RETRACTABLE TECHNOLOGIES INC
Form 10-K
March 28, 2019
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

or

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

For the transition period from to

Commission file number 001-16465

Retractable Technologies, Inc.

(Exact name of registrant as specified in its charter)

Texas (State or other jurisdiction of incorporation or organization)	**75-2599762** (I.R.S. Employer Identification No.)
511 Lobo Lane **Little Elm, Texas** (Address of principal executive offices)	**75068-5295** (Zip Code)

972-294-1010

Registrant s telephone number, including area code

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

Title of each class	Name of each exchange on which registered
Common	**NYSE American LLC**

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

Preferred Stock

(Title of class)

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

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

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

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

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

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x	Smaller reporting company x
	Emerging growth company o

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

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

The aggregate market value of the common equity held by non-affiliates as of June 29, 2018, was $10,309,114, assuming a closing price of $0.7365 and outstanding shares held by non-affiliates of 13,997,440.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

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

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. As of March 7, 2019, there were 32,666,454 shares of our Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the Annual Meeting of Shareholders to be held May 7, 2019 are incorporated by reference into Part III hereof.

Table of Contents

RETRACTABLE TECHNOLOGIES, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2018

TABLE OF CONTENTS

Table of Contents

PART I

FORWARD-LOOKING STATEMENT WARNING

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

Item 1. Business.

DESCRIPTION OF BUSINESS

General Development of Business

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

In 2007, we filed a lawsuit claiming that we have been blocked from gaining market access due to actions taken by BD. In August 2017, a district court dismissed our remaining claims against BD and entered a take nothing judgment. We filed for appeal. On March 26, 2019, the U.S. Court of Appeals for the Fifth Circuit issued an opinion affirming the take nothing judgment. We are evaluating this ruling and conferring with legal counsel regarding possible future action.

Financial Information

We have only one reporting segment. See Item 8 for our financial statements.

Principal Products, Markets, and Distribution

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

VanishPoint® syringe sales have historically comprised most of our sales. VanishPoint® syringe sales were 93.0%, 89.9%, and 84.9% of our revenues in 2016, 2017, and 2018.

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

Table of Contents

In the second quarter of 2016, we began selling the EasyPoint® needle. EasyPoint® needles made up 10.3% of revenues in 2018. The EasyPoint® is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefilled syringes to give injections. The EasyPoint® needle can also be used to aspirate fluids and collect blood.

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

Our products are sold to and used by healthcare providers primarily in the U.S. (with 13.9% of revenues in 2018 generated from sales outside the U.S.) which include, but are not limited to, acute care hospitals, alternate care facilities, doctors offices, clinics, emergency centers, surgical centers, long-term care facilities, Veterans Administration facilities, military organizations, public health facilities, and prisons.

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

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

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

Sources and Availability of Raw Materials

Our product components, including needle adhesives and packaging materials, are purchased from various suppliers. There is no scarcity of such materials or such suppliers.

Intellectual Property

Intellectual property rights, particularly patent rights, are material to our business. The patent rights are jointly owned by the Company and Thomas J. Shaw, our founder and CEO, and have varying expiration dates. Under the terms of an exclusive license agreement that has been in effect since 1995, the Company is exclusively licensed to use the patent rights held by Mr. Shaw, and Mr. Shaw receives a five percent (5%) royalty on gross sales of products subject to the license.

The last unexpired U.S. patent covering VanishPoint® syringes (as presently manufactured and marketed) will expire in 2020. Following the expiration of such patent, competitors will be permitted to attempt to copy the VanishPoint® syringe as presently manufactured. Issued patents covering possible future modifications to the VanishPoint® syringe and core technology of the VanishPoint® syringe will expire during the years 2028 through 2032. If the VanishPoint® syringes are modified to incorporate the modifications covered in the unexpired patents,

Table of Contents

then competitors will not be permitted to attempt to copy such modified syringes in the countries where the patents remain in effect. Other patent applications covering inventions applicable to the VanishPoint® syringe are pending.

The Company has unexpired patents which relate to the EasyPoint® technology and other products as well.

The Company has registered the following trade names and trademarks for our products: VanishPoint®, EasyPoint®, Patient Safe®, VanishPoint® logos, RT and design, the VanishPoint® and design, the spot design and the Company slogans The New Standard for Safety ® and We Make Safety Safe ®.

We are involved in patent litigation detailed in Item 3.

Seasonality

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

Working Capital Items

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

Dependence on Customers

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

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 domestic market and foreign market, we hold a Quality Management System certification to ISO 13485:2016. Additionally, for all products manufactured for sale into the applicable countries, we hold a Quality Management System certification in compliance with the Medical Device Single Audit Program (MDSAP). For all products manufactured for sale into European Union countries, we hold a Full Quality Assurance System certification to Directive 93/42/EEC Annex II (excluding section 4). All of these certifications are issued by our notified body, BSI, and are reviewed annually.

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

Competitive Conditions

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

We compete primarily on the basis of healthcare worker and patient safety, product performance, and quality. We believe our competitive advantages include, but are not limited to, our leadership in quality and innovation. We believe our products continue to be the most effective safety devices in today s market. Our syringe products include passive safety activation, require less disposal space, and are activated while in the patient,

Table of Contents

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.

EasyPoint® retractable needles offer unique safety benefits not found in other commercially available safety needles. Manually activated safety needles that compete with EasyPoint® must be removed from the patient, exposing the contaminated needle prior to activation of the manual safety mechanism. EasyPoint® needles allow for activation of the automated retraction mechanism while the needle is still in the patient, reducing exposure to the contaminated needle and effectively reducing the risk of needlestick injuries. EasyPoint® retractable needles are compatible with Luer-fitting syringes, including pre-filled syringes. In addition, EasyPoint® retractable needles may be activated with fluid in the syringe, making it applicable for aspiration procedures such as blood collection.

Environmental Compliance

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

Employees

As of March 7, 2019, we had 125 employees. 123 of such employees were full time employees.

Available Information

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

Item 1A. Risk Factors.

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

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

We Compete in a Marketplace Dominated by BD

We operate in a marketplace that is dominated by BD, the major syringe manufacturer in the U.S. We initiated a lawsuit in 2007 against BD. The suit was for patent infringement, antitrust practices, and false advertising. The court severed the patent claims from the other claims. The antitrust and false advertising case was dismissed in district court in August 2017 and we were awarded a take nothing judgment. We filed for appeal. On March 26, 2019, the U.S. Court of Appeals for the Fifth Circuit issued an opinion affirming the take nothing judgment. We are evaluating this ruling and conferring with legal counsel regarding possible future action.

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

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

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

Table of Contents

We Are Challenged by Uncertainties in Obtaining and Enforcing Intellectual Property Rights

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.

VanishPoint® syringes comprised 84.9% of sales in 2018 and a principal remaining patent protecting those syringes (as presently manufactured and marketed) will expire in 2020. Following the expiration of such patent, competitors will be permitted to attempt to copy the VanishPoint® syringe as presently manufactured. Issued patents covering possible future modifications to the VanishPoint® syringe and core technology of the VanishPoint® syringe will expire during the years 2028 through 2032. If the VanishPoint® syringes are modified to incorporate the modifications covered in the unexpired patents, then competitors will not be permitted to attempt to copy such modified syringes in the countries where the patents remain in effect. There is no assurance that the modifications will be incorporated or profitably sold. Other patent applications covering inventions applicable to the VanishPoint® syringe are pending.

When the current patents for the VanishPoint® syringes and other products expire, we may experience a significant and rapid loss of sales, and our competitive position in the marketplace may weaken if other competitors use our technology. Such occurrences could have a material adverse effect on profitability.

We do not maintain patent or trademark protection in all foreign countries, but, where possible, have taken steps to protect our patents and trademarks in those countries where we market our products or where we believe other manufacturers are most likely to attempt to replicate our technology. Our lack of patent and trademark protection in certain foreign countries heightens the risk that our designs may be copied by a competitor in those countries.

Our Patents Are Subject to Litigation

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

Operations May Be Affected By Foreign Trade Policy

We are subject to risks associated with foreign trade policy. In 2018, we used Chinese manufacturers to produce 85.3% of our products. Trade protection measures, including tariffs, and/or changes to import or export requirements could materially adversely impact our operations. As of the date of this filing, syringes are not included among the Chinese products on which the U.S. has proposed tariffs. We cannot predict the impact of potential changes to U.S. foreign trade policy. Additionally, we derive 13.9% of our revenues from international sales. International sales, particularly in emerging market countries, are further subject to a variety of regulatory, economic, and political risks as well.

Table of Contents

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

Presently existing patent coverage for VanishPoint® syringes (as presently manufactured) will expire in 2020. Following the patent expiration, expected declines in sales of VanishPoint® syringes, which currently comprise 84.9% of our revenues, means that our future success is dependent on new products. We have engaged in research and development for many years to develop other commercially successful products. Often, new products take a number of years to develop and sales of a new product may be disappointing. Based on industry-wide trends, we anticipate that demand may increase for one of our newer products, the EasyPoint® needle. Sales in 2017 and 2018 for this product were 6.0% and 10.3%, respectively, of our total revenues.

