

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from to

Commission file number 001-16465

Retractable Technologies, Inc.

(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of
incorporation or organization)

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

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

75068-5295
(Zip Code)

972-294-1010

Registrant's telephone number, including area code

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

Title of each class
Common

Trading Symbol
RVP

Name of each exchange on which registered
NYSE American LLC

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

Preferred Stock
(Title of class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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 ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the common equity held by non-affiliates as of June 30, 2020, was \$121,416,123, assuming a closing price of \$7.02 and outstanding shares held by non-affiliates of 17,295,744.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

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

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of March 12, 2021, there were 33,982,604 shares of our Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's [Proxy Statement filed on an even date herewith for the Annual Meeting of Shareholders to be held May 11, 2021](#) are incorporated by reference into Part III hereof.

RETRACTABLE TECHNOLOGIES, INC.
FORM 10-K
For the Fiscal Year Ended December 31, 2020

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PART I

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words “could,” “may,” “believes,” “anticipates,” “intends,” “expects,” and similar such 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, the impact of COVID-19 on all facets of logistics and operations, as well as costs, our ability to complete capital improvements and ramp up domestic production in response to government agreements, potential tariffs, our ability to maintain liquidity, our maintenance of patent protection, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, foreign trade risk, our ability to access the market, production costs, 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. Our syringes are used for vaccinations and our revenues for 2020 materially increased over prior years due to demand during the COVID-19 pandemic. Our principal customer was the U.S. government which purchased products representing 39.0% (\$31.6 million) of our revenues in 2020. We have manufacturing facilities in Little Elm, Texas and use manufacturers in China as well. We are increasing our capacity for production at our U.S. manufacturing facility, funded in part by a grant by the U.S. government.

Description of Business

Our dominant revenue-generating products are our injection devices (syringes and needles). Such products are marketed under the VanishPoint[®], Patient Safe[®], and EasyPoint[®] brands. Other products which make up approximately 4.3% of our revenues include our blood collection devices and IV catheters. We have only one reporting segment. Most of our products incorporate a feature whereby our needles retract which is a safety feature designed to protect healthcare workers from needlestick injuries. Our VanishPoint[®] 1mL syringes meet the criteria set by pharmaceutical manufacturers for low dead space, which results in a reduction of wasted medication caused by residual medication remaining in the syringe after a dose has been administered. In some instances, the low dead space allows for additional doses to be obtained from a medication vial.

In 2020, the U.S. government was a significant customer due to efforts to vaccinate the U.S. population against COVID-19. On May 1, 2020, we received an order from the Department of Health and Human Services to supply certain automated safety syringes through May 2021 for \$83.8 million (the “HHS Order”), plus \$10 million in expedited freight costs. As of December 31, 2020, we recorded sales of \$31.6 million under the 2020 HHS Order, representing 39.0% of our overall revenues for 2020. In February 2021, we received a new contract from the Department of Health and Human Services for additional safety syringes representing \$54.2 million in expected revenues and reimbursable freight costs for a five-month base period of performance (February 15, 2021 to July 14, 2021) with additional renewal periods available at the option of the U.S. government.

During 2020, we also continued to provide products to our existing and new private healthcare customers. Our growth in sales in 2020 was predominantly driven by demand for syringes for COVID-19 vaccines and flu vaccines. Meeting demand for COVID-19 vaccines will continue to be our primary focus for the first half of 2021. As of December 31, 2020, our production and deliveries materially met or exceeded contract requirements despite the significant increase in demand.

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.

VanishPoint® syringe sales have historically comprised most of our sales. VanishPoint® syringe sales were 84.0%, 85.3%, and 84.0% of our revenues in 2018, 2019, and 2020. EasyPoint® products accounted for 11.8% of sales in 2020.

We currently have under development additional safety products that add to or build upon our current product line offering. Notwithstanding the foregoing, our primary focus over the last year has centered on providing existing products to meet demand related to COVID-19 vaccinations.

Our products are sold to and used by healthcare providers primarily in the U.S. (with 9.8% of revenues in 2020 generated from sales outside the U.S.).

In years not dominated by direct sales to the U.S. government, representatives of group purchasing organizations (“GPOs”) and purchasing representatives (rather than the end-users of the product) make the vast majority of decisions relating to the purchase of medical supplies. 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.

Sources and Availability of Raw Materials

Our product components, including needle adhesives and packaging materials, are purchased from various suppliers. There is no current 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 generally receives a five percent (5%) royalty on gross sales of products subject to the license and he receives fifty percent (50%) of the royalties paid to the Company by certain sublicensees of the technology subject to the license.

Recent and expected modifications to our VanishPoint® syringes will effectively cause the modified VanishPoint® syringes products to have extended patent expiration dates. Following the expiration of patents related to the old design, competitors may attempt to copy aspects of such prior design, but not the current design. Patents related to recent modifications to the VanishPoint® syringes and core technology of the VanishPoint® syringes will expire during the years 2028 through 2032. Other patent applications covering inventions applicable to the VanishPoint® syringes 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”®.

Seasonality

Historically, unit sales have increased during the flu season. We cannot determine what percent of our increase in domestic sales (excluding the HHS Order) in the second half of 2020 were attributable to flu shots versus preparation for a COVID-19 vaccine.

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 Contracts

In 2020, we entered into a material contract with the U.S. government providing a significant grant and accepted the HHS Order under an existing contract for the sale of syringes. In February 2021, we and the Department of Health and Human Services entered into a new contract and it placed another material order with us for syringes. All such contracts may be terminated by the U.S. government but given current conditions with COVID-19, we do not believe termination (or renegotiation) is likely.

Government Approval and Government Regulations

The development, manufacture, marketing, sale, promotion, and distribution of our products are subject to government regulation by the U.S. Food and Drug Administration (FDA) and similar international regulatory agencies. Regulation by various international, federal and state agencies address the development and approval to market medical products, as well as approval and supervision of manufacturing, labeling, packaging, supply chains, distribution and record-keeping.

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.

Compliance with domestic and international laws and regulations may affect our business. Among other effects, health care regulations and significant changes thereto may substantially increase the time, difficulty, and costs incurred in developing, obtaining, and maintaining approval to market, and marketing newly developed and existing products. We expect this regulatory environment will continue to require effort and investment to ensure compliance. Failure to comply could delay the release of a new product or result in regulatory and enforcement actions, the seizure or recall of a product, the suspension or revocation of the authority necessary for a product's production and sale, and other civil or criminal sanctions including fines and penalties.

The regulation of data privacy and security, and the protection of the confidentiality of certain personal information (including patient health information, financial information, and other sensitive personal information), is increasing. For example, the European Union, various other countries, and various U.S. states (e.g., California) have enacted stricter data protection laws that contain enhanced financial penalties for noncompliance. Similarly, the U.S. Department of Health and Human Services has issued rules governing the use, disclosure, and security of protected health information, and the FDA has issued further guidance concerning cybersecurity for medical devices. In addition, certain countries have issued or are considering "data localization" laws, which limit companies' ability to transfer protected data across country borders. Failure to comply with data privacy and security laws and regulations can result in business disruption and enforcement actions, which could include civil or criminal penalties.

The sale of medical products is subject to laws and regulations pertaining to health care fraud and abuse, including state and federal anti-kickback, anti-self-referral, and false claims laws in the United States.

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

In a typical year, the cost of compliance with government regulations does not have a material effect on our capital expenditures, earnings, or competitive position (as measured against other U.S. entities). We believe that we do not incur material costs in connection with compliance with environmental laws.

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 VanishPoint® 1mL syringes meet the criteria set by pharmaceutical manufacturers for low dead space, which results in a reduction of wasted medication caused by residual medication remaining in the syringe after a dose has been administered. In some instances, the low dead space allows for additional doses to be obtained from a medication vial. Our syringe products include passive safety activation, require less disposal space, and are activated while in the patient, reducing exposure to the contaminated needle. Our price per unit is competitive or even lower than the competition once all the costs incurred during the life cycle of a syringe are considered. Such life cycle costs include disposal costs, testing and treatment costs for needlestick injuries, and treatment for contracted illnesses resulting from needlestick injuries.

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.

Employees

As of March 9, 2021, we had 182 employees. 178 of such employees were full time employees. We provide equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, gender, national origin, age, disability, marital status, ancestry, veteran status, workers’ compensation status or any other characteristic protected by federal, state, or local law. We have adopted a policy of zero tolerance for any form of unlawful discrimination or retaliation.

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.

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 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 our products.

VanishPoint[®] syringes comprised 84.0% of sales in 2020. When the patents of 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.

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 2020, we used Chinese manufacturers to produce 85.2% of our products. We are currently working to expand our U.S. manufacturing facility, however.

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.

Trade protection measures, including tariffs, and/or changes to import or export requirements could materially adversely impact our operations. We cannot predict the impact of potential changes to U.S. foreign trade policy. Additionally, we derive 9.8% 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.

We Are Controlled by One Shareholder

Thomas J. Shaw, our President and Chief Executive Officer, has investment or voting power over a total of 46.1% of the outstanding Common Stock as of March 12, 2021. Mr. Shaw therefore has the ability to direct our operations and financial affairs and significant influence 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.

Our Stock Has Recently Experienced Significant Price Fluctuation

Our stock price experienced significant fluctuation during 2020 and may continue to be unpredictable. Our stock price fluctuated in 2020 from a low price in January of \$1.36 per share to a high in December of \$15.79 per share. As of March 12, 2021, the stock price was \$13.65 per share. We expect that the overall increase is connected with our recent orders from the Department of Health and Human Services and the Technology Investment Agreement, a contract with the U.S. government described in Item 2 of this report ("TIA"). We do not have assurance that the TIA will translate into increased sales of our products. Additionally, the products sold to the Department of Health and Human Services will be used in connection with administering a vaccine for COVID-19. We cannot predict our sales volumes if the country slows its immunization efforts.

Challenges from the Significant Orders

In 2020, the U.S. government was a significant customer representing 39.0% (\$31.6 million) of our net sales. With additional 2021 deliveries under the HHS Order plus the new February 2021 contract from the U.S. government, the U.S. government will likely continue to be a materially significant customer in 2021. This presents unusual challenges to our business. Our 2021 performance under these orders will be somewhat dependent upon our timely completion of expansions to our facility and machinery, which we cannot guarantee will occur according to schedule. Moreover, in light of the government's significant volume requirements, we may not be able to maintain our usual service levels to our existing customers. However, during 2020, we not only fulfilled obligations under the government's order, but we also increased delivery volumes to existing customers.

