of the Directors serving on our Board of Directors are independent Directors as defined in the listing standards of the NYSE MKT. For the period between February 2, 2015 and May 29, 2015, the Company elected to use the exception in Section 801(h) of the NYSE MKT Company Guide allowing 50% of the Directors (rather than a majority) to be independent. Our current independent Directors are Marco Laterza, Amy Mack, and Walter O. Bigby, Jr. Each of our committees is constituted solely by independent Directors.

Item 14. Principal Accounting Fees and Services.

AUDIT FEES

The aggregate fees billed by CF & Co., L.L.P. for professional services rendered for the audit of our annual financial statements for 2015 and 2014 and the reviews of the financial statements included in our Forms 10-Q or services normally provided by the accountant in connection with statutory and regulatory filings for those fiscal years were \$189,000 in each year.

AUDIT RELATED FEES

The aggregate fees billed by CF & Co., L.L.P. for professional services rendered for the audit of our 401(k) plan for 2015 and 2014 were \$13,000 in each year. Audit-related fees for Form S-8 were \$1,800 in 2015.

TAX FEES

The aggregate fees billed by CF & Co., L.L.P. for preparation of federal and state income tax returns and tax consulting costs related to notices from taxing authorities for 2015 and 2014 were \$102,429 and \$209,429, respectively. 2015 and 2014 fees also include consultation on state sales tax matters and preparation of certain sales tax returns.

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PRE-APPROVAL POLICIES AND PROCEDURES

The engagement of CF & Co., L.L.P. was entered into pursuant to the approval policies and procedures of the Audit Committee. Before CF & Co., L.L.P. was engaged to render services the engagement was approved by the Audit Committee. The engagement is for audit and tax services which were detailed separately. The Audit Committee implemented its approval procedures, i.e., they were not delegated to any other party. All of the services provided were pre-approved by the Audit Committee.

PART IV**Item 15. Exhibits, Financial Statement Schedules.**

- (a) (1) All financial statements: See Retractable Technologies, Inc. Index to Financial Statements on Page F-2.
- (2) Those financial statement schedules required to be filed by Item 8 of this form, and by paragraph (b) below. Schedule II-Schedule of Valuation and Qualifying Accounts for the years ended December 31, 2015, 2014, and 2013:

| | Balance at beginning of period | | Additions | | Deductions | | Balance at end of period |
|--|---|----|------------------|----|-------------------|----|-------------------------------------|
| Provision for Inventories | | | | | | | |
| Fiscal year ended 2013 | \$ 239,752 | \$ | 530,000 | \$ | 88,357 | \$ | 681,395 |
| Fiscal year ended 2014 | \$ 681,395 | \$ | | \$ | | \$ | 681,395 |
| Fiscal year ended 2015 | \$ 681,395 | \$ | | \$ | | \$ | 681,395 |
| Provision for Accounts Receivable | | | | | | | |
| Fiscal year ended 2013 | \$ 2,186,190 | \$ | 50,000 | \$ | 537,684 | \$ | 1,698,506 |
| Fiscal year ended 2014 | \$ 1,698,506 | \$ | 27,300 | \$ | | \$ | 1,725,806 |
| Fiscal year ended 2015 | \$ 1,725,806 | \$ | 116,395 | \$ | 46,720 | \$ | 1,795,481 |
| Deferred Tax Valuation | | | | | | | |
| Fiscal year ended 2013 | \$ 6,160,648 | \$ | 2,417,018 | \$ | | \$ | 8,577,666 |
| Fiscal year ended 2014 | \$ 8,577,666 | \$ | 807,790 | \$ | | \$ | 9,385,456 |
| Fiscal year ended 2015 | \$ 9,385,456 | \$ | | \$ | 1,633,484 | \$ | 7,751,972 |
| Provision for Rebates | | | | | | | |
| Fiscal year ended 2013 | \$ 21,993,267 | \$ | (A) 17,912,447 | \$ | (B) 13,112,048 | \$ | (C) 26,793,666 |
| Fiscal year ended 2014 | \$ 26,793,666 | \$ | 19,115,643 | \$ | 12,070,529 | \$ | 33,838,780 |
| Fiscal year ended 2015 | \$ 33,838,780 | \$ | 19,488,956 | \$ | 12,155,856 | \$ | 41,171,880 |

(A) Represents estimated rebates deducted from gross revenues

(B) Represents rebates credited to the distributor and charge offs against the allowance

(C) Includes \$3,733,199; \$4,160,099; and \$3,611,962 in Accounts payable for 2015, 2014, and 2013, respectively. The remainder includes a contra-account for credits taken by the distributor for which a credit memorandum has not been issued by the Company

(3) Exhibits:

The following exhibits are filed herewith or incorporated herein by reference to exhibits previously filed with the SEC.