The Majority of Our Sales Are Filled Using Third Party Manufacturers

Most international sales, as well as a substantial portion of domestic sales, are filled by production from Chinese manufacturers. In the event that we become unable to purchase such product from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes. Even with increased domestic production, we may not be able to avoid a disruption in supply. In 2018, the 1mL and 3mL syringes made up 75.4% of our unit sales and 75.7% of our revenues. We have a strong relationship with our Chinese manufacturers and we communicate with them frequently.

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. or find other manufacturers. This could temporarily increase unit costs as we ramp up domestic production.

We Are Controlled by One Shareholder

Thomas J. Shaw, our President and Chief Executive Officer, has investment or voting power over a total of 55.9% of the outstanding Common Stock. Mr. Shaw therefore has the ability to direct our operations and financial affairs and to elect members of our Board of Directors. His interests may not always coincide with the Company s interests or the interests of other stockholders. This concentration of ownership, for example, may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could materially adversely affect the market price of our Common Stock. Mr. Shaw s rights under the Technology License Agreement, as the owner of the technology we produce, present similar conflicts of interest.

We Face Inherent Product Liability Risks

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

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

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

Table of Contents

Item 1B. Unresolved Staff Comments.

Not applicable and none.

Item 2. Properties.

Our headquarters are located at 511 Lobo Lane, on 35 acres, which we own, overlooking Lake Lewisville in Little Elm, Texas. The headquarters are in good condition and houses our administrative offices and manufacturing facility. The manufacturing facility produced approximately 14.4% of the units that were manufactured in 2018. In the event that we become unable to purchase product from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes. The 5mL and 10mL syringes are sold principally in the international market. In 2018, we used approximately 15% of our current U.S. productive capacity.

A loan in the original principal amount of approximately $4,210,000 is secured by our land and buildings. See Note 8 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 including, among other things, a requirement to notify certain customers and others regarding misleading disclosures. In connection with BD s subsequent appeal, on December 2, 2016, the United States Court of Appeals for the Fifth Circuit overturned the antitrust damages. The finding of false advertising liability was affirmed and the case was remanded to the Eastern District of Texas for a redetermination as to the amount of damages to which we are entitled. On August 17, 2017, District Court for the Eastern District of Texas issued the Court s Final Judgment ordering that we take nothing in our suit against BD and dismissing the case. We filed a notice of Appeal with the United States Court of Appeals for the Fifth Circuit on November 3, 2017. Oral arguments occurred on October 3, 2018. On March 26, 2019, the U.S. Court of Appeals for the Fifth Circuit issued an opinion affirming the District Court s take nothing judgment.

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. The case remains stayed as a result of the ongoing proceedings regarding the claims in the separate proceeding described above.

Item 4. Mine Safety Disclosures.

Not applicable.

Table of Contents

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.

MARKET INFORMATION

Our Common Stock has been listed on the NYSE American (or its predecessor entities) under the symbol RVP since May 4, 2001.

SHAREHOLDERS

As of March 7, 2019, there were 32,666,454 shares of Common Stock held by 199 shareholders of record, not including Cede & Co. participants or beneficial owners thereof.

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, 2018, there was an aggregate of $11.8 million in preferred dividends in arrears. As of December 31, 2017, there was an aggregate of $11.3 million in preferred dividends in arrears.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information relating to our equity compensation plans as of December 31, 2018:

Equity Compensation Plan Information

	Number of securities to be issued upon exercise of outstanding options,	Weighted average exercise price of outstanding	Number of securities remaining available for future issuance under equity compensation

	warrants and rights (a)		options, warrants and rights (b)	plans (excluding securities reflected in column(a)) (c)
Plan category				
Equity compensation plans approved by security holders	1,357,803	$	1.54	
Total	1,357,803	$	1.54	

Table of Contents

STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total return for our Common Stock from December 31, 2013 to December 31, 2018, 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, 2013, and that all dividends are reinvested.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Purchases by affiliate(s) during 2018 were not repurchases by or on behalf of the issuer. Based on our review, affiliates properly filed Section 16(a) beneficial ownership reports.

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, 2015 and 2014 and the Balance Sheet data as of December 31, 2016, 2015, and 2014 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,				
	2018	**2017**	**2016**	**2015**	**2014**
Sales, net	$ 33,275	$ 34,494	$ 29,827	$ 29,552	$ 34,521
Cost of sales	23,053	24,522	19,485	18,987	22,499
Gross profit	10,222	9,972	10,342	10,565	12,022
Total operating expenses	11,803	13,750	13,849	13,773	14,180
Income from insurance proceeds	261				
Loss from operations	(1,320)	(3,778)	(3,507)	(3,208)	(2,158)
Litigation proceeds				7,725	
Interest and other income	144	65	26	25	34
Interest expense	(177)	(211)	(213)	(220)	(223)
Income (loss) before income taxes	(1,353)	(3,924)	(3,694)	4,322	(2,347)
Provision (benefit) for income taxes	(13)	(188)	1	8	8
Net income (loss)	(1,340)	(3,736)	(3,695)	4,314	(2,355)
Preferred Stock dividend requirements	(705)	(705)	(705)	(709)	(915)

Table of Contents

	As of and for the Years Ended December 31,				
	2018	2017	2016	2015	2014
Deemed capital contribution on extinguishment of preferred stock				2,306	
Income (loss) applicable to common shareholders	$ (2,045)	$ (4,441)	$ (4,400)	$ 5,911	$ (3,270)
Earnings (loss) per share basic	$ (0.06)	$ (0.14)	$ (0.15)	$ 0.21	$ (0.12)
Earnings (loss) per share diluted	$ (0.06)	$ (0.14)	$ (0.15)	$ 0.20	$ (0.12)
Weighted average shares outstanding basic	32,666,454	31,958,121	29,354,437	27,822,593	27,375,450
Weighted average shares outstanding diluted	32,666,454	31,958,121	29,354,437	29,481,294	27,375,450
Current assets	$ 23,847	$ 26,608	$ 26,677	$ 30,811	$ 33,983
Current liabilities	$ 8,539	$ 7,900	$ 7,172	$ 8,096	$ 15,100
Property, plant, and equipment, net	$ 10,852	$ 11,353	$ 12,092	$ 11,468	$ 10,853
Total assets	$ 36,792	$ 38,155	$ 38,779	$ 42,294	$ 45,106
Long-term debt, net of current maturities	$ 2,640	$ 3,081	$ 3,498	$ 3,417	$ 3,425
Stockholders equity	$ 25,614	$ 27,174	$ 28,108	$ 30,781	$ 26,581
Redeemable Preferred Stock (in shares)	781,445	781,445	781,445	781,445	987,445
Capital leases					
Cash dividends per common share	$	$	$	$	$
Gross profit margin	30.7%	28.9%	34.7%	35.8%	34.8%

Events that could affect the trends indicated above include changes in manufacturing costs, changing average sales prices, changing raw material cost, the gaining of market access, protection of our patents, foreign currency exchange rates, the Medical Device Excise Tax, the impact of flu season requirements, new or changing regulations or changes in trade policy, or 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.

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

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words could, may, believes, anticipates, intends, expects, and simila words constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, potential tariffs, our ability to maintain liquidity, our maintenance of patent protection, the impact of current and future Court decisions regarding current litigation, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, foreign trade risk, our ability to quickly increase capacity in response to an increase in demand, our ability to access the market, our ability to maintain or decrease 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.

Table of Contents

Overview

We have been manufacturing and marketing our products since 1997. VanishPoint® syringes comprised 84.9% of our sales in 2018. We also manufacture and market the EasyPoint® needle, 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 associated with catheter hub contamination.

In the second quarter of 2016, we began selling the EasyPoint® needle. EasyPoint® needles made up 10.3% of revenues in 2018. The EasyPoint® is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefilled syringes to give injections. The EasyPoint® needle can also be used to aspirate fluids and collect blood. Based on industry-wide trends, we anticipate that demand may increase for the EasyPoint® needle.

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 practices engaged in by BD, the dominant maker and seller of disposable syringes. We initiated an antitrust and false advertising lawsuit in 2007 against BD. Although a district court judgment in 2015 awarded us approximately $340 million in antitrust damages from BD and the Fifth Circuit affirmed a finding of false advertising liability against BD, we were ultimately awarded a take nothing judgment in August 2017 and the case was dismissed. We appealed that ruling and oral arguments occurred October 3, 2018. On March 26, 2019, the U.S. Court of Appeals for the Fifth Circuit issued an opinion affirming the take nothing judgment. We are evaluating this ruling and conferring with legal counsel regarding possible future action.

Our litigation expenses were significantly less in 2017 and 2018 than previous years. 2017 costs related to additional compensation, bonuses to Ms. Larios and Mr. Cowan, and stock option expense related to options granted in 2016 affect comparability of 2018 results to 2017 results.

In November 2018, we terminated 19 employees earning total annual compensation of approximately $1.12 million. Some of these positions may be filled in the future. Severance costs associated with the 2018 terminations were $244 thousand.

In January 2018, Congress imposed another two-year moratorium on the 2.3% medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax is not expected to go into effect until January 1, 2020.