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. Additionally, our success depends on the quality, reliability, and safety of our products and defects in our products could damage our reputation. 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 healthcare rulemaking could affect our business. We cannot predict the timing or impact of any future rulemaking or changes in the law.

We May Experience Losses in Our Investment Account

Our investment portfolio is subject to market risk. As a result, the value and liquidity of our cash equivalents and marketable securities could fluctuate substantially. Likewise, our other income and expenses could vary materially depending on gains or losses realized on the sale or exchange of investments and other factors. Increased volatility in the financial markets and overall economic uncertainty could increase the risk that actual amounts realized on our investments may differ from the fair values currently assigned to them. Because 31.5% of our liquid assets are invested in the market, fluctuations in market values could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

Health Crises Could Have an Adverse Effect on Our Business

Particularly during 2020, several states and local jurisdictions imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Although our manufacturing facility has continued to operate during the 2020-2021 COVID-19 pandemic due to its status as an essential business, we continue to monitor the evolving

situation and cannot guarantee that the situation would be the same for any future pandemic. In the future, we may elect or be required to close temporarily which would result in a disruption in our activities and operations. Our supply chain, including transportation channels, may be impacted by any such restrictions as well. Any such disruption could impact our sales and operating results.

Widespread health crises also negatively affect economies which could affect demand for our products. With a new contract in place for 2021 sales directly to the U.S. government, our risk is somewhat mitigated for the 2021 year. However, in the event of a resurgence of this disease or in the case of any future pandemic, there is no guarantee that revenues from syringes needed for vaccines would offset the effects to our business of a global economic decline.

Health systems and other healthcare providers in our markets that provide procedures that use our products have suffered financially and operationally and may not be able to return to pre-pandemic levels of operations. Travel and import restrictions may also disrupt our ability to manufacture or distribute our devices. Any import or export or other cargo restrictions related to our products or the raw materials used to manufacture our products could restrict our ability to manufacture and ship products and harm our business, financial condition, and results of operations.

Our key personnel and other employees could still be affected by COVID-19 or any future pandemic, which could affect our ability to operate efficiently. In addition, the conduct of clinical trials and/or regulatory reviews of our new products may continue to be affected by the COVID-19 pandemic and would be affected in any future pandemic. Our sales and marketing personnel often rely on in-person and onsite access to healthcare providers which is currently restricted as hospitals are still not operating at pre-pandemic levels.

Disruption of Critical Information Systems or Material Breaches in the Security of Our Systems Could Harm Our Business, Customer Relations, and Financial Condition

Information technology helps us operate efficiently, interface with customers and suppliers, maintain financial accuracy and efficiency, and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions, or the loss of or damage to intellectual property through security breach. If our data management systems do not effectively collect, store, process, and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast, and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows, and the timeliness with which we report our internal and external operating results. Third parties may attempt to fraudulently induce employees or customers into sensitive information, which may in turn be used to access our information technology systems. In addition, unauthorized persons may attempt to hack into our systems to obtain our confidential or proprietary information or confidential information we hold on behalf of third parties. If the unauthorized persons successfully hack into or interfere with our system, we may experience a negative impact to our business and reputation. We have programs in place to detect, contain, and respond to data security incidents, and we make ongoing improvements to our systems in order to minimize vulnerabilities, in accordance with industry and regulatory standards. However, we may not be able to anticipate and prevent these intrusions or mitigate them when and if they occur. We also rely on external vendors to supply and/or support certain aspects of our information technology systems. The systems of these external vendors may contain defects in design or manufacture or other problems that could unexpectedly compromise information security of our own systems, and we are dependent on these third parties to deploy appropriate security programs to protect their systems. It is possible for such vulnerabilities to remain undetected for an extended period, including several years or longer. The costs to us to eliminate or alleviate network security problems, bugs, viruses, worms, ransomware and other malicious software programs, and security vulnerabilities could be significant. Our efforts to address these problems may not be successful and could result in unexpected interruptions, delays, cessation of service, and harm to our business operations. Depending on the type of breach, we could also be exposed to a risk of loss or litigation and potential liability, which could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

Illegal Distribution and Sale by Third Parties of Counterfeit Versions of Our Products Could Have A Negative Impact

Third parties may illegally distribute and sell counterfeit versions of our products which do not meet our rigorous manufacturing and testing standards. Our reputation and business could suffer harm as a result. In addition, diversion of products into other channels may result in reduced revenues.

We Are Subject to Various Risks Related To The PPP Loan.

Under our promissory note in favor of Independent Bank pursuant to the Paycheck Protection Program (the “PPP Loan”), we will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA. There can be no assurance that we will be eligible or able to take advantage of certain of the changes under the PPP Flexibility Act. The PPP Loan application required us to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or governmental regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to administrative penalties and could be required to repay the PPP Loan. Our request for loan forgiveness remains subject to audit and review by governmental entities.

General Risk Factors

We face risk factors common to other U.S. businesses. We could be subject to complex and costly regulation. Our business could suffer if we or our suppliers encounter manufacturing problems or disruptions to transportation channels. We could be subject to risks associated with doing business outside of the U.S, including risks associated with global economic, regulatory, or political changes, or health crises. Current or worsening economic conditions may adversely affect our business and financial condition.

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 14.8% of the units that were manufactured in 2020. 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.

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.

Effective July 1, 2020, we entered into a Technology Investment Agreement (“TIA”) with the United States Government Department of Defense, U.S. Army Contracting Command-Aberdeen Proving Ground, Natick Contracting Division & Edgewood Contracting Division (ACC-APG, NCD & ECD) on behalf of the Biomedical Advanced Research and Development Authority (BARDA) for \$53,664,286 in government funding for expanding our domestic production of needles and syringes. Pursuant to the terms of the TIA, we are expecting to make significant additions to our facilities which should allow us to increase domestic production. We have substantially completed construction of new controlled environment facilities and have begun construction of additional warehousing facilities which should be completed within the second quarter of 2021. The estimated cost of the controlled environment within existing properties is \$6.4 million, and construction of the new warehouse is estimated to be \$5.8 million. The cost of the controlled environment will be funded by the U.S. government under the TIA, while the cost of the new warehouse will be our financial obligation.

Item 3. Legal Proceedings.

Please refer to Note 10 to the financial statements for a complete description of all legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

MARKET INFORMATION

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

SHAREHOLDERS

As of March 12, 2021, there were 33,982,604 shares of Common Stock held by 184 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. Dividends on Common Stock cannot be paid so long as preferred dividends are unpaid. As of December 31, 2020, there was an aggregate of \$5.0 million in preferred dividends in arrears. As of December 31, 2019, there was an aggregate of \$12.3 million in preferred dividends in arrears.

EQUITY COMPENSATION PLAN INFORMATION

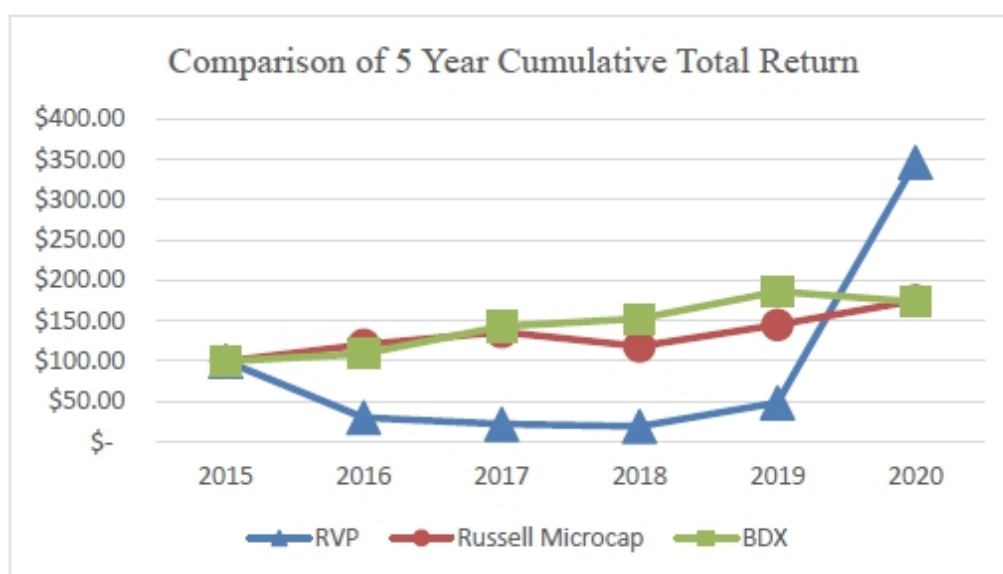
The following table sets forth information relating to our equity compensation plans as of December 31, 2020:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)
Equity compensation plans approved by security holders	199,450	\$2.05	—
Total	199,450	\$2.05	—

STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total return for our Common Stock (RVP) from December 31, 2015 to December 31, 2020, 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, 2015, and that all dividends are reinvested.



UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In addition to the transactions disclosed previously in Item 2 of Part II of the Quarterly Reports on Form 10-Q, in October 2020, we purchased a total of 30,000 shares of Series IV Preferred Stock and 25,000 shares of Series V Preferred Stock from six shareholders in exchange for a total of \$400,000 (of which \$303,330 is to be paid over a three-year period beginning February 2021) and 110,000 shares of Common Stock. Such preferred shareholders agreed to waive all unpaid dividends in arrears associated with their Preferred Stock, which resulted in a waiver of a total of \$757,759 in unpaid dividends in arrears.

In December 2020, we purchased a total of 20,000 shares of Series III Preferred Stock, 5,000 shares of Series IV Preferred Stock, and 9,000 shares of Series V Preferred Stock from five shareholders in exchange for a total of \$286,000 and 34,000 shares of Common Stock. Such preferred shareholders agreed to waive all unpaid dividends in arrears associated with their Preferred Stock, which resulted in a waiver of a total of \$592,892 in unpaid dividends.