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(b) Exhibits

| Exhibit No. | Description of Document |
|--------------------|--|
| 3(i) | Restated Certificate of Formation with Certificates of Designation, Preferences, Rights and Limitations of Class B Preferred Stock (all Series)* |
| 3(ii) | Fourth Amended and Restated Bylaws of RTI** |
| 4 | Restated Certificate of Formation with Certificates of Designation, Preferences, Rights and Limitations of Class B Preferred Stock (all Series)* |
| 10.1 | Sample United States Distribution Agreement*** |
| 10.2 | Sample Foreign Distribution Agreement*** |
| 10.3 | Employment Agreement between RTI and Thomas J. Shaw dated as of January 1, 2008 (This is a management compensation contract.)**** |
| 10.4 | Technology License Agreement between Thomas J. Shaw and RTI dated the 23rd day of June 1995*** |
| 10.5 | First Amendment to Technology License Agreement between Thomas J. Shaw and RTI dated the 3rd day of July, 2008***** |
| 10.6 | Second Amendment to Technology License Agreement between Thomas J. Shaw and Retractable Technologies, Inc. dated as of the 7th day of September, 2012 |
| 10.7 | Retractable Technologies, Inc. First Amended 2008 Stock Option Plan |
| 10.8 | Thomas J. Shaw Nonqualified Stock Option Agreement Issued Outside of Any Plan |
| 10.9 | Voting Agreement Between Thomas J. Shaw and Suzanne August dated November 8, 2006 |
| 14 | Retractable Technologies, Inc. Code of Business Conduct and Ethics |
| 23 | Consent of Independent Registered Public Accounting Firm |
| 31.1 | Certification of Principal Executive Officer |
| 31.2 | Certification of Principal Financial Officer |
| 32 | Section 1350 Certifications |
| 101 | The following materials from this report, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of December 31, 2015 and 2014, (ii) the Statements of Operations for the years ended December 31, 2015, 2014, and 2013, (iii) the Statements of Changes in Stockholders' Equity for the years ended December 31, 2015, 2014, and 2013, (iv) the Statements of Cash Flows for the years ended December 31, 2015, 2014, and 2013, and (v) Notes to Financial Statements. |

* Incorporated herein by reference to RTI's Form 10-Q filed on November 15, 2010

** Incorporated herein by reference to RTI's Form 8-K filed on May 13, 2010

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*** Incorporated herein by reference to RTI s Registration Statement on Form 10-SB filed on June 23, 2000

**** Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2008

***** Incorporated herein by reference to RTI s Form 10-K filed on March 31, 2009

Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2012

Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2014

Incorporated herein by reference to RTI s Form 10-K filed on March 31, 2010

Incorporated herein by reference to RTI s Schedule TO filed on October 17, 2008

Incorporated herein by reference to RTI s Form 8-K filed on February 19, 2010

Filed herewith

(c) Excluded Financial Statement Schedules: None

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RETRACTABLE TECHNOLOGIES, INC.
(Registrant)

By: /s/ Thomas J. Shaw
THOMAS J. SHAW
CHAIRMAN, PRESIDENT, AND
CHIEF EXECUTIVE OFFICER

Date: March 30, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Douglas W. Cowan
DOUGLAS W. COWAN
VICE PRESIDENT, CHIEF FINANCIAL OFFICER, PRINCIPAL
ACCOUNTING OFFICER, TREASURER, AND DIRECTOR

March 30, 2016

/s/ Amy Mack
AMY MACK
DIRECTOR

March 30, 2016

/s/ Marco Laterza
MARCO LATERZA
DIRECTOR

March 30, 2016

/s/ Walter O. Bigby, Jr.
WALTER O. BIGBY, JR.
DIRECTOR

March 30, 2016