In 2016, we granted a right to three of our executive officers to purchase shares directly from the Company. Thomas J. Shaw was the only officer to exercise such right prior to expiration, buying a total of three million shares in two transactions in 2017 for an aggregate purchase price of $2.35 million.

We received approximately $1 million from our insurance carrier in the second quarter of 2017 and used these funds to repair our buildings from earlier storm damage. The remaining proceeds of $261 thousand were recognized as Insurance proceeds in the fourth quarter of 2018.

Product purchases from our Chinese manufacturers have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufacturing cost. In 2018, our Chinese manufacturers

Table of Contents

produced approximately 85.3% of our products. In the event that we become unable to purchase products from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes.

In 1995, we entered into a license agreement with Thomas J. Shaw for the exclusive right to manufacture, market, and distribute products utilizing his patented automated retraction technology and other patented 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 2018, 2017, or 2016. Dollar amounts have been rounded for ease of reading.

Comparison of Year Ended

December 31, 2018 and Year Ended December 31, 2017

Domestic sales accounted for 86.1% and 78.3% of the revenues in 2018 and 2017, respectively. Domestic revenues increased 6.0% principally due to increased volume mitigated by lower average price. Domestic unit sales increased 12.0%. Domestic unit sales were 81.0% of total unit sales for 2018. International revenues decreased from $7.5 million in 2017 to $4.6 million in 2018, primarily due to lower volumes. Overall unit sales decreased 3.8%. 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 manufactured product decreased $1.5 million principally due to lower volumes and lower unit cost of manufacture. Royalty expense increased $80 thousand due to increased gross sales. Gross profit margins increased from 28.9% in 2017 to 30.7% in 2018 principally due to lower cost of manufacturing.

Operating expenses decreased 14.2% from the prior year due to lower legal expense, no bonuses paid in 2018, lower travel and entertainment cost, decreased costs of engineering samples, and no stock option expense in 2018. These decreases were mitigated by severance costs.

Recognition of Insurance proceeds of $261 thousand is due to actual building repairs being less than the insurance payment.

The loss from operations was $1.3 million in 2018 compared to a loss from operations of $3.8 million in 2017.

We recorded $188 thousand in tax benefits in connection with the enactment of the Tax Cut and Jobs Act (the Act) on December 22, 2017. The Act established new tax provisions that affect us including the elimination of the corporate alternative minimum tax and changing rules related to uses and limitations of net operating loss carry forwards created after December 31, 2017. Carry forward credits from alternative minimum taxes paid in prior years became refundable in tax years beginning January 1, 2018. Such credits were, however, subject to sequestration. However, in January 2019, the IRS had a ruling that provided that Alternative Minimum Tax payments are not subject to sequestration, bringing the total benefit to $202 thousand, an increase of $13 thousand from last year.

Table of Contents

Cash flow from operations was negative $1.2 million in 2018 due to our Net loss, increased inventory, and use of Insurance proceeds for repairs. The decrease in cash was mitigated by a decrease in accounts receivable and an increase in liabilities.

In 2018, we transferred $3 million from our cash accounts into securities with maturities of one to three years. This transfer significantly affects our net decrease in cash in 2018. However, the securities may increase investment income in the future.

Comparison of Year Ended

December 31, 2017 and Year Ended December 31, 2016

Domestic sales accounted for 78.3% and 88.2% of the revenues in 2017 and 2016, respectively. Domestic revenues increased 2.7% principally due to increased sales of EasyPoint® and the blood collection set. Domestic unit sales increased 7.1%. Domestic unit sales were 69.5% of total unit sales for 2017. International revenues increased from $3.5 million in 2016 to $7.5 million in 2017, primarily due to increased volumes mitigated by lower average prices. Overall unit sales increased 28.3%. 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 manufactured product increased $4.7 million principally due to higher volumes. Royalty expense increased $337 thousand due to increased gross sales. Gross profit margins decreased from 34.7% in 2016 to 28.9% in 2017 principally due to a larger portion of international sales which bear a lower average sales price.

Operating expenses decreased 0.7% from the prior year due to decreased legal expenses and no impairment costs incurred in 2017, offset by increased staffing in Sales and marketing, stock option expense, and bonuses paid in 2017.

The loss from operations was $3.8 million in 2017 compared to $3.5 million in 2016.

We recorded $188 thousand in tax benefits in connection with the enactment of the Tax Cut and Jobs Act (the Act) on December 22, 2017. The Act established new tax provisions that affect us including the elimination of the corporate alternative minimum tax and changing rules related to uses and limitations of net operating loss carry forwards created after December 31, 2017. Carry forward credits from alternative minimum taxes paid in prior years became refundable in tax years beginning January 1, 2018.

Cash flow from operations was a negative $2.9 million for 2017 due to our Net loss, increased accounts receivable and other current assets, mitigated by noncash expenses of depreciation and stock option expense, lower inventory levels, increased liabilities, and insurance proceeds.

LIQUIDITY AND CAPITAL RESOURCES

At the present time, Management does not intend to publicly raise equity capital. Due to the funds received from prior litigation and direct purchase of stock, 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 uncertain.

In 2018, we transferred $3 million from our cash accounts into securities with maturities of one to three years. This transfer significantly affects our net decrease in cash in 2018. However, the securities may increase investment income in the future.

Historical Sources of Liquidity

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

Table of Contents

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 14.4%) of our products in the U.S. or find other manufacturers. 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. Some international sales of our products are shipped directly from China to the customer. 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.

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 legal costs and we continue to evaluate these costs. We also decreased our workforce, as discussed in the Overview of this Item 7. In the future, if such cost cutting measures prove insufficient, we may reduce the number of units being produced, further reduce the workforce, reduce the salaries of officers and other employees, and/or defer royalty payments.

External Sources of Liquidity

We have obtained several loans since 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 public sale of equity. We granted a right to three of our executive officers to engage in private purchases of stock at market prices. Thomas J. Shaw was the only officer to exercise such right prior to expiration, buying a total of three million shares in two transactions in 2017 for an aggregate purchase price of $2.35 million.

Capital Resources

In 2017, we received approximately $1 million to make necessary repairs to our buildings from storm damage. Such repairs were completed in 2018. The remaining insurance proceeds of $261 thousand were recognized in the fourth quarter of 2018. There were no material commitments for capital projects as of December 31, 2018.

OFF-BALANCE SHEET ARRANGEMENTS

None.

Table of Contents

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 and operating leases as of December 31, 2018:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Contractual Obligations					
Long-term debt	$ 3,046,008	$ 406,361	$ 522,166	$ 587,041	$ 1,530,440
Operating leases	165,849	81,694	84,155		
Total	$ 3,211,857	$ 488,055	$ 606,321	$ 587,041	$ 1,530,440

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

Not applicable.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

RETRACTABLE TECHNOLOGIES, INC.

FINANCIAL STATEMENTS AND

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

DECEMBER 31, 2018 AND 2017

Table of Contents

RETRACTABLE TECHNOLOGIES, INC.

INDEX TO FINANCIAL STATEMENTS

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of

Retractable Technologies, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Retractable Technologies, Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and schedules (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company s Management. Our responsibility is to express an opinion on the Company s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by Management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Moss Adams LLP

Dallas, TX

March 28, 2019

We have served as the Company s auditor since 2016.

Table of Contents

RETRACTABLE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,647,292	$ 14,877,899
Accounts receivable, net of allowance for doubtful accounts of $149,665 and $101,872, respectively	4,912,356	5,105,556
Held-to-maturity securities, at amortized cost	996,233	
Inventories, net	7,545,094	6,206,161
Income taxes receivable	100,887	
Other current assets	644,803	418,154
Total current assets	23,846,665	26,607,770
Property, plant, and equipment, net	10,851,747	11,353,202
Held-to-maturity securities, at amortized cost (non-current)	1,989,923	
Income taxes receivable	100,835	188,456
Other assets	2,849	6,052
Total assets	$ 36,792,019	$ 38,155,480
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,369,677	$ 4,957,750
Current portion of long-term debt	406,361	410,949
Accrued compensation	540,852	547,021
Dividends payable	55,113	55,113
Accrued royalties to shareholder	769,324	793,489
Insurance proceeds		466,293
Other accrued liabilities	1,387,287	657,923
Income taxes payable	10,025	11,407
Total current liabilities	8,538,639	7,899,945
Long-term debt, net of current maturities	2,639,647	3,081,409
Total liabilities	11,178,286	10,981,354
Commitments and contingencies See Note 9		
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 shares (liquidation preference of $2,140,000)	171,200	171,200
Series III, Class B; outstanding: 129,245 shares (liquidation preference of $1,615,563)	129,245	129,245
Series IV, Class B; outstanding: 342,500 shares (liquidation preference of $3,767,500)	342,500	342,500
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: 32,666,454		
Additional paid-in capital	61,871,756	62,092,206
Accumulated deficit	(37,039,468)	(35,699,525)
Total stockholders equity	25,613,733	27,174,126
Total liabilities and stockholders equity	$ 36,792,019	$ 38,155,480