We are relying on Section 3(a)(9) of the Securities Act of 1933, as amended (the “Securities Act”) to exempt the foregoing transactions from the registration requirements of the Securities Act.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Purchases by affiliate(s) during 2020 were not repurchases by or on behalf of the issuer.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
December 31, 2020 ⁽¹⁾	14,300	\$7.50 ⁽²⁾	14,300	0

(1) On November 24, 2020, we delivered to holders of Class B Series I Preferred Stock a Notice of Redemption notifying such preferred shareholders that, pursuant to the Certificate of Designation for the Series I Preferred Stock, we determined to redeem all Series I Preferred Stock. The redemption date was December 31, 2020. The redemption was publicly announced on Form 8-K on December 1, 2020.

(2) Not all Series I Preferred Shareholders have submitted adequate documentation to receive the redemption payments.

Item 6. Selected Financial Data.

Not required.

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

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words "could," "may," "believes," "anticipates," "intends," "expects," and similar such 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, the impact of COVID-19 on all facets of logistics and operations, as well as costs, our ability to complete capital improvements and ramp up domestic production in response to government agreements, potential tariffs, our ability to maintain liquidity, our maintenance of patent protection, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, foreign trade risk, our ability to access the market, production costs, 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.

Overview

We have been manufacturing and marketing our products since 1997. VanishPoint[®] syringes comprised 84.0% of our sales in 2020. EasyPoint[®] products accounted for 11.8% of sales in 2020. We also manufacture and market a blood collection tube holder, IV safety catheter, and VanishPoint[®] Blood Collection Set.

Our products have been and continue to be distributed nationally and internationally through numerous distributors.

On May 1, 2020, we were awarded the HHS Order under an existing contract by the Department of Health and Human Services of the United States to supply automated retraction safety syringes for COVID-19 vaccination efforts, which order was in the amount of \$83.8 million plus \$10 million in expedited freight costs. As of December 31, 2020, we recorded sales of \$31.6 million under the 2020 HHS Order, representing 39.0% of our overall revenues

for 2020, and we expect the remaining sales under the HHS Order in 2021. During 2020 and through March 2021, we have timely completed our delivery obligations under the HHS Order.

The Department of Health and Human Services awarded us another contract on February 12, 2021 to supply low dead space safety syringes for COVID-19 vaccination efforts. The base price for the contract and purchase order is \$54,217,800 for the five-month base period of performance (February 15, 2021 to July 14, 2021). Such price includes both the fixed price for the products as well as cost reimbursement for freight. The terms of the contract allow for extensions at the option of the U.S. government for up to seven additional one-month periods. If all option periods are exercised, the value of the contract could increase by an additional \$92,772,680, including the price of the products and freight reimbursement. For each period, the freight cost is estimated at approximately 25% of the overall price.

Effective July 1, 2020, we entered into the TIA with the United States Government Department of Defense, U.S. Army Contracting Command-Aberdeen Proving Ground, Natick Contracting Division & Edgewood Contracting Division (ACC-APG, NCD & ECD) on behalf of the Biomedical Advanced Research and Development Authority (BARDA) for \$53,664,286 in government funding for expanding our domestic production of needles and syringes. Pursuant to the terms of the TIA, we are expecting to make significant additions to our facilities which should allow us to increase domestic production. Additionally, the TIA provides for reimbursement for equipment and supplies. As of early March 2021, we have negotiated contracts for the purchase of automated assembly equipment, molds, and molding equipment, as well as portions of auxiliary equipment, for approximately \$42.1 million. As of March 2021, we have substantially completed construction of expanded facilities consisting of approximately 27,800 square feet of additional controlled environment within existing properties and we expect to complete approximately 55,000 square feet of new warehouse space within the second quarter of 2021. The estimated cost of the controlled environment within existing properties is \$6.4 million. The increase from the original \$6 million estimate is due to change orders and an expedited completion date in order to receive certain manufacturing equipment at an earlier date. The cost of the controlled environment will be funded by the U.S. government under the TIA, while the cost of the new warehouse will be our financial obligation.

Both of the abovementioned orders from the Department of Health and Human Services as well as the TIA from the U.S. government are material events particular to the COVID-19 pandemic and may not be indicative of future operations. While the addition of manufacturing equipment and facilities will greatly increase our production capacity, we cannot be assured that there will be increased demand for our products once orders from the U.S. government have been filled. If future orders are not placed by the U.S. government and orders from new and existing customers do not materialize, we would have significant excess productive capabilities.

On April 17, 2020, we entered into the PPP Loan in the principal amount of \$1,363,000 in favor of Independent Bank pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act, administered by the U.S. Small Business Administration ("SBA"). The PPP Loan's original maturity date is April 17, 2022 and bears interest at a rate of 1.0% per annum. We have applied for forgiveness for the entirety of the loan granted under the PPP. We cannot be certain of the amount, if any, which may be forgiven.

As detailed in Note 4 to the financial statements, we held \$8.1 million in debt and equity securities as of December 31, 2020, which represented 11.6% of our current assets. We continually monitor our invested balances.

During 2020, we hired 48 new full-time employees, predominantly as production line workers, and terminated several back office employees. We also moderately increased non-executive pay. The net effect of these actions caused a net increase of approximately \$1.8 million in our operating expenses for 2020 as compared to 2019.

Historically, unit sales have increased during the flu season. We cannot determine what percent of our increase in domestic sales (excluding the HHS Order) in the second half of 2020 were attributable to flu shots versus preparation for a COVID-19 vaccine.

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 2020, our Chinese manufacturers produced approximately 85.2% 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 and EasyPoint[®] needles.

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 of products subject to the license and he receives fifty percent (50%) of the royalties paid to the Company by certain sublicensees of the technology subject to the license.

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 2020 and 2019. Dollar amounts have been rounded for ease of reading.

Comparison of Year Ended December 31, 2020 and Year Ended December 31, 2019

Domestic sales, including sales to the U.S. government, accounted for 90.2% and 76.3% of the revenues in 2020 and 2019, respectively. Domestic revenues increased 131.4% principally due to increased volumes. Domestic unit sales increased 120.0%. Domestic unit sales were 85.9% of total unit sales for 2020. Domestic unit sales excluding the HHS Order rose approximately 36.4%. International revenues decreased 18.6% representing a return to normal levels after unusually high volumes in 2019. Our international orders may be subject to significant fluctuation over time. Overall unit sales increased 74.0%. Other than the Department of Health and Human Services, our increased sales are predominantly attributable to existing customers as well as several new smaller customers who do not operate as distributors. Our sales under the HHS Order were approximately \$31.6 million in 2020 and we expect the remaining sales under the HHS Order in 2021, as well as orders of at least \$54.2 million under the new February 2021 contract.

Cost of manufactured product increased 62.7% principally due to an increase in units sold. Royalty expense increased 58.7% due to increased gross sales. Gross profit margins increased from 33.8% in 2019 to 45.2% in 2020 principally due to an overall increase in sales.

Operating expenses increased 15.9% from the prior year due substantially to increased headcount and other employee-related expenses attributable to a larger volume of orders and the expansion activities required by the TIA.

Income from operations was \$24.1 million in 2020 compared to income from operations of \$3.0 million in 2019 due to the increase in net revenues and resulting gross profit.

Interest and other income increased \$1.8 million for the year ended December 31, 2020 compared to the same period last year principally due unrealized gains from our investments.

For the year ended December 31, 2020, we recorded a provision for income taxes of \$1,850,234. For a detailed description of the determination and components of calculating the provision, please refer to Note 11 of the financial statements.

During 2020, we engaged in private purchase agreements to purchase shares of outstanding preferred stock in exchange for cash consideration and the issuance of new common stock. We repurchased a total of 22,500 shares of Series III Class B Convertible Preferred Stock, 342,500 shares of Series IV Class B Convertible Preferred Stock,

and 34,000 shares of Series V Class B Convertible Preferred Stock. The aggregate cash consideration equaled \$3,786,000, of which \$482,670 was paid in 2020 with the remainder payable over a three-year period beginning in February 2021. The aggregate consideration was 754,000 shares of Common Stock. As a result of the transactions, \$7,642,049 in unpaid dividends were waived by the shareholders, as measured from the effective date of the transactions. In connection with the transactions, the difference between the fair value of the consideration transferred to the preferred shareholders and the carrying amount of the preferred stock was added to net income available to common shareholders as a deemed capital contribution for the purpose of the calculation of earnings per share. As a result of the described transactions, a total of \$2,975,708 was included in the calculation of Income (loss) applicable to common stockholders. Amounts payable as the result of our purchase of preferred stock also comprises a portion of the long-term liabilities set forth on our Balance Sheets. As further discussed in Note 9 of the financial statements, the long-term liabilities of \$24,478,697 also includes amounts related to reimbursements from the U.S. government in connection with the TIA.

A comparison of the results of operations for the years ended December 31, 2019 and December 31, 2018 is omitted from this discussion. Such comparison was included in our Annual Report on Form 10-K filed with the SEC on March 30, 2020 in Item 7 of Part II thereof.

LIQUIDITY AND CAPITAL RESOURCES

Discussion of Statement of Cash Flow Items

Cash flow from operations was \$19.0 million in 2020, principally due to our net income for the year. The increase in cash was offset by an increase in accounts receivable, largely driven by the HHS Order. There was also an increase in inventory. Additionally, we have recorded a deferred tax asset of \$4,631,206 which is material to the adjustments to total cash flow from operations. The deferred tax asset represents amounts available to reduce income taxes payable on taxable income in future years. The determination and calculation of such asset is further discussed in Note 11 of the financial statements.

Cash used by investing activities was \$19.3 million for the year ended December 31, 2020 due primarily to the purchase of property, plant and equipment, but offset by the net proceeds from the sales and purchases of debt and equity securities. The \$21.0 million impact to cash from the purchase of such fixed assets reflects down payments on orders for certain assets detailed in this report in connection with the TIA.

Cash provided by financing activities was \$12.0 million for the year ended December 31, 2020. This was primarily due to the proceeds from the PPP Loan, proceeds from the exercise of stock options, and proceeds from the government under the TIA for down payments on our orders for fixed assets.