See accompanying notes to financial statements

Table of Contents

RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2018	**2017**	**2016**
Sales, net	$ 33,274,702	$ 34,493,838	$ 29,826,636
Cost of Sales			
Costs of manufactured product	20,108,798	21,658,062	16,957,073
Royalty expense to shareholder	2,944,102	2,864,188	2,527,508
Total cost of sales	23,052,900	24,522,250	19,484,581
Gross profit	10,221,802	9,971,588	10,342,055
Operating expenses:			
Sales and marketing	4,404,441	4,658,548	4,025,786
Research and development	621,365	740,567	571,842
General and administrative	6,776,705	8,351,053	8,795,310
Impairment of assets			456,119
Total operating expenses	11,802,511	13,750,168	13,849,057
Income from insurance proceeds	260,514		
Loss from operations	(1,320,195)	(3,778,580)	(3,507,002)
Interest and other income	144,124	65,695	26,522
Interest expense	(177,190)	(210,761)	(213,295)
Loss before income taxes	(1,353,261)	(3,923,646)	(3,693,775)
Provision (benefit) for income taxes	(13,318)	(187,608)	1,132
Net loss	(1,339,943)	(3,736,038)	(3,694,907)
Preferred Stock dividend requirements	(704,996)	(704,996)	(704,996)
Loss applicable to common shareholders	$ (2,044,939)	$ (4,441,034)	$ (4,399,903)
Basic loss per share	$ (0.06)	$ (0.14)	$ (0.15)
Diluted loss per share	$ (0.06)	$ (0.14)	$ (0.15)
Weighted average common shares outstanding:			
Basic	32,666,454	31,958,121	29,354,437
Diluted	32,666,454	31,958,121	29,354,437

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, 2015	98,500	$ 98,500	171,200	$ 171,200	129,245	$ 129,245	342,500	$ 342,500	40,000	$ 40,000	28,619,874	$
Stock options exercised											1,046,580	
Dividends												
Stock option compensation												
Net loss												
Balance as of December 31, 2016	98,500	98,500	171,200	171,200	129,245	129,245	342,500	342,500	40,000	40,000	29,666,454	
Issuance of new Common Stock											3,000,000	
Dividends												
Stock option compensation												
Net loss												
Balance as of December 31, 2017	98,500	98,500	171,200	171,200	129,245	129,245	342,500	342,500	40,000	40,000	32,666,454	
Dividends												
Net loss												
Balance as of December 31, 2018	98,500	$ 98,500	171,200	$ 171,200	129,245	$ 129,245	342,500	$ 342,500	40,000	$ 40,000	32,666,454	$

See accompanying notes to financial statements

Table of Contents

RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	Additional Paid-in Capital	Accumulated Deficit	Total
Balance as of December 31, 2015	$ 58,268,036	$ (28,268,580)	$ 30,780,901
Stock options exercised	855,021		855,021
Dividends	(220,450)		(220,450)
Stock option compensation	387,726		387,726
Net loss		(3,694,907)	(3,694,907)
Balance as of December 31, 2016	59,290,333	(31,963,487)	28,108,291
Issuance of new Common Stock	2,350,100		2,350,100
Dividends	(220,450)		(220,450)
Stock option compensation	672,223		672,223
Net loss		(3,736,038)	(3,736,038)
Balance as of December 31, 2017	62,092,206	(35,699,525)	27,174,126
Dividends	(220,450)		(220,450)
Net loss		(1,339,943)	(1,339,943)
Balance as of December 31, 2018	$ 61,871,756	$ (37,039,468)	$ 25,613,733

See accompanying notes to financial statements

Table of Contents

RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net loss	$ (1,339,943)	$ (3,736,038)	$ (3,694,907)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	886,814	834,951	872,868
Share-based compensation		672,223	387,726
Inventories reserve	(297,731)		176,424
Provision for doubtful accounts	47,793	24,272	92,000
Impairment of assets			456,119
(Increase) decrease in assets:			
Accounts receivable	145,407	(1,861,990)	1,541,159
Inventories	(1,041,202)	811,063	(897,023)
Other current assets	(226,649)	(225,606)	1,375,484
Income taxes receivable	(13,266)	(188,456)	
Other assets			(750)
Increase (decrease) in liabilities:			
Accounts payable	411,927	485,994	(1,225,762)
Other accrued liabilities	699,030	(205,342)	119,342
Insurance proceeds	(466,293)	466,293	
Income taxes payable	(1,382)		2,408
Net cash used by operating activities	(1,195,495)	(2,922,636)	(794,912)
Cash flows from investing activities:			
Purchase of property, plant, and equipment	(382,156)	(91,878)	(1,947,172)
Investments	(2,986,156)		
Net cash used by investing activities	(3,368,312)	(91,878)	(1,947,172)
Cash flows from financing activities:			
Repayments of long-term debt	(446,350)	(436,280)	(263,200)
Proceeds from long-term debt			525,017
Proceeds from sale of common stock		2,350,100	
Proceeds from the exercise of stock options			855,021
Payment of Preferred Stock dividends	(220,450)	(220,450)	(220,755)
Net cash provided (used) by financing activities	(666,800)	1,693,370	896,083
Net decrease in cash and cash equivalents	(5,230,607)	(1,321,144)	(1,846,001)
Cash and cash equivalents at:			
Beginning of period	14,877,899	16,199,043	18,045,044
End of period	$ 9,647,292	$ 14,877,899	$ 16,199,043
Supplemental schedule of cash flow information:			
Interest paid	$ 177,190	$ 210,761	$ 213,295
Income taxes paid	$ 1,173	$ 1,031	$ 2,000
Supplemental schedule of noncash investing and financing activities:			
Preferred dividends declared, not paid	$ 55,113	$ 55,113	$ 55,113

See accompanying notes to financial statements

Table of Contents

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 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; the VanishPoint® Blood Collection Set; and the EasyPoint® needle. The Company also sells VanishPoint® autodisable syringes in the international market in addition to the Company s 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 cash, money market accounts, and investments with original maturities of three months or less.

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 7, 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.

Inventories

Inventories are valued at the lower of cost or net realizable value, with cost being determined using actual average cost. The Company compares the average cost to the net realizable value and records the lower value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. 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.

Table of Contents

Investments Held-to-Maturity Securities

The Company holds high-grade debt securities. Since Management has the intent and ability to hold these securities until they mature, these investments have been accounted for as held-to-maturity investments. The investments are carried at amortized cost. Premiums and discounts on investments in debt securities are amortized over the contractual lives of these securities. The method of amortization results in a constant effective yield on these securities.

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 operations.

The Company s property, plant, and equipment primarily consist of buildings, land, assembly equipment, molding machines, molds, office equipment, furniture, and fixtures. Depreciation and amortization are calculated using the straight-line method over the following useful lives:

Production equipment	3 to 13 years
Office furniture, fixtures, and equipment	3 to 10 years
Buildings	39 years
Building improvements	15 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 or appraised values of the underlying assets.

During 2016, the Company recognized an impairment charge of $456,119 associated with its Patient Safe® production equipment. The Company determined it was more cost effective to outsource this production through an overseas manufacturer, and thus the Company s Patient Safe® production equipment was taken out of service. Minimal cash flows were expected to be generated by this equipment. Accordingly, the Company reduced the carrying value of the Patient Safe® production equipment to an estimated fair value of zero.

Fair Value Measurements

For assets and liabilities that are measured using quoted prices in active markets, total fair value is the published market price per unit multiplied by the number of units held without consideration of transaction costs. Assets and liabilities that are measured using significant other observable inputs are valued by reference to similar assets or liabilities, adjusted for contract restrictions and other terms specific to that asset or liability. For these items, a significant portion of fair value is derived by reference to quoted prices of similar assets or liabilities in active markets. For all remaining assets and liabilities, fair value is derived using a fair value model, such as a discounted cash flow model or Black-Scholes model.

Financial instruments

Short-term financial instruments, including cash and cash equivalents, certificates of deposit, 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. Investments in U.S. Treasury Notes are classified as held-to-maturity and are presented at their amortized cost, net of discounts and premiums. 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, certificates of deposit, U.S. Treasury Notes, 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 2018, 2017, and 2016:

	Years Ended December 31,		
	2018	2017	2016
Number of significant customers	2	2	1
Aggregate dollar amount of net sales to significant customers	$ 13.1 million	$ 14.0 million	$ 9.4 million
Percentage of net sales to significant customers	39.2%	40.5%	31.4%

The Company increased its allowance for doubtful accounts by approximately $48 thousand in 2018 due to additional potential nonpayment.

The Company manufactures some of its products in Little Elm, Texas, as well as utilizing manufacturers in China. There are multiple sources of these materials. The Company obtained roughly 85.3% of its products in 2018 from its Chinese manufacturers. Purchases from Chinese manufacturers aggregated 82.9% and 78.4% of products in 2017 and 2016, respectively. In the event that the Company becomes unable to purchase products from its Chinese manufacturers, the Company would need to find an alternate manufacturer for its blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and would increase domestic production for the 1mL and 3mL syringes and EasyPoint® needles.

Revenue recognition

The Company recognizes revenue when it has satisfied all performance obligations to the customer, generally when title and risk of loss pass to the customer. Payments from customers with approved credit terms are typically due 30 days from the invoice date. 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 recognized in the period the related sales are recognized and 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 $3,896,341 and $4,115,628 as of December 31, 2018 and 2017, 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. End-users do not receive any contractual allowances on their purchases. Any product shipped or distributed for evaluation purposes is expensed.