Historical Sources of Liquidity

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

Internal Sources of Liquidity

Margins

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. Additionally, the effect of an overall increase in units sold also has a positive effect on margins. 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

We have sufficient cash reserves, received a PPP Loan, and have begun to realize income from operations. We also have access to our investments which may be liquidated in the event that we need to access the funds for operations.

Contracts with the U.S. Government

As discussed above, we were awarded a material delivery order by the Department of Health and Human Services of the United States in the total amount of approximately \$83.8 million, plus certain expedited freight expenses. For the year ended December 31, 2020, our sales under this HHS Order were approximately \$31.6 million and we expect such sales to increase each quarter through May 2021. In February 2021, we received a new contract from the Department of Health and Human Services for additional safety syringes representing \$54.2 million in expected revenues and reimbursable freight costs for a five-month base period of performance (February 15, 2021 to July 14, 2021) with additional renewal periods available at the option of the U.S. government.

As discussed above, we entered into a TIA with the U.S. government for approximately \$53.7 million in government funding for expanding our domestic production of needles and syringes. As of December 31, 2020, we have received approximately \$10.7 million for down payments on the purchase of certain fixed assets. Pursuant to the terms of the TIA, we have begun making significant additions to our facilities which should allow us to increase domestic production. We have substantially completed construction of new controlled environment facilities and we have begun construction of warehousing facilities which are expected to be completed in the second quarter of 2021. While a portion of the planned construction will be funded by the U.S. government, we expect to fund the construction of the new warehouse and expect the cost to be approximately \$5.8 million. Through December 31, 2020, have paid a total of approximately \$320,000 in progress payments for the new warehouse.

Option Exercises

Stock options were exercised by our employees and directors during 2020, and, consequently, we received approximately \$923 thousand to exercise such options.

External Sources of Liquidity

We recently received a PPP Loan, as described above, in the principal amount of \$1,363,000. We have applied for forgiveness of this loan but we cannot be certain of the amount, if any, which may be forgiven.

It is unlikely we would choose to raise funds by the public sale of equity despite recent increases in the value of our stock. Our stock price increased materially during 2020 and during the first several months of 2021.

We consider our investment portfolio a source of liquidity as well. For example, in the third quarter of 2020, we liquidated approximately \$4.0 million from our investment portfolio for operational needs. As of December 31, 2020, \$8.1 million was invested in third party securities.

Capital Resources

Since the execution of the TIA on July 1, 2020, we have begun construction for significant expansion to our facilities. As of March 2021, we have substantially completed construction of expanded facilities consisting of approximately 27,800 square feet of additional controlled environment within existing properties and we expect to complete approximately 55,000 square feet of new warehouse space within the second quarter of 2021. The estimated cost of the controlled environment within existing properties is \$6.4 million. The increase from the original \$6 million estimate is due to change orders and an expedited completion date in order to receive certain manufacturing equipment at an earlier date. As of early March 2021, we have negotiated contracts for the purchase of automated assembly equipment, molds, and molding equipment, as well as portions of auxiliary equipment, for approximately \$42.1 million. To fund the purchase of the automated assembly equipment, auxiliary equipment, and construction of the controlled environment, we are reimbursed by the U.S. government according to the terms in the TIA. The TIA also

allows us to request an advance of funds for larger purchases when necessary. The expenditures which are not reimbursable from the U.S. government under the TIA are funded with cash from operations.

OFF-BALANCE SHEET ARRANGEMENTS

None.

CONTRACTUAL OBLIGATIONS

Not applicable to smaller reporting companies.

CRITICAL ACCOUNTING ESTIMATES

We are responsible for developing estimates for amounts reported as assets and liabilities, and revenues and expenses in conformity with U.S. generally accepted accounting principles ("GAAP"). Those estimates require that we develop assumptions of future events based on past experience and expectations of economic factors. Among the more critical estimates management makes is the estimate for customer rebates. The amount reported as a contractual allowance for rebates involves examination of past historical trends related of our sales to customers and the related credits issued once contractual obligations of the customers have been met. The establishment of a liability for future claims of rebates against sales in the current period requires that we have an understanding of the relevant sales with respect to product categories, sales distribution channels, and the likelihood of contractual obligations being satisfied. We examine the results of estimates against actual results historically and use the determination to further develop our basis for assumptions in future periods, as well as the accuracy of past estimates.

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

Not applicable to smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

RETRACTABLE TECHNOLOGIES, INC.

**FINANCIAL STATEMENTS AND
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

DECEMBER 31, 2020, 2019, and 2018

RETRACTABLE TECHNOLOGIES, INC.
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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, 2020 and 2019, the related statements of operations, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition - Rebates

As described in Note 2 to the financial statements, the Company’s rebate accrual at December 31, 2020 is \$3,435,352. The Company recognizes revenue when it has satisfied all performance obligations to the customer. Under certain contracts, revenue is recorded based on the 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. Once rebates are issued they are applied against the customer’s receivable balance.

We identified management's estimates of rebates attributable to contractual pricing allowances, which are based on management's evaluation of available internal and external data and for which the Company has not received tracking reports, as a critical audit matter. The Company's evaluation uses internally developed assumptions, which involves a high degree of judgement. This leads to a high degree of auditor judgment and an increased extent of effort is required when performing audit procedures to evaluate the methodology and reasonableness of the estimates and assumptions.

The following are the most relevant procedures we performed to address this critical audit matter:

- We evaluated and tested the appropriateness of management's process for estimating rebates, including:
 - o Testing the completeness, accuracy, and relevance of the underlying data used in management's estimate.
 - o Obtaining management's analysis and supporting documentation related to sales distribution, and testing whether sales distribution factors used in the calculation of rebates were supported by the analysis provided by management.
- We developed an independent expectation of rebates based on historic trends in sales to distributors and credits issued and compared such expectation to the Company's estimate, including testing the completeness and accuracy of the data used in the calculation, application of product categories and sales distribution channels determined by management and used in the calculation, and recalculation of the rebates.
- We compared the year end rebate allowance to credits issued subsequent to year end and investigated variances between management's estimate and actual results.

/s/ Moss Adams LLP

Dallas, Texas
March 31, 2021

We have served as the Company's auditor since 2016.

RETRACTABLE TECHNOLOGIES, INC.
BALANCE SHEETS

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,566,682	\$ 5,934,749
Accounts receivable, net of allowance for doubtful accounts of \$205,822 and \$146,832	32,910,919	6,564,371
Investments in debt and equity securities, at fair value	8,081,833	7,771,660
Inventories, net	10,234,646	7,450,592
Income taxes receivable	—	50,392
Other current assets	684,317	635,201
Total current assets	<u>69,478,397</u>	<u>28,406,965</u>
Property, plant, and equipment, net	30,816,504	10,632,057
Income taxes receivable	—	50,393
Deferred tax asset	4,631,206	—
Other assets	44,567	88,315
Total assets	<u><u>\$ 104,970,674</u></u>	<u><u>\$ 39,177,730</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 16,256,444	\$ 5,007,604
Current portion of long-term debt	1,030,763	260,939
Accrued compensation	826,762	607,339
Dividends payable	49,091	54,800
Accrued royalties to shareholder	1,973,781	921,445
Other accrued liabilities	3,398,904	1,387,149
Income taxes payable	4,365,770	17,944
Total current liabilities	<u>27,901,515</u>	<u>8,257,220</u>
Other long-term liabilities	24,478,697	—
Long-term debt, net of current maturities	2,710,337	2,378,055
Total liabilities	<u>55,090,549</u>	<u>10,635,275</u>
Commitments and contingencies – See Note 10		
Stockholders' equity:		
Preferred Stock, \$1 par value:		
Class B; authorized: 5,000,000 shares		
Series I, Class B; outstanding: 0 and 96,000 shares at December 31, 2020 and 2019	—	96,000
Series II, Class B; outstanding: 156,200 and 171,200 shares at December 31, 2020 and 2019 (liquidation preference of \$1,952,500)	156,200	171,200
Series III, Class B; outstanding: 106,745 and 129,245 shares at December 31, 2020 and 2019 (liquidation preference of \$1,334,313)	106,745	129,245
Series IV, Class B; outstanding: 0 and 342,500 shares at December 31, 2020 and 2019	—	342,500
Series V, Class B; outstanding: 0 and 34,000 shares at December 31, 2020 and 2019	—	34,000
Common Stock, no par value; authorized: 100,000,000 shares; outstanding: 33,957,204 and 32,674,954 shares at December 31, 2020 and 2019	—	—
Additional paid-in capital	59,285,401	61,660,744
Accumulated deficit	(9,668,221)	(33,891,234)
Total stockholders' equity	<u>49,880,125</u>	<u>28,542,455</u>
Total liabilities and stockholders' equity	<u><u>\$ 104,970,674</u></u>	<u><u>\$ 39,177,730</u></u>

See accompanying notes to financial statements

RETRACTABLE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2020	2019	2018
Sales, net	<u>\$ 81,862,453</u>	<u>\$ 41,797,179</u>	<u>\$ 33,274,702</u>
Cost of Sales			
Costs of manufactured product	39,377,794	24,209,401	20,108,798
Royalty expense to shareholder	5,476,306	3,449,822	2,944,102
Total cost of sales	<u>44,854,100</u>	<u>27,659,223</u>	<u>23,052,900</u>
Gross profit	<u>37,008,353</u>	<u>14,137,956</u>	<u>10,221,802</u>
Operating expenses:			
Sales and marketing	4,061,904	4,217,863	4,404,441
Research and development	574,527	516,095	621,365
General and administrative	8,301,169	6,432,158	6,786,041
Total operating expenses	<u>12,937,600</u>	<u>11,166,116</u>	<u>11,811,847</u>
Income from insurance proceeds	—	—	260,514
Income (loss) from operations	<u>24,070,753</u>	<u>2,971,840</u>	<u>(1,329,531)</u>
Interest and other income	2,262,758	351,166	153,460
Interest expense	(260,264)	(166,897)	(177,190)
Income (loss) before income taxes	<u>26,073,247</u>	<u>3,156,109</u>	<u>(1,353,261)</u>
Provision (benefit) for income taxes	1,850,234	7,875	(13,318)
Net income (loss)	<u>24,223,013</u>	<u>3,148,234</u>	<u>(1,339,943)</u>
Preferred Stock dividend requirements	(573,868)	(702,618)	(704,996)
Deemed contribution on extinguishment of preferred stock	2,975,708	—	—
Income (loss) applicable to common stockholders	<u>\$ 26,624,853</u>	<u>\$ 2,445,616</u>	<u>\$ (2,044,939)</u>
Basic earnings (loss) per share	<u>\$ 0.80</u>	<u>\$ 0.07</u>	<u>\$ (0.06)</u>
Diluted earnings (loss) per share	<u>\$ 0.80</u>	<u>\$ 0.07</u>	<u>\$ (0.06)</u>
Weighted average common shares outstanding:			
Basic	<u>33,169,307</u>	<u>32,672,475</u>	<u>32,666,454</u>
Diluted	<u>33,300,654</u>	<u>32,672,475</u>	<u>32,666,454</u>

See accompanying notes to financial statements

RETRACTABLE TECHNOLOGIES, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	<u>Series I Class B</u>		<u>Series II Class B</u>		<u>Series III Class B</u>		<u>Series IV Class B</u>		<u>Series V Class B</u>		<u>Common</u>	
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>
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	—
Conversion of Preferred Stock into Common Stock	(2,500)	(2,500)	—	—	—	—	—	—	(6,000)	(6,000)	8,500	—
Dividends	—	—	—	—	—	—	—	—	—	—	—	—
Net income	—	—	—	—	—	—	—	—	—	—	—	—
Balance as of December 31, 2019	96,000	96,000	171,200	171,200	129,245	129,245	342,500	342,500	34,000	34,000	32,674,954	—
Exchange of Preferred Stock for Common Stock	—	—	—	—	(22,500)	(22,500)	(342,500)	(342,500)	(34,000)	(34,000)	754,000	—
Conversion of Preferred Stock into Common Stock	(81,700)	(81,700)	(15,000)	(15,000)	—	—	—	—	—	—	96,700	—
Stock Option Exercises	—	—	—	—	—	—	—	—	—	—	431,550	—
Redemption	(14,300)	(14,300)	—	—	—	—	—	—	—	—	—	—
Dividends	—	—	—	—	—	—	—	—	—	—	—	—
Net income	—	—	—	—	—	—	—	—	—	—	—	—
Balance as of December 31, 2020	—	\$ —	156,200	\$156,200	106,745	\$106,745	—	\$ —	—	\$ —	33,957,204	\$ —

See accompanying notes to financial statements

RETRACTABLE TECHNOLOGIES, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
Balance as of December 31, 2017	\$ 62,092,206	\$ (35,699,525)	\$ 27,174,126
Dividends	(220,450)	—	(220,450)
Net loss	<u>—</u>	<u>(1,339,943)</u>	<u>(1,339,943)</u>
Balance as of December 31, 2018	61,871,756	(37,039,468)	25,613,733
Conversion of Preferred Stock into Common Stock	8,500	—	—
Dividends	(219,512)	—	(219,512)
Net income	<u>—</u>	<u>3,148,234</u>	<u>3,148,234</u>
Balance as of December 31, 2019	61,660,744	(33,891,234)	28,542,455
Exchange of Preferred Stock for Common Stock	(3,090,672)	—	(3,489,672)
Conversion of Preferred Stock into Common Stock	96,700	—	—
Stock Option Exercises	922,512	—	922,512
Redemption	(92,950)	—	(107,250)
Dividends	(210,933)	—	(210,933)
Net income	<u>—</u>	<u>24,223,013</u>	<u>24,223,013</u>
Balance as of December 31, 2020	<u>\$ 59,285,401</u>	<u>\$ (9,668,221)</u>	<u>\$ 49,880,125</u>

See accompanying notes to financial statements

RETRACTABLE TECHNOLOGIES, INC.
STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net income (loss)	\$ 24,223,013	\$ 3,148,234	\$ (1,339,943)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Depreciation and amortization	832,069	852,080	886,814
Realized gains on investments	(162,595)	(7,925)	—
Net unrealized gains on investments	(1,870,010)	(129,315)	—
Deferred taxes	(4,631,206)	—	—
Inventories reserve	—	—	(297,731)
Provision for doubtful accounts, net of write-offs	59,440	—	47,793
Loss on disposal of assets	33,140	—	—
(Increase) decrease in operating assets:			
Accounts receivable	(14,626,910)	(1,652,015)	145,407
Inventories	(2,784,054)	94,502	(1,041,202)
Other current assets	(49,116)	9,602	(226,649)
Income taxes receivable	100,785	100,937	(13,266)
Other assets	43,748	77,541	—
Increase (decrease) in operating liabilities:			
Accounts payable	11,248,840	(362,072)	411,927
Accrued liabilities	2,232,059	55,150	699,030
Insurance proceeds	—	—	(466,293)
Income taxes payable	4,347,826	7,919	(1,382)
Net cash provided (used) by operating activities	<u>18,997,029</u>	<u>2,194,638</u>	<u>(1,195,495)</u>
Cash flows from investing activities:			
Purchase of property, plant, and equipment	(21,049,656)	(632,078)	(382,156)
Purchase of debt and equity securities	(2,242,897)	(7,360,398)	(2,986,156)
Proceeds from the sales of debt and equity securities	3,965,329	2,712,134	—
Net cash used by investing activities	<u>(19,327,224)</u>	<u>(5,280,342)</u>	<u>(3,368,312)</u>
Cash flows from financing activities:			
Proceeds of long-term debt	1,363,000	—	—
Repayments of long-term debt	(260,894)	(407,014)	(446,350)
Proceeds from TIA	10,636,822	—	—
Proceeds from the exercise of stock options	922,512	—	—
Repurchase of preferred stock	(482,670)	—	—
Payment of Preferred Stock dividends	(216,642)	(219,825)	(220,450)
Net cash provided (used) by financing activities	<u>11,962,128</u>	<u>(626,839)</u>	<u>(666,800)</u>
Net increase (decrease) in cash and cash equivalents	11,631,933	(3,712,543)	(5,230,607)
Cash and cash equivalents at:			
Beginning of period	5,934,749	9,647,292	14,877,899
End of period	<u>\$ 17,566,682</u>	<u>\$ 5,934,749</u>	<u>\$ 9,647,292</u>
Supplemental schedule of cash flow information:			
Interest paid	\$ 260,264	\$ 166,897	\$ 177,190
Income taxes paid	\$ 2,106,000	\$ —	\$ 1,173
Supplemental schedule of noncash investing and financing activities:			
Preferred dividends declared, not paid	\$ 49,091	\$ 54,800	\$ 55,113
Conversion of preferred stock to common stock	\$ 96,700	\$ 8,500	\$ —
Redemption price payable	\$ 107,250	\$ —	\$ —
Preferred stock repurchase payable	\$ 3,007,002	\$ —	\$ —
Amounts receivable under TIA	\$ 11,779,078	\$ —	\$ —

See accompanying notes to financial statements

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, as well as a standard 3mL syringe packaged with an 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 insignificant.

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.

Investments in debt and equity securities

The Company holds high-grade exchange-traded and closed-end funds (ETFs), mutual funds, equity securities, and debt securities as investments. These assets are readily marketable and are carried at fair value as of the date of the Balance Sheets. Net unrealized and realized gains or losses on investments in debt and equity securities are reflected as a component of Interest and other income. Realized gains or losses on investments in debt and equity securities are recognized using the specific identification method.

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 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 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.

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

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

U.S. Treasury Notes are reported at their fair value based upon quoted prices in active markets. Investments in certificates of deposit (CD) with original maturities of greater than three months are reported at their estimated fair value based upon the duration of the CD and the interest rate earned on the CD versus current interest rates of similar duration CDs. The fair value of long-term liabilities, based on Management's estimates, approximates their reported values.

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, exchange-traded and closed-end funds, mutual funds, equity securities, 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 that are well-established entities. The Company assesses market risk in debt and equity securities through consultation with its outside investment advisors. Management is responsible for directing investment activity based on current economic conditions. In 2020, a significant portion of the Company's sales were to the U.S. government, which Management does not consider a credit risk. As a consequence, Management considers any exposure from concentrations of credit risks to be limited.

The following table reflects our significant customers in 2020, 2019, and 2018:

	Years Ended December 31,		
	2020	2019	2018
Number of significant customers	2	3	2
Aggregate dollar amount of net sales to significant customers	\$41.6 million	\$19.0 million	\$13.1 million
Percentage of net sales to significant customers	50.6%	45.6%	39.2%

The Company increased its allowance for doubtful accounts by approximately \$125 thousand in 2020.

In 2020, approximately \$31.6 million of the Company's sales were to the Department of Health and Human Services of the United States in partial fulfillment of a recent \$83.8 million delivery order to supply automated retraction safety syringes (the "HHS Order"). Management expects the U.S. government to remain a significant customer through at least July 2021.

The Company manufactures some of its products in Little Elm, Texas, as well as utilizing manufacturers in China. The Company obtained roughly 85.2% of its products in 2020 from its Chinese manufacturers. Purchases from Chinese manufacturers aggregated 82.6% and 85.3% of products in 2019 and 2018, 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. Regardless of vendor availability, the Company expects to increase its domestic syringe production capacity at its facilities pursuant to the plans outlined in the TIA as hereinafter defined.

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 \$3,435,352 and \$3,586,726 as of December 31, 2020 and 2019, 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.

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 upon shipment of the product.

The Company recognizes revenue from licensing agreements when collection of such amounts from third parties is reasonably assured. If the Company licenses its products for sale, the Company is obligated to pay Thomas J. Shaw, the owner of certain patented technology, a certain percentage of such revenue pursuant to the terms of the Technology License Agreement between the Company and Mr. Shaw.