Table of Contents

The Company provides product warranties that: i) the products are fit for medical use as generally defined within the boundaries of United States FDA approval; ii) the products are not defective; and iii) the products will conform to the descriptions set forth in their respective labeling, provided that they are used in accordance with such labeling and the Company s written directions for use. The Company has historically not incurred significant warranty claims.

The Company s domestic return 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 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.

The Company requires certain customers to pay in advance of product shipment. Such prepayments from customers are recorded in Other accrued liabilities and are generally recognized as revenue within 30 to 60 days of receipt at the time product is shipped.

Disaggregated information of revenue recognized from contracts with customers is as follows:

	For the year ended December 31, 2018:				
Geographic Segment	**Syringes**	**Blood Collection Products**	**EasyPoint® Needles**	**Other Products**	**Total Product Sales**
U.S. sales	$ 23,803,483	$ 1,365,936	$ 3,401,389	$ 75,766	$ 28,646,574
North and South America sales (excluding U.S.)	3,521,823	8,805	252	66,564	3,597,444
Other international sales	940,740	48,101	11,768	30,075	1,030,684
Total	$ 28,266,046	$ 1,422,842	$ 3,413,409	$ 172,405	$ 33,274,702

	For the year ended December 31, 2017:				
Geographic Segment	**Syringes**	**Blood Collection Products**	**EasyPoint® Needles**	**Other Products**	**Total Product Sales**
U.S. sales	$ 23,794,258	$ 1,098,667	$ 2,065,777	$ 57,010	$ 27,015,712
North and South America sales (excluding U.S.)	6,182,952	3,859		193,934	6,380,745
Other international sales	1,032,508	43,473		21,400	1,097,381
Total	$ 31,009,718	$ 1,145,999	$ 2,065,777	$ 272,344	$ 34,493,838

For the year ended December 31, 2016:

Geographic Segment	Syringes	Blood Collection Products	EasyPoint® Needles	Other Products	Total Product Sales
U.S. sales	$ 24,349,061	$ 571,242	$ 1,339,386	$ 48,557	$ 26,308,246
North and South America sales (excluding U.S.)	2,643,366	2,778		95,374	2,741,518
Other international sales	744,636	16,834		15,402	776,872
Total	$ 27,737,063	$ 590,854	$ 1,339,386	$ 159,333	$ 29,826,636

Table of Contents

Income taxes

The Tax Cuts and Job Act (the Act) was enacted on December 22, 2017, and the U.S. federal corporate tax rate was reduced from 35% to 21%. U.S. generally accepted accounting principles require companies to account for the effects of changes in income tax rates and laws in the period the change is enacted. Financial results, including provisional amounts, have been calculated for the income tax effects of the change. The U.S. Securities and Exchange Commission issued Staff Accounting Bulletin 118 (SAB 118) allowing companies to use provisional estimates to record the effects of the Act. SAB 118, as codified by Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2018-05 Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update), allows companies to complete accounting for these effects no later than one year from the enactment date of the Act. During 2018, the Company completed its analysis of the provisional estimates made to record the effects of the Act. On January 14, 2019, the IRS issued a statement saying that alternative minimum tax (AMT) refunds for taxable years beginning after December 31, 2017 will not be subject to sequestration. Prior to this statement from the IRS, refundable AMT credits under Section 53(e) were subject to sequestration, as required by the Balanced Budget and Emergency Deficit Control Act of 1985, as amended. The previously recorded AMT receivable was reduced in anticipation of sequestration. Based upon this development, the Company recorded an additional tax benefit of approximately $13 thousand for the year ended December 31, 2018 to reflect the full amount of refundable AMT credits.

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.

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 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 or loss 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 79,441 shares of Common Stock underlying issued and outstanding stock options at December 31, 2017, as their effect was antidilutive. The potential dilution, if any, is shown on the following schedule:

	Years Ended December 31,		
	2018	**2017**	**2016**
Net loss	$ (1,339,943)	$ (3,736,038)	$ (3,694,907)
Preferred dividend requirements	(704,996)	(704,996)	(704,996)
Loss applicable to common shareholders	$ (2,044,939)	$ (4,441,034)	$ (4,399,903)
Weighted average common shares outstanding	32,666,454	31,958,121	29,354,437
	32,666,454	31,958,121	29,354,437

Weighted average common and common equivalent shares outstanding - assuming dilution			
Basic loss per share	$ (0.06)	$ (0.14)	$ (0.15)
Diluted loss per share	$ (0.06)	$ (0.14)	$ (0.15)

Table of Contents

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 the following share-based compensation costs:

	Years Ended December 31,		
	2018	2017	2016
Cost of sales	$	$ 272,811	$ 141,782
Sales and marketing		143,255	77,583
Research and development		45,174	23,623
General and administrative		210,983	144,738
	$	$ 672,223	$ 387,726

Options awarded to employees in 2016 were amortized over twelve months. The Company amortized four months expense for options granted in September 2016 and amortized the remainder in 2017. Non-employee Directors option expense was all expensed in the fourth quarter of 2016.

The Company early-adopted FASB Accounting Standards Update (ASU) 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting for its annual period ended December 31, 2016. This ASU addresses several aspects of the accounting for share-based compensation transactions including: (a) income tax consequences when awards vest or are settled, (b) classification of awards as either equity or liabilities, (c) a policy election to account for forfeitures as they occur rather than on an estimated basis and (d) classification of excess tax impacts on the statement of cash flows. As a result of adoption, excess tax benefits in 2016 resulting from the exercise of non-qualified stock options were recognized in the income tax provision rather than in additional-paid-in capital. As there were previously no excess income tax benefits recognized in additional-paid-in capital or other material changes to the Company s accounting for share based compensation resulting from adoption of this ASU, no cumulative effect adjustments were required.

Insurance Proceeds

Receipts from insurance up to the amount of any loss recognized by the Company are considered recoveries. Any such recoveries are recorded when they are received. Insurance proceeds are not recognized as a component of earnings (loss) from operations until all repairs are made.

Table of Contents

Recently Adopted Pronouncements

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash . These amendments require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments do not provide a definition of restricted cash or restricted cash equivalents. The updated guidance was effective for the Company s quarter ended March 31, 2018. The adoption of ASU 2016-18 did not have a material effect on the Company s financial statements as the Company currently holds no restricted cash or restricted cash equivalents.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Payments (ASU 2016-15), clarifying guidance on the classification of certain cash receipts and payments in the statement of cash flows. This ASU was effective for the Company s quarter ended March 31, 2018. The adoption of ASU 2016-15 did not have a material impact on the Company s financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers , as well as several subsequently issued clarifying amendments, 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. The ASU, as amended, 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. The ASU, as amended, was effective commencing with the Company s quarter ended March 31, 2018. The Company adopted this amended guidance on a Modified Retrospective basis in the first quarter of 2018. The adoption of the ASU, as amended, had no impact on the opening balance of retained earnings. The Company applied the guidance of ASU No. 2014-09, as amended, to those contracts that were not completed as of January 1, 2018. In implementing the guidance of ASU 2014-09, as amended, the Company applied the practical expedients of FASB ASU No. 2016-12 Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. Under ASU 2016-12, the Company applies the guidance of ASU 2014-09, as amended, to a portfolio of contracts with similar characteristics, as opposed to individual contracts, as applying the guidance to the portfolio does not materially differ from applying the guidance to individual contracts. In addition, the Company accounts for shipping and handling as activities to fulfill the promise to transfer goods to a customer as opposed to a performance obligation. Historically, freight and handling activities billed to customers have not been material.

In August 2018, the Securities and Exchange Commission (SEC) adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification . The amendments were effective November 5, 2018. The amendments eliminate or revise several redundant or duplicative requirements between SEC rules and GAAP, including the elimination of the disclosure of the ratio of earnings to fixed charges and the presentation of dividends per share on the face of the statement of operations for interim periods. Among the amendments is the requirement to present the changes in shareholders equity in the interim financial statements (either in a separate statement or footnote) in quarterly reports on Form 10-Q. The amendments are effective for all filings made on or after November 5, 2018. In light of the timing of effectiveness of the amendments and proximity of effectiveness to the filing date for most filers quarterly reports, the SEC staff has indicated that it would not object if the filer s first presentation of the changes in shareholders equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. The Company elected to adopt the provisions of Securities Act Release No. 33-10532 for the quarter ended September 30, 2018.