Disaggregated information of revenue recognized from contracts with customers and licensing fees recognized are as follows:

Geographic Segment	For the year ended December 31, 2020:				
	Syringes	Blood Collection Products	EasyPoint [®] Needles	Other Products	Total Product Sales
U.S. sales (excluding HHS Order)	\$ 30,446,858	\$ 2,116,108	\$ 9,542,122	\$ 64,375	\$ 42,169,463
HHS Order sales to U.S. government	31,634,343	—	—	—	31,634,343
North and South America sales (excluding U.S.)	5,733,116	8,450	86,816	1,064,768	6,893,150
Other international sales	917,478	239,329	235	8,455	1,165,497
Total	<u>\$ 68,731,795</u>	<u>\$ 2,363,887</u>	<u>\$ 9,629,173</u>	<u>\$ 1,137,598</u>	<u>\$ 81,862,453</u>

For the year ended December 31, 2019:					
Geographic Segment	Syringes	Blood Collection Products	EasyPoint® Needles	Other Products	Total Product Sales
U.S. sales	\$ 26,722,414	\$ 2,130,767	\$ 2,970,374	\$ 74,369	\$ 31,897,924
North and South America sales (excluding U.S.)	7,863,796	6,313	7,996	370,885	8,248,990
Other international sales	1,052,217	578,617	635	18,796	1,650,265
Total	<u>\$ 35,638,427</u>	<u>\$ 2,715,697</u>	<u>\$ 2,979,005</u>	<u>\$ 464,050</u>	<u>\$ 41,797,179</u>

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	<u>\$ 28,266,046</u>	<u>\$ 1,422,842</u>	<u>\$ 3,413,409</u>	<u>\$ 172,405</u>	<u>\$ 33,274,702</u>

Income taxes

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

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. In prior periods, the Company established a valuation allowance for its net deferred tax asset as future taxable income which could not be reasonably assured. Penalties and interest related to income taxes are classified as General and administrative expense and Interest expense, respectively. During the quarter ended June 30, 2020, the Company released its valuation allowance based on available evidence supporting that its deferred tax assets will be realized in full.

Earnings per share

The Company computes basic earnings or loss 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. At December 31, 2020, the calculation of diluted EPS under the treasury stock method included 131,347 shares of Common Stock underlying issued and outstanding stock options. Common stock issuable upon the conversion of convertible preferred stock is excluded from the calculation of diluted EPS for 2020, 2019, and 2018 because the effect was antidilutive. At December 31, 2019 and December 31, 2018, the calculation of diluted EPS excluded 639,300 and 1,357,803 shares of common stock, respectively, underlying issued and outstanding stock options, as the exercise prices of the stock options were greater than the average stock prices. The potential dilution, if any, is shown on the following schedule:

	Years Ended December 31,		
	2020	2019	2018
Net income (loss)	\$ 24,223,013	\$ 3,148,234	\$ (1,339,943)
Preferred stock dividend requirements	(573,868)	(702,618)	(704,996)

	Years Ended December 31,		
	2020	2019	2018
Deemed contribution on extinguishment of preferred stock	2,975,708	—	—
Income (loss) applicable to common stockholders	<u>\$ 26,624,853</u>	<u>\$ 2,445,616</u>	<u>\$ (2,044,939)</u>
Weighted Average common shares outstanding	<u>33,169,307</u>	<u>32,672,475</u>	<u>32,666,454</u>
Weighted Average common and common equivalent shares outstanding - assuming dilution	<u>33,300,654</u>	<u>32,672,475</u>	<u>32,666,454</u>
Basic earnings (loss) per share	<u>\$ 0.80</u>	<u>\$ 0.07</u>	<u>\$ (0.06)</u>
Diluted earnings (loss) per share	<u>\$ 0.80</u>	<u>\$ 0.07</u>	<u>\$ (0.06)</u>

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

The Company has determined to apply this guidance to its accounting treatment of the preferred stock transactions described in Note 19.

Shipping and handling costs

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

Self-insured employee benefit costs

The Company self-insures certain health insurance benefits for its employees under certain policy limits. The Company has additional coverage provided by an insurance company for any individual with claims in excess of \$100,000 and/or total plan claims in excess of \$1,000,000 for the plan year.

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 Black-Scholes fair value method. The Company records share-based compensation expense on a straight-line basis over the requisite service period.

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 income (loss) from operations until all repairs are made.

Leases

The Company determines if an arrangement is a lease at inception. Operating and finance leases are included in Other assets, Other accrued liabilities, and Other long-term liabilities on the Balance Sheets. Right-of-use

“ROU”) assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As the Company’s leases do not provide an implicit rate, the incremental borrowing rate based on information available at the commencement date was used in determining the present value of lease payments.

The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Leases with an initial term of twelve months or less are not recorded on the Balance Sheets; however, rent expense is recognized on a straight-line basis over the lease term.

Technology Investment Agreement (TIA)

Effective July 1, 2020, the Company entered into a Technology Investment Agreement (“TIA”) with the United States Government Department of Defense, U.S. Army Contracting Command-Aberdeen Proving Ground, Natick Contracting Division & Edgewood Contracting Division (ACC-APG, NCD & ECD) on behalf of the Biomedical Advanced Research and Development Authority (BARDA) for \$53,664,286 in government funding for expanding the Company’s domestic production of needles and syringes. Pursuant to the terms of the TIA, the Company is expected to make significant additions to its facilities which should allow the Company to increase domestic production. As reimbursements are received from the U.S. government for such expenditures, the Company records a deferred liability. The deferred liability will be systematically amortized as a gain over the life of the related property, plant, and equipment as to offset the related depreciation expense of the assets acquired. The amortization will be presented separately from the depreciation expense on the Statements of Operations.

Recently Adopted Pronouncements

The Company adopted ASU 2016-13, “Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” as well as subsequent clarifying amendments on January 1, 2020. 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 previously will still be permitted, although the inputs to those techniques will change to reflect the full amount of expected credit losses. The adoption of ASU 2016-13, as well as the Targeted Transition Relief as provided by ASU 2019-05, “Financial Instruments – Credit Losses (Topic 326) – Targeted Transition Relief” did not have a significant impact on the Company’s financial statements.

The Company adopted 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)” on January 1, 2020. 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 Internal-Use Software. 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 adoption of this ASU did not have a significant impact on the Company’s financial statements or disclosures.

In August 2018, the FASB issued ASU 2018-13 “Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement.” The amendment modifies, among other things, disclosure requirements on fair value measurements and eliminates certain disclosures related to transfers and valuation levels of Level 3 fair value measurements. Additionally, the amendment requires disclosure of changes in unrealized gains and losses in other comprehensive income for Level 3 fair value measurements and certain qualitative factors related to significant unobservable inputs used in Level 3 valuations. The amendment was effective for annual periods beginning after December 15, 2019 and interim periods within the annual period. The adoption of ASU 2018-13 did not have a significant effect on the

Company's financial statements, as the Company does not currently have any investments classified as Level 3 fair value measurements.

Recently Issued Pronouncements

In December 2019, the FASB issued ASU 2019-12, "Income Taxes: Simplifying the Accounting for Income Taxes". The new standard is intended to simplify the accounting for income taxes by eliminating certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within the annual period, with early adoption permitted. Adoption of the standard requires certain changes primarily be made prospectively, with some changes to be made retrospectively. The Company has determined that the adoption of ASU 2019-12 will not have a material impact on its financial statements.

In March 2020, the FASB issued ASU No. 2020-04, "Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting", to ease the potential burden in accounting for reference rate reform. The new guidance provides optional expedients for contracts that reference LIBOR, if certain criteria are met, that can be applied through December 31, 2022. As reference rate reform is still an ongoing process, the Company will continue to evaluate the timing and potential impact of adoption for optional expedients when deemed necessary.

3. INVENTORIES

Inventories consist of the following:

	December 31,	
	2020	2019
Raw materials	\$ 1,358,552	\$ 1,254,313
Finished goods	9,173,302	6,493,487
	10,531,854	7,747,800
Inventory reserve	(297,208)	(297,208)
	<u>\$ 10,234,646</u>	<u>\$ 7,450,592</u>

4. FAIR VALUE OF FINANCIAL INSTRUMENTS

ASC 820, "Fair Value Measurements", defines fair value, establishes a framework for measuring fair value and requires additional disclosures regarding certain fair value measurements. ASC 820 establishes a three-tier hierarchy for measuring fair value, as follows:

- Level 1 – quoted market prices in active markets for identical assets and liabilities
- Level 2 – inputs other than quoted prices that are directly or indirectly observable
- Level 3 - unobservable inputs where there is little or no market activity

The following tables summarize the values of assets designated as Investments in debt and equity securities:

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Equity securities	\$ 3,990,533	\$ —	\$ —	\$ 3,990,533
Mutual funds and exchange traded funds	4,013,956	—	—	4,013,956
Certificates of deposit	—	77,344	—	77,344
	<u>\$ 8,004,489</u>	<u>\$ 77,344</u>	<u>\$ —</u>	<u>\$ 8,081,833</u>

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Mutual funds and exchange traded funds	\$ 6,708,746	\$ —	\$ —	\$ 6,708,746
Certificates of deposit	—	1,062,914	—	1,062,914
	<u>\$ 6,708,746</u>	<u>\$ 1,062,914</u>	<u>\$ —</u>	<u>\$ 7,771,660</u>

The Company holds high-grade ETFs, mutual funds, individual equity stocks, and debt securities as investments. These assets are readily marketable and are carried at fair value as of the date of the Balance Sheets. The Company intends to hold these assets for possible future operating requirements.

The following table summarizes gross unrealized gains and losses from Investments in debt and equity securities:

	December 31, 2020			
	Cost	Gross Unrealized		Aggregate
		Gains	Losses	Fair Value
Equity securities	\$ 2,098,144	\$ 1,892,389	\$ —	\$ 3,990,533
Mutual funds and exchange traded funds	3,909,364	104,592	—	4,013,956
Certificates of deposit	75,000	2,344	—	77,344
	<u>\$ 6,082,508</u>	<u>\$ 1,999,325</u>	<u>\$ —</u>	<u>\$ 8,081,833</u>

	December 31, 2019			
	Cost	Gross Unrealized		Aggregate
		Gains	Losses	Fair Value
Mutual funds and exchange traded funds	\$ 6,592,345	\$ 116,401	\$ —	\$ 6,708,746
Certificates of deposit	1,050,000	12,914	—	1,062,914
	<u>\$ 7,642,345</u>	<u>\$ 129,315</u>	<u>\$ —</u>	<u>\$ 7,771,660</u>

5. PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment consist of the following:

	December 31,	
	2020	2019
Land	\$ 261,893	\$ 261,893
Buildings and building improvements	11,593,952	11,566,115
Production equipment	20,290,331	19,903,236
Office furniture and equipment	3,630,455	3,527,577
Construction in progress	21,365,915	765,176
	<u>57,142,546</u>	<u>36,023,997</u>
Accumulated depreciation	<u>(26,326,042)</u>	<u>(25,391,940)</u>
	<u>\$ 30,816,504</u>	<u>\$ 10,632,057</u>

Depreciation expense for the years ended December 31, 2020, 2019, and 2018 was \$832,069; \$851,673; and \$883,610, respectively.

6. LICENSE AGREEMENT

In 1995, the Company entered into a license agreement with the Chief Executive Officer of the Company, Thomas J. Shaw, 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 Mr. Shaw. The license agreement provides for quarterly payments of a 5% royalty fee on gross sales. Additionally, if the Company sublicenses the technology and the sublicensee's customers are not known to the Company, then Mr. Shaw shall be entitled to receive from the Company fifty percent (50%) of the royalties actually paid to the Company by such sublicensee. The royalty fee expense is

recognized in the period in which it is earned. Royalty fees of \$5,476,306; \$3,449,822; and \$2,944,102 are included in Cost of sales for the years ended December 31, 2020, 2019, and 2018, respectively. Royalties payable under this agreement aggregated \$1,973,781 and \$921,445 at December 31, 2020, and 2019, respectively. Gross sales upon which royalties are based were \$109,526,118; \$67,529,783; and \$58,882,042; for 2020, 2019, and 2018, respectively.

7. OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	December 31,	
	2020	2019
Prepayments from customers	\$ 1,686,868	\$ 998,601
Accrued professional fees	331,204	263,757
Current portion – preferred stock repurchase	1,092,282	—
Other accrued expenses	288,550	124,791
Total	<u>\$ 3,398,904</u>	<u>\$ 1,387,149</u>

8. LONG-TERM DEBT

Long-term debt consists of the following:

	December 31,	
	2020	2019
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 5.0% at December 31, 2020.	\$ 2,378,100	\$ 2,638,994
Loan from Independent Bank pursuant to the Paycheck Protection Program. Original maturity date is April 17, 2022. The interest rate is equal to 1.0% per annum.	1,363,000	—
	<u>3,741,100</u>	<u>2,638,994</u>
Less: current portion	(1,030,763)	(260,939)
	<u>\$ 2,710,337</u>	<u>\$ 2,378,055</u>

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, 2020, are as follows:

2021	\$ 1,030,763
2022	896,210
2023	304,120
2024	319,685
2025	336,488
Thereafter	853,834
	<u>\$ 3,741,100</u>

9. OTHER LONG-TERM LIABILITIES

Other long-term liabilities consists of the following:

	December 31,	
	2020	2019
Technology Investment Agreement (TIA)	22,444,324	—
Stock repurchase	2,034,373	—
Total	<u>\$24,478,697</u>	<u>\$ —</u>

The TIA provides for reimbursement to the Company for the purchase of equipment and supplies related to the expansion of the Company's domestic production of needles and syringes. Under the TIA, reimbursable amounts will be reflected as a liability until the time its deferred income can be systematically amortized over a period matching the useful life of the purchased assets.

The stock repurchase liability represents the long-term portion, at net present value, of \$3,303,330 gross payable by the Company to former preferred shareholders as a result of private stock purchases in 2020 of 320,333 shares of Class B Series IV preferred stock and 25,000 shares of Class B Series V preferred stock. The purchase price is payable in three annual installments of \$1,101,110.

10. COMMITMENTS AND CONTINGENCIES

On November 7, 2019, the Company filed a lawsuit in the 44th District Court of Dallas County, Texas (No. DC-19-17946) against Locke Lord, LLP and Roy Hardin in connection with their legal representation of the Company in its previous litigation against Becton, Dickinson and Company ("BD"). The Company alleges that the defendants breached their fiduciary duties, committed malpractice, and were negligent in their representation of the Company. The Company seeks actual and exemplary damages, disgorgement, costs, and interest. On October 6, 2020, the Court dismissed Defendants' motion to dismiss, which order was appealed by the Defendants on October 9, 2020 to the Court of Appeals, Fifth District of Texas at Dallas. Oral argument for the appeal has been set for April 7, 2021.

11. INCOME TAXES

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

	For the Years Ended December 31,		
	2020	2019	2018
Current tax provision (benefit)			
Federal	\$ 4,431,590	\$ —	\$ (13,318)
State	2,049,850	7,875	—
Total current provision (benefit)	<u>6,481,440</u>	<u>7,875</u>	<u>(13,318)</u>
Deferred tax provision (benefit)			
Federal	(3,428,399)	—	—
State	(1,202,807)	—	—
Total deferred tax provision (benefit)	<u>(4,631,206)</u>	<u>—</u>	<u>—</u>
Total income tax provision (benefit)	<u>\$ 1,850,234</u>	<u>\$ 7,875</u>	<u>\$ (13,318)</u>

The Company had \$23.3 million in tax benefits attributable to net operating losses for federal tax purposes as of December 31, 2019, which were fully utilized as of December 31, 2020. The Company has state net operating losses of \$3.6 million as of December 31, 2020 which will begin to expire in 2029. The Company also had credits for alternative minimum taxes ("AMT") paid of \$100 thousand as of December 31, 2019. The alternative minimum tax was repealed with the enactment of the Tax Cuts and Jobs Act. The Company recorded the AMT credit as a tax receivable on its financial statements as of December 31, 2019 rather than as a deferred tax asset, as this amount is a refundable credit. The AMT credit refund receivable at December 31, 2019 was claimed on the Company's 2019 corporate income tax return and was received in 2020.

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

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,	
	2020	2019
Deferred tax assets		
Net operating loss carry forwards	\$ 198,675	\$ 5,748,724
Accrued expenses and reserves	824,920	573,382
Employee stock option expense	15,188	75,591
Nonemployee stock option expense	8,515	8,207
Inventories	98,748	110,455
Impairment	—	111,178
Deferred income – TIA contract	5,675,617	—
Unrealized gains/losses	—	30,434
Deferred tax assets	<u>6,821,663</u>	<u>6,657,971</u>
Deferred tax liabilities		
Unrealized gains/losses	(508,197)	—
Property, plant, and equipment	(1,682,260)	(1,628,133)
Deferred tax liabilities	<u>(2,190,457)</u>	<u>(1,628,133)</u>
Net deferred assets	<u>4,631,206</u>	<u>5,029,838</u>
Valuation allowance	—	(5,029,838)
Net deferred tax assets	<u>\$ 4,631,206</u>	<u>\$ —</u>

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%. Deferred income tax assets represent amounts available to reduce income taxes payable on taxable income in future years.

Deferred tax assets are periodically reviewed for realizability. In prior periods, the Company established a valuation allowance for its net deferred tax asset as future taxable income which could not be reasonably assured. The valuation allowance was fully released during the year ended December 31, 2020. The valuation allowance was decreased by \$5,029,838 for 2020 and decreased by \$1,121,560 for 2019.

Under the Tax Cuts and Jobs Act, 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. Carryback of these losses is no longer permitted.

The CARES Act temporarily removed the 80% of taxable income limitation to allow NOL carryforwards to fully offset income. For tax years beginning before 2021, the Company can take an NOL deduction equal to 100% of taxable income. For tax years beginning after 2021, the Company can take: (1) a 100% deduction of NOLs arising in tax years prior to 2018, and (2) a deduction limited to 80% of modified taxable income for NOLs arising in tax years after 2017.

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

	December 31,		
	2020	2019	2018
Income tax at the federal statutory rate	21.0%	21.0%	21.0%
State tax, net of federal tax	4.2	2.0	3.5
Change in valuation allowance	(19.2)	(35.6)	(24.3)
Permanent differences	(0.6)	—	(0.3)
Return-to-provision and other	1.7	12.9	(0.9)
Tax Reform and Jobs Act tax rate change	—	—	0.1
Effective tax rate	<u>7.1%</u>	<u>0.3%</u>	<u>(0.9)%</u>

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, 2017, 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.

12. DIVIDENDS

The Board declared and the Company paid cash dividends to Series I and Series II Class B Preferred Shareholders within one month of the end of each quarter in 2018, 2019, and 2020, resulting in cumulative annual payments of: \$49,250, and \$171,200 to Series I and Series II preferred shareholders, respectively, in 2018; \$48,625, and \$171,200 to Series I and Series II preferred shareholders, respectively, in 2019; \$48,000, and \$168,642 to Series I and Series II preferred shareholders, respectively, in 2020; and one payment of \$10,041, and \$39,050 to Series I and Series II preferred shareholders, respectively, in 2021.

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.

The Company has one class of Preferred Stock outstanding: Class B Convertible Preferred Stock ("Class B Stock"). The Class B Stock has two series: Series II and Series III. Series I, Series IV, and Series V were cancelled by Board resolution effective March 16, 2021.

The Class B Series II and III stock had 156,200 and 106,745 shares outstanding, respectively, at December 31, 2020. The remaining 4,737,055 authorized shares have not been assigned a series.

Series I Class B Stock

There were 0 and 96,000 shares of \$1 par value Series I Class B Stock outstanding at December 31, 2020 and 2019, respectively. Holders of Series I Class B Stock were 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 \$48,000 in 2020 and \$48,625 in 2019. At December 31, 2020, no dividends were in arrears.

Series I Class B Stock was redeemable at the option of the Company at a price of \$7.50 per share, plus all unpaid dividends. Such a redemption took place effective December 31, 2020. Each share of Series I Class B Stock was, at the option of the stockholder, convertible to one share of Common Stock. 81,700 shares of Series I Class B Stock was converted to Common Stock in 2020 and the remaining 14,300 shares were redeemed by the Company as of December 31, 2020 for a total redemption price payable of \$107,250. 2,500 shares of Series I Class B Stock were converted into Common Stock in 2019. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series I Class B Stock then outstanding would have been 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 156,200 and 171,200 shares of \$1 par value Series II Class B Stock outstanding at December 31, 2020 and 2019, respectively. Holders of Series II Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the Board of Directors. Holders of Series II Class B Stock generally have no voting rights until dividends are in arrears and unpaid for twelve consecutive quarters. In such case, the holders of Series II Class B Stock have the right to elect one-third of the Board of Directors of the Company. The Company paid dividends of \$168,642 in 2020 and \$171,200 in 2019. At December 31, 2020, no dividends were in arrears.