Table of Contents

Recently Issued Pronouncements

In June 2016, the FASB issued Accounting Standards Update 2016-13, Financial Instruments Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, as well as subsequent clarifying amendments. Among other things, these amendments require the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Many of the loss estimation techniques applied today will still be permitted, although the inputs to those techniques will change to reflect the full amount of expected credit losses. This ASU is effective for the Company s quarter ending March 31, 2020 with early application permitted for the Company s quarter ending March 31, 2019. The Company is currently assessing the impact that adoption of this guidance will have on its financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) , as well as several subsequently issued clarifying amendments. Under the ASU, as amended, 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 guidance, lessor accounting is largely unchanged. The lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases . This amendment clarifies Topic 842 and corrected unintended application of guidance and is effective concurrent with Topic 842 or upon issuance if Topic 842 was early adopted. In August 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements . This amendment provides additional transition options allowing entities to recognize a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption rather than the earliest period presented and provides a practical expedient to lessors to elect, by class of underlying assets, to account for non-lease and lease components as a single arrangement. The Company intends to adopt the provisions of ASU 2018-11 through a cumulative effect adjustment. Topic 842, and its subsequent amendments, is effective for the Company s quarter ending March 31, 2019, with early adoption permitted. The Company has completed evaluating the various accounting policy elections associated with this ASU, as amended, including transition methods and practical expedients, identifying contracts for evaluation, and reviewing contracts to determine if they contain leases. The Company has completed evaluating the timing and impact of adopting ASU 2016-02, as amended, and anticipates recording lease assets and liabilities currently comprising less than $250,000 on its Balance Sheets, with no material impact to its Statements of Operations or to its accumulated deficit.

In August 2018, the FASB issued ASU 2018-15, Intangibles Goodwill and Other Internal-Use Software (Subtopic 350-40): Customer s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract (a Consensus of the FASB Emerging Issues Task Force) . This amendment requires that implemented costs incurred in a hosting arrangement that is a service contract should be accounted for in accordance with ASC 350-40. Accordingly, costs incurred during the preliminary project and post-implementation stages are expensed and costs associated with the application development phase are capitalized. The amendment also requires that capitalized costs be amortized over the term of the hosting arrangement and that capitalized costs should be evaluated for impairment. The amendment is effective for annual periods beginning after December 15, 2019 and interim periods within those annual periods. The Company is currently assessing the impact that adoption of this ASU will have on its financial statements and related disclosures.

Table of Contents

3. INVENTORIES

Inventories consist of the following:

	Year Ended December 31,	
	2018	2017
Raw materials	$ 1,399,543	$ 1,511,339
Finished goods	6,442,759	5,289,761
	7,842,302	6,801,100
Inventory reserve	(297,208)	(594,939)
	$ 7,545,094	$ 6,206,161

4. HELD-TO-MATURITY DEBT SECURITIES

The Company s investment securities classified as held-to maturity consist of high-grade debt securities and certificates of deposit. These investments are carried at amortized cost. Gross unrecognized gains and losses and fair value of these securities at December 31, 2018 are as follows:

	December 31, 2018			
	Amortized Cost	Gross Unrecognized Gains	Losses	Aggregate Fair Value
Current	$ 996,233	$	$ (964)	$ 995,269
Long-Term	1,989,923		(389)	1,989,534
Total	$ 2,986,156	$	$ (1,353)	$ 2,984,803

The fair value of investments in held-to maturity securities is valued under the market approach through the use of quoted prices.

5. PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment consist of the following:

	December 31,	
	2018	2017
Land	$ 261,893	$ 261,893
Buildings and building improvements	11,566,115	11,566,115
Production equipment	19,948,303	19,742,577
Office furniture and equipment	3,540,846	3,500,834

Construction in progress	202,109	65,693
	35,519,266	35,137,112
Accumulated depreciation	(24,667,519)	(23,783,910)
	$ 10,851,747	$ 11,353,202

Depreciation expense for the years ended December 31, 2018, 2017, and 2016 was $883,610; $830,715; and $867,080, respectively.

6. LICENSE AGREEMENT

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 $2,944,102; $2,864,188;

Table of Contents

and $2,527,508 are included in Cost of sales for the years ended December 31, 2018, 2017, and 2016, respectively. Royalties payable under this agreement aggregated $769,324 and $793,489 at December 31, 2018, and 2017, respectively. Gross sales upon which royalties are based were $58,882,042; $57,283,780; and $50,550,165 for 2018, 2017, and 2016, respectively.

7. OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	December 31,	
	2018	2017
Prepayments from customers	$ 860,926	$ 355,742
Accrued property taxes	170,568	14,681
Accrued professional fees	294,903	231,826
Other accrued expenses	60,890	55,674
	$ 1,387,287	$ 657,923

8. LONG-TERM DEBT

Long-term debt consists of the following:

	December 31,	
	2018	2017
Loan from American First National Bank. Maturity date is April 10, 2028. The loan, in the original amount of $4,209,608, 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 equal to prime rate plus 0.25%. The interest rate was 5.75% at December 31, 2018.	$ 2,878,980	$ 3,094,301
Note payable to Deutsche Leasing USA, Inc. The interest rate was 3.69%. The original amount of the note was $276,495 with a 36 month maturity which ended 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.		56,180
Note payable to Deutsche Leasing USA, Inc. The interest rate is 4.25%. The original amount of the note was $525,017 with a 36 month maturity ending in November 2019. Beginning December 2016, the loan became payable in equal installments of principal and interest of approximately $15,500. Collateralized by molding machines and ancillary equipment.	167,028	341,877
	3,046,008	3,492,358
Less: current portion	(406,361)	(410,949)
	$ 2,639,647	$ 3,081,409

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, 2018, are as follows:

2019	$	406,361
2020		253,280
2021		268,886
2022		284,988
2023		302,053
Thereafter		1,530,440
	$	3,046,008

Table of Contents

9. COMMITMENTS AND CONTINGENCIES

In May 2010, the Company and an officer s suit against Becton, Dickinson and Company (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 including, among other things, a requirement to notify certain customers and others regarding misleading disclosures. In connection with BD s subsequent appeal, on December 2, 2016, the United States Court of Appeals for the Fifth Circuit overturned the antitrust damages. The finding of false advertising liability was affirmed and the case was remanded to the Eastern District of Texas for a redetermination as to the amount of damages to which the Company is entitled. On August 17, 2017, the District Court for the Eastern District of Texas issued the Court s Final Judgment ordering that the Company take nothing in its suit against BD and dismissing the case. The Company filed a notice of Appeal with the United States Court of Appeals for the Fifth Circuit on November 3, 2017. Briefing for the appeal was completed by the parties on May 2, 2018 and oral argument occurred on October 3, 2018. On March 26, 2019, the U.S. Court of Appeals for the Fifth Circuit issued an opinion affirming the District Court s take nothing judgment.

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 preceding paragraph. The case remains stayed as a result of the ongoing proceedings regarding the Lanham Act claims in the separate proceeding described above.

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, 2018, 2017, and 2016 was $79,331; $77,015; and $74,772, respectively. Future annual minimum rental payments as of December 31, 2018, are presented below:

2019	$	81,694
2020		84,155
Total	$	165,849

10. INCOME TAXES

The provision (benefit) for income taxes consists of the following:

	For the Years Ended December 31,		
	2018	2017	2016
Current tax provision (benefit)			
Federal	$ (13,318)	$	$
State		848	1,132
Total current provision (benefit)	(13,318)	848	1,132
Deferred tax provision (benefit)			
Federal		(188,456)	
State			
Total deferred tax provision (benefit)		(188,456)	
Total income tax provision (benefit)	$ (13,318)	$ (187,608)	$ 1,132

Table of Contents

The Company has $27.2 million in tax benefits attributable to net operating losses for federal tax purposes. The loss carry forwards will begin to expire in 2028 for federal tax purposes and will begin to expire for state tax purposes in 2021. The Company also has credits for alternative minimum taxes (AMT) paid of $202 thousand. The alternative minimum tax was repealed with the enactment of the Act. AMT credits carried over may be used to offset regular tax liability for any tax year. Any unused credits are 50% refundable for tax years 2018-2020, and 100% refundable for tax years beginning 2021. The Company has recorded the AMT credit as a tax receivable on its financial statements rather than as a deferred tax asset, as this amount is a refundable credit.

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,	
	2018	**2017**
Deferred tax assets		
Net operating loss carry forwards	$ 6,668,238	$ 6,127,210
Accrued expenses and reserves	436,627	509,666
Employee stock option expense	76,150	76,150
Nonemployee stock option expense	8,268	8,268
Inventory	132,114	224,353
Impairment	112,000	112,000
Deferred tax assets	7,433,397	7,057,647
Deferred tax liabilities		
Property and equipment	(1,281,999)	(1,231,693)
Deferred tax liabilities	(1,281,999)	(1,231,693)
Net deferred assets	6,151,398	5,825,954
Valuation allowance	(6,151,398)	(5,825,954)
Net deferred tax assets	$	$

Utilization of the net operating loss carry forwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions.

Deferred income tax calculations reflect the effects of temporary differences between the carrying amounts of assets and liabilities and their tax bases, as well as from net operating loss carry forwards, and are stated at the U.S. tax rate of 21% beginning in 2018. Net operating losses incurred after December 31, 2017 can only offset 80% of taxable income. However, these net operating losses may be carried forward indefinitely instead of limited to twenty years under previous tax law. Carrybacks of these losses are no longer permitted. Deferred income tax assets represent amounts available to reduce income taxes payable on taxable income in future years. The Company has fully reserved these future tax deductions.

The valuation allowance increased $325,444 for 2018. The valuation allowance decreased $3,371,379 for 2017.

Table of Contents

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

	December 31,		
	2018	2017	2016
Income tax at the federal statutory rate	21.0%	35.0%	35.0%
State tax, net of federal tax	3.5	2.9	2.9
Change in valuation allowance	(24.3)	85.9	(39.1)
Permanent differences	(0.3)	5.7	4.7
Return-to-provision and other		(37.6)	(3.5)
Tax Reform and Jobs Act tax rate change	0.1	(81.1)	
Incentive stock options		(6.0)	
Effective tax rate	%	4.8%	%

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, 2015, 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.

11. STOCK OPTION GRANTS AND EXERCISES

On September 9, 2016, the Compensation and Benefits Committee approved grants of incentive stock options to the Company s employees under the First Amended 2008 Stock Option Plan with exercise prices at fair market value ($2.75 per share), a ten-year term, and one-year vesting period, except to the extent that such vesting period would violate the First Amended 2008 Stock Option Plan. In total, the stock options are exercisable into 500,400 shares of Common Stock. The value of an option for the purchase of one underlying common share was valued at $1.783, using the Black Scholes Option Pricing Model using a risk-free rate of 1.51%, a volatility factor of 67.1%, and a 7.1 year expected life.

On December 27, 2016, the Compensation and Benefits Committee approved grants of stock options to the Company s chief financial officer, general counsel, and all three independent directors for 50,000 shares each with ten-year terms under the First Amended 2008 Stock Option Plan with exercise prices at fair market value ($1.05 per share). The executive officers options vested on December 27, 2017 and the independent directors options vested immediately. The value of an option for the purchase of one underlying common share was valued at $0.728, using the Black Scholes Option Pricing Model using a risk-free rate of 2.37%, a volatility factor of 72.5%, and a 7.1 year expected life.

No stock options were exercised in 2017 or 2018. Stock options were exercised at various dates in 2016 and, consequently, a total of 1,046,580 shares of Common Stock were issued in 2016 for an aggregate payment of $855,021. These options were granted in 2008 and 2009 at exercise prices of $0.81 and $1.30.

12. DIVIDENDS

The Board declared and the Company paid dividends to Series I and Series II Class B Preferred Shareholders in the following amounts: $12,313 and $42,800, respectively, on April 21, 2016, July 28, 2016, October 20, 2016, January 6, 2017, April 24, 2017, July 20, 2017, October 20, 2017, January 19, 2018, April 24, 2018, July 20, 2018, October 23, 2018, and January 18, 2019.

13. 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.

Table of Contents

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, 2018 and 2017. 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, 2018 and 2017. 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 $49,250 in each of 2018, 2017, and 2016. At December 31, 2018, no dividends were in arrears.

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. No shares of Series I Class B Stock were converted into Common Stock in 2018 or 2017. 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 shares of $1 par value Series II Class B Stock outstanding at December 31, 2018 and 2017. 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 $171,200 in each of 2018, 2017, and 2016. At December 31, 2018, 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. No shares were converted in 2018 or 2017. 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 shares of $1 par value Series III Class B Stock outstanding at December 31, 2018 and 2017. 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, 2018, approximately $4,275,000 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.

Table of Contents

No shares were converted in 2018 or 2017. 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 shares of $1 par value Series IV Class B Stock outstanding at December 31, 2018 and 2017. 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, 2018, approximately $6,484,000 of dividends which have not been declared were in arrears.

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. No shares of Series IV Class B Stock were converted into Common Stock in 2018 or 2017. 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, plus all 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, 2018 and 2017. 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, 2018, approximately $1,009,000 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. No shares of Series V Class B Stock were converted into Common Stock in 2018 or 2017. 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 all 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 32,666,454 shares were outstanding at December 31, 2018 and 2017. Additionally, as of December 31, 2018, a total of 2,139,248 shares of Common Stock were issuable upon the conversion of Preferred Stock and the exercise of stock options.

14. RELATED PARTY TRANSACTIONS

The Company has a license agreement with the Chief Executive Officer of the Company. See Note 6.

In 2016, the Company granted a right to three of its executive officers to purchase shares of Common Stock directly from the Company at market prices. Two such officers allowed their purchase rights to expire in 2018. Thomas J. Shaw, CEO, exercised his purchase rights on January 12, 2017, buying two million shares at market price for an aggregate purchase price of $1.78 million, and he exercised the remainder of his purchase rights on August 23, 2017 by purchasing one million shares at market price for aggregate consideration of $570,100.

Table of Contents

In November 2016, the Company granted a stock option to its Chief Executive Officer for the purchase of three million shares of Common Stock. Such stock option terminated by its terms before becoming exercisable following a December 27, 2016 shareholder vote against such option.

15. STOCK OPTIONS

Stock options

Options for the purchase of 3,649,508 shares of Common Stock have been issued under the 2008 Stock Option Plan. Options for the purchase of 1,357,803 shares under the 2008 Stock Option Plan were outstanding as of December 31, 2018. No shares are available for future issuance under the 2008 Stock Option Plan which expired July 25, 2018. A stock option for 3,000,000 shares granted to Thomas J. Shaw on November 2, 2016 terminated by its terms prior to becoming exercisable following a December 27, 2016 shareholder vote against such option.

The Compensation and Benefits Committee administered the Company s stock option plan prior to its termination.

Employee options

A summary of Director, officer, and employee options granted and outstanding under the 2008 Stock Option Plan is presented below:

	Years Ended December 31,					
	2018		2017		2016	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	1,805,519	$ 1.51	1,817,919	$ 1.52	2,125,069	$ 0.94
Granted		$		$	750,400	$ 2.18
Exercised		$		$	(1,046,580)	$ (0.82)
Forfeited	(505,216)	$ (1.36)	(12,400)	$ (2.75)	(10,970)	$ (1.08)
Outstanding at end of period	1,300,303	$ 1.57	1,805,519	$ 1.51	1,817,919	$ 1.52
Exercisable at end of period	1,300,303	$ 1.57	1,803,119	$ 1.51	1,218,519	$ 1.06

No options were issued in 2018 or 2017 to employees. 600,400 employee stock options were issued in 2016. A grant of three million options to the Company s chief executive officer terminated by its terms prior to becoming exercisable. The fair value of the September 2016 grants exercisable into 500,400 shares was $1.783 per share of underlying Common Stock and was estimated on the date of the grant using the Black Scholes pricing model with the following assumptions: expected volatility of 67.1%, risk free interest rate of 1.51%, and an expected life of 7.1

years. These options were issued under the First Amended 2008 Stock Option Plan. The fair value of the December 2016 grants exercisable into 100,000 shares was $0.728 per share of underlying Common Stock and was estimated on the date of the grant using the Black Scholes pricing model with the following assumptions: expected volatility of 72.5%, risk free interest rate of 2.37%, and an expected life of 7.1 years. These options were issued under the First Amended 2008 Stock Option Plan.

No options were issued to non-employee directors in 2018 or 2017. 150,000 stock options were issued to non-employee directors in 2016. The fair value of the 2016 grants was $0.728 per share of underlying Common Stock and was estimated on the date of the grant using the Black Scholes pricing model with the following

Table of Contents

assumptions: expected volatility of 72.5%, risk free interest rate of 2.37%, and an expected life of 7.1 years. These options were issued under the First Amended 2008 Stock Option Plan.

The following table summarizes information about Director, officer, and employee options outstanding under the stock option plan at December 31, 2018:

Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
$ 1.46	50,000	4.37	50,000
$ 0.81	535,303	0.54	535,303
$ 1.05	250,000	7.99	250,000
$ 2.75	465,000	7.70	465,000

Non-employee options

A summary of options outstanding and held by non-employees is as follows:

	Years Ended December 31,					
	2018		2017		2016	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	57,500	$ 0.81	57,500	$ 0.81	57,500	$ 0.81
Granted		$		$		$
Exercised		$		$		$
Forfeited		$		$		$
Outstanding at end of period	57,500	$ 0.81	57,500	$ 0.81	57,500	$ 0.81
Exercisable at end of period	57,500	$ 0.81	57,500	$ 0.81	57,500	$ 0.81

The following table summarizes information about non-employee options outstanding under the stock option plan at December 31, 2018:

Exercise Price	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
$ 0.81	57,500	0.54	57,500

The Company recorded $388 thousand of stock-based compensation expense in 2016. In 2017, the Company recognized stock-based compensation expense of $672 thousand. The Company recorded no stock-based compensation expense in 2018. The total intrinsic value of options exercised was $0; $0; and $1,414,892 in 2018, 2017, and 2016, respectively. There were no options outstanding and exercisable with

exercise prices lower than market price at December 31, 2018.

Table of Contents

Options Pricing Models Assumptions

The expected life is based on the Company s historical experience with option exercise trends. The assumptions for expected volatility is based on a calculation of volatility over the five-years preceding the grant date. Risk-free interest rates are set using grant-date U.S. Treasury yield curves. In its calculations, the Company assumed no dividends.

16. 401(k) PLAN

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. The 401(k) Plan is available to all employees on the first day of the month after 90 days of service. 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 first quarter of 2016, the Company reinstituted a policy of matching. For 2016, 2017, and 2018, the Company matched each participant s elective deferrals up to 2% of the participant s compensation for the pay period. The total match was $122,369 in 2016 and $145,474 in 2017 and $145,146 in 2018.

17. BUSINESS SEGMENT

The following is a summary of the Company s sales and long-lived assets by geography:

	2018	2017	2016
U.S. sales	$ 28,646,574	$ 27,015,712	$ 26,308,246
North and South America sales (excluding U.S.)	3,597,444	6,380,745	2,741,518
Other international sales	1,030,684	1,097,381	776,872
Total sales	$ 33,274,702	$ 34,493,838	$ 29,826,636
Long-lived assets			
U.S.	$ 10,738,253	$ 11,215,583	$ 11,930,293
International	$ 113,494	$ 137,619	$ 161,744

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.

18. BONUSES

In February 2017, Mr. Cowan and Ms. Larios were each granted cash bonuses of $250,000. Ms. Larios received her bonus in the first quarter of 2017. Mr. Cowan received his bonus in the fourth quarter of 2017.

19. STORM DAMAGE AND INSURANCE PROCEEDS

On March 26, 2017, a hail storm passed through Little Elm, Texas, resulting in damage to the Company s two buildings. During April 2017, the Company performed an inspection of its facilities and determined that possible roof damage had been sustained. In late April 2017, the Company s insurance carrier inspected the two buildings and confirmed that damage occurred from the hail storm. This damage was principally to the roofs of the buildings but also many of the HVAC units and a wall alongside one of the buildings were also damaged.

The Company s insurance carrier has assessed damages of $1,009,960 and the Company s deductible is $5,000. The Company received these funds from its carrier in the second quarter of 2017. Repairs commenced during the third quarter of 2017. All repairs were completed in the fourth quarter of 2018.

Table of Contents

During 2017, the Company incurred and recognized $538,667 in repairs due to the storm damage. Repair expense during 2018 was $203,289. This repair expense was offset by the insurance proceeds, resulting in no impact to the Statements of Operations. The remaining insurance proceeds of $261 thousand were recognized as income in the fourth quarter of 2018.

20. SUBSEQUENT EVENTS

On March 26, 2019, the U.S. Court of Appeals for the Fifth Circuit issued an opinion affirming the take nothing judgment of the District Court in the Company and an officer s suit against BD. The Company is evaluating this ruling and conferring with legal counsel regarding possible future action.

SELECTED QUARTERLY FINANCIAL DATA - UNAUDITED

The selected quarterly financial data for the periods ended December 31, 2018, and 2017, 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. Certain quarterly amounts may differ from full year totals due to rounding.

	(In thousands, except for per share and outstanding stock amounts) 2018			
	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Sales, net	$ 7,673	$ 7,475	$ 9,863	$ 8,264
Cost of sales	4,813	5,407	7,067	5,766
Gross profit	2,860	2,068	2,796	2,498
Total operating expenses	3,017	3,007	2,856	2,923
Income from insurance proceeds				261
Loss from continuing operations	(157)	(939)	(60)	(164)
Interest and other income	28	35	39	42
Interest expense	(50)	(44)	(42)	(41)
Provision (benefit) for income taxes				(13)
Net loss	(179)	(948)	(63)	(150)
Preferred stock dividend requirements	(176)	(176)	(176)	(177)
Loss applicable to common shareholders	$ (355)	$ (1,124)	$ (239)	$ (327)
Basic loss per share	$ (0.01)	$ (0.03)	$ (0.01)	$ (0.01)
Diluted loss per share	$ (0.01)	$ (0.03)	$ (0.01)	$ (0.01)
Loss per share from continuing operations	$ (0.01)	$ (0.03)	$ (0.01)	$ (0.01)
Weighted average common shares outstanding - basic	32,666,454	32,666,454	32,666,454	32,666,454
Weighted average common shares outstanding - diluted	32,666,454	32,666,454	32,666,454	32,666,454
Gross profit margin	37.3%	27.7%	28.3%	30.2%

Table of Contents

	(In thousands, except for per share and outstanding stock amounts) 2017			
	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Sales, net	$ 6,924	$ 7,646	$ 10,412	$ 9,512
Cost of sales	4,599	5,437	7,152	7,335
Gross profit	2,325	2,209	3,260	2,177
Total operating expenses	3,477	3,514	3,293	3,466
Loss from continuing operations	(1,152)	(1,305)	(33)	(1,289)
Interest and other income	10	14	19	22
Interest expense	(48)	(58)	(53)	(52)
Provision (benefit) for income taxes				(188)
Net loss	(1,190)	(1,349)	(67)	(1,131)
Preferred stock dividend requirements	(176)	(176)	(176)	(176)
Loss applicable to common shareholders	$ (1,366)	$ (1,525)	$ (243)	$ (1,307)
Basic loss per share	$ (0.04)	$ (0.05)	$ (0.01)	$ (0.04)
Diluted loss per share	$ (0.04)	$ (0.05)	$ (0.01)	$ (0.04)
Loss per share from continuing operations	$ (0.04)	$ (0.05)	$ (0.01)	$ (0.04)
Weighted average common shares outstanding - basic	31,333,121	31,666,454	32,166,454	32,666,454
Weighted average common shares outstanding - diluted	31,333,121	31,666,454	32,166,454	32,666,454
Gross profit margin	33.6%	28.9%	31.3%	22.9%

Major variances for 2018 as compared to 2017 are due to increased domestic sales, offset by a decline in international sales. Costs of manufacture declined due to lower volumes and lower unit costs. In 2018, there were lower legal expenses, no bonuses, and no stock option expense. These reductions were reduced somewhat by severance costs. We recognized Insurance proceeds in 2018. We had tax credits due to AMT of $188,000 in 2017 and $13,000 in 2018.

Table of Contents

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

There were no reportable disagreements with accountants on accounting and financial disclosures.

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, 2018, our disclosure controls and procedures were effective.

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 (2013)* 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. Management, with the participation of our CEO and CFO, concluded that our internal control over financial reporting as of December 31, 2018, was effective. No material weaknesses in our internal control over financial reporting were identified by Management.

Our Management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all instances of fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the fourth quarter of 2018 or subsequent to December 31, 2018, which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information in the sections Proposal 1 The Election of Three Class 1 Directors and Corporate Governance in the 2019 proxy statement are incorporated herein by reference.

Item 11. Executive Compensation.

The information in the section Compensation in the 2019 proxy statement is incorporated herein by reference.

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

The information in the section Security Ownership in the 2019 proxy statement is incorporated herein by reference. See also Item 5 of Part II of this Annual Report for Equity Compensation Plan Information.

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

The information in the section Corporate Governance in the 2019 proxy statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information in the section Accounting Matters in the 2019 proxy statement is incorporated herein by reference.

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, 2018, 2017, and 2016:

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Provision for Inventories				
Fiscal year ended 2016	$ 681,395	$ 176,424	$ 262,296	$ 595,523
Fiscal year ended 2017	$ 595,523	$	$ 584	$ 594,939
Fiscal year ended 2018	$ 594,939	$	$ 297,731	$ 297,208
Provision for Accounts Receivable				
Fiscal year ended 2016	$ 1,795,481	$ 92,000	$ 155,496	$ 1,731,985
Fiscal year ended 2017	$ 1,731,985	$ 24,272	$ 1,654,385	$ 101,872
Fiscal year ended 2018	$ 101,872	$ 47,793	$	$ 149,665
Deferred Tax Valuation				
Fiscal year ended 2016	$ 7,751,972	$ 1,445,361	$	$ 9,197,333
Fiscal year ended 2017	$ 9,197,333	$	$ 3,371,379	$ 5,825,954
Fiscal year ended 2018	$ 5,825,954	$ 325,444	$	$ 6,151,398

Table of Contents

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Provision for Rebates		(A)	(B)	(C)
Fiscal year ended 2016	$ 41,171,880	$ 19,693,872	$ 21,882,467	$ 38,983,285
Fiscal year ended 2017	$ 38,983,285	$ 21,738,072	$ 55,927,164	$ 4,794,193
Fiscal year ended 2018	$ 4,794,193	$ 24,372,111	$ 24,579,457	$ 4,586,847

(A) Represents estimated rebates deducted from gross revenues

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

(C) Includes $3,896,341; $4,115,628; and $3,591,534 in Accounts payable for 2018, 2017, and 2016, respectively.

(3) Exhibits:

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

(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	Voting Agreement Between Thomas J. Shaw and Suzanne August dated November 8, 2006
14	Retractable Technologies, Inc. Code of Business Conduct and Ethics
31.1	Certification of Principal Executive Officer

Table of Contents

Exhibit No.	Description of Document
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, 2018, and 2017, (ii) the Statements of Operations for the years ended December 31, 2018, 2017, and 2016, (iii) the Statements of Changes in Stockholders Equity for the years ended December 31, 2018, 2017, and 2016, (iv) the Statements of Cash Flows for the years ended December 31, 2018, 2017, and 2016, 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
***	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 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

Item 16. Form 10-K Summary.

None.

Table of Contents

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

March 28, 2019

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 28, 2019

/s/ Amy Mack
AMY MACK
DIRECTOR

March 28, 2019

/s/ Marco Laterza
MARCO LATERZA
DIRECTOR

March 28, 2019

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

March 28, 2019

/s/ Darren E. Findley
DARREN E. FINDLEY
DIRECTOR

March 28, 2019

20