Series II Class B Stock is redeemable 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. 15,000 shares were converted into Common Stock in 2020. No shares were converted in 2019. 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, prior to any distributions to holders of Series III Class B Stock or Common Stock.

Series III Class B Stock

There were 106,745 and 129,245 shares of \$1 par value Series III Class B Stock outstanding at December 31, 2020 and 2019. 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, 2020, approximately \$4,037,000 of dividends which have not been declared were in arrears.

Series III Class B Stock is redeemable 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. No shares were converted in 2020 or 2019. 22,500 shares were exchanged for Common Stock in private transactions in 2020. Please see Note 19 for a description of private exchange transactions in 2020. 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 II Class B Stock have been satisfied and prior to any distributions to holders of Common Stock.

Series IV Class B Stock

There were 0 and 342,500 shares of \$1 par value Series IV Class B Stock outstanding at December 31, 2020 and 2019, respectively. Holders of Series IV Class B Stock were entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly, if declared by the Board of Directors. At December 31, 2020, approximately \$101,000 of dividends which have not been declared were in arrears.

Series IV Class B Stock was redeemable 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 was, at the option of the stockholder any time, convertible into one share of Common Stock. No shares of Series IV Class B Stock were converted into Common Stock in 2020 or 2019. 342,500 shares were exchanged for Common Stock in private transactions in 2020. Please see Note 19 for a description of private exchange transactions in 2020. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series IV Class B Stock then outstanding would have been 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 0 and 34,000 shares of \$1 par value Series V Class B Stock outstanding at December 31, 2020 and 2019, respectively. Holders of Series V Class B Stock were entitled to receive a cumulative annual dividend of \$0.32 per share, payable quarterly, if declared by the Board of Directors. At December 31, 2020, approximately \$830,000 of dividends which have not been declared were in arrears.

Series V Class B Stock was redeemable 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 was, at the option of the stockholder any time, convertible into Common Stock. 0 and 6,000 shares of Series V Class B Stock were converted into Common Stock in 2020 and 2019, respectively. 34,000 shares were exchanged for Common Stock in private transactions in 2020. Please see Note 19 for a description of private exchange transactions in 2020. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series V Class B Stock then outstanding would have been 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 33,957,204 and 32,674,954 shares were outstanding at December 31, 2020 and 2019, respectively. Additionally, as of December 31, 2020, a total of 462,395 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.

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 199,450 shares under the 2008 Stock Option Plan were outstanding as of December 31, 2020. No shares are available for future issuance under the 2008 Stock Option Plan, which expired July 25, 2018.

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

Stock option exercises

Stock options were exercised by the Company's employees and directors during 2020, and, consequently, a total of 431,550 shares of Common Stock were issued for an aggregate payment to the Company of \$922,512 to exercise such options.

Director, officer, and 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,					
	2020		2019		2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	639,300	\$ 2.12	1,300,303	\$ 1.57	1,805,519	\$ 1.51
Granted	—	\$ —	—	\$ —	—	\$ —
Exercised	(431,550)	\$ (2.14)	—	\$ —	—	\$ —
Forfeited	(8,300)	\$ (2.75)	(661,003)	\$ (1.05)	(505,216)	\$ (1.36)
Outstanding at end of period	<u>199,450</u>	\$ 2.05	<u>639,300</u>	\$ 2.12	<u>1,300,303</u>	\$ 1.57
Exercisable at end of period	<u>199,450</u>	\$ 2.05	<u>639,300</u>	\$ 2.12	<u>1,300,303</u>	\$ 1.57

No options were issued in 2020, 2019, or 2018 to employees or non-employee directors.

The following table summarizes information about Director, officer, and employee options outstanding under the stock option plan at December 31, 2020:

Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
\$ 1.05	82,500	5.99	82,500
\$ 2.75	116,950	5.70	116,950

Non-employee options

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

	Years Ended December 31,					
	2020		2019		2018	
	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
Granted	—	\$ —	—	\$ —	—	\$ —
Exercised	—	\$ —	—	\$ —	—	\$ —
Forfeited	—	\$ —	(57,500)	\$ (0.81)	—	\$ —
Outstanding at end of period	—	\$ —	—	\$ —	57,500	\$ 0.81
Exercisable at end of period	—	\$ —	—	\$ —	57,500	\$ 0.81

The Company recorded no stock-based compensation expense in 2018, 2019, or 2020. At December 31, 2020, there were 199,450 stock options with exercise prices lower than the closing market price. The intrinsic value of these options at December 31, 2020 was \$1,733,856.

Options Pricing Models – Assumptions

The expected life is based on the Company's historical experience with option exercise trends. The assumptions for expected volatility are 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. The Company elected a policy to account for forfeitures as they occur, rather than on an estimated basis.

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. For 2020, 2019, 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 \$162,008; \$117,917; and \$145,146 in 2020, 2019, and 2018, respectively.

17. BUSINESS SEGMENT

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

	2020	2019	2018
U.S. sales	\$ 73,803,806	\$ 31,897,924	\$ 28,646,574
North and South America sales (excluding U.S.)	6,893,150	8,248,990	3,597,444
Other international sales	1,165,497	1,650,265	1,030,684
Total sales	<u>\$ 81,862,453</u>	<u>\$ 41,797,179</u>	<u>\$ 33,274,702</u>
Long-lived assets	2020	2019	
U.S.	\$ 30,751,259	\$ 10,542,688	
International	\$ 65,245	\$ 89,369	

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

The Company has operating leases for a warehouse and equipment. The leases have a remaining lease term of less than one year. The Company currently has no finance leases. The ROU asset is determined based on the lease liability adjusted for lease incentives received. Lease expense is recognized on a straight-line basis over the lease term. The leases may include various expenses incidental to the use of the property, such as common area maintenance, property taxes and insurance. These costs are separate from the minimum rent payment and are not considered in the determination of the lease liability and ROU asset. The Company has not noted any material instances in its leases where these costs were combined with the minimum rent payment and has therefore elected the policy to not separate lease from non-lease components if they are combined with the minimum rent payment. The option periods are not included in the determination of the lease liability and right-of-use asset as the Company is not reasonably certain if it will extend at the time of lease commencement.

The operating lease cost component of the lease expense was \$103,312 and \$80,648 for the years ended December 31, 2020 and 2019, respectively. The cash paid for amounts included in the measurement of lease liabilities as a component of cash flows related to leases was \$106,101 and \$80,648 for the years ended December 31, 2020 and 2019, respectively.

Assets and liabilities associated with these leases included in the Balance Sheets are as follows:

	December 31,	
	2020	2019
OPERATING LEASES		
Other assets	\$ 38,892	\$ 82,359
Other accrued liabilities	\$ 38,892	\$ 82,359
Other long-term liabilities	—	—
Total operating lease liabilities	<u>\$ 38,892</u>	<u>\$ 82,359</u>

19. PRIVATE EXCHANGES AND REDEMPTION

Private Exchanges of Preferred Stock for Common Stock

In 2020, the Company entered into several agreements with shareholders to purchase its outstanding Class B Convertible Preferred Stock. The consideration for these purchases consisted of both cash and Common Stock. In addition, in each such transaction, the preferred shareholder counterparty waived their rights to unpaid

dividends in arrears. In total, 22,500 shares of Series III Class B Convertible Preferred Stock, 342,500 shares of Series IV Class B Convertible Preferred Stock, and 34,000 shares of Series V Class B Convertible Preferred Stock were purchased by the Company. The aggregate cash consideration equaled \$3,786,000, of which \$482,670 was paid in 2020 with the rest payable over a three-year period beginning February 2021. The aggregate stock consideration was 754,000 shares of Common Stock. As a result of the transactions, \$7,642,049 in unpaid dividends in arrears were waived, as measured from the effective date of each transaction.

Redemption of Class B Series I Preferred Stock

The Company caused a redemption of its Class B Series I Preferred Stock on December 31, 2020 pursuant to the terms of the Certificate of Designation for such series of preferred stock which required a redemption price of \$7.50 per share. Pursuant to such redemption, all shares of the Class B Series I Preferred Stock existing on December 31, 2020 (14,300 shares) were cancelled.

20. PAYCHECK PROTECTION PROGRAM LOAN

On April 17, 2020, the Company entered into a promissory note in the principal amount of \$1,363,000 (the “PPP Loan”) in favor of Independent Bank pursuant to the Paycheck Protection Program (the “PPP”) of the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), administered by the U.S. Small Business Administration (“SBA”). The PPP Loan’s original maturity date is April 17, 2022 and bears interest at a rate of 1.0% per annum. The PPP Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties. The PPP Loan is unsecured and is a non-recourse obligation. The Company has requested forgiveness for the PPP Loan but cannot be assured that such request will be granted.

Assuming the PPP Loan is not forgiven, the Company’s obligations thereunder are as follows at December 31, 2020:

2021	\$ 755,907
2022	607,093
	<u>\$ 1,363,000</u>

21. COVID-19

To date, the Company’s manufacturing facility in Little Elm, Texas has continued to operate due to its status as an essential business. As a result of the COVID-19 pandemic, the Company has implemented certain safety precautions at its facility to reduce the risk of the potential spread of the novel coronavirus. The Company has implemented arrangements to reduce the number of office staff employees working on-site at the production facility, as well as instituting personal distancing policies and monitoring of essential production staff to minimize the risk of infection. The Company continues to monitor the evolving situation and will work to further mitigate risks to staff and to customers. The Company is continuing to evaluate the ever-changing circumstances surrounding this pandemic as it relates to its ability to continue to source materials and products, maintain a workforce, and operate its business effectively and efficiently. Despite the global disruption of the coronavirus pandemic, the Company has not experienced a significant disruption to its supply chain. During 2020, the Company has experienced an increase in demand for its products and has been able to meet such demand with increased volumes despite the pandemic. The Company is unable to predict with certainty its ability to maintain its current operational functionality.

22. TECHNOLOGY INVESTMENT AGREEMENT

Effective July 1, 2020, the Company entered into the TIA with the U.S. government. The principal purpose of the TIA is to fund the expansion of the Company’s manufacturing capacity for hypodermic safety needles and corresponding syringes in response to the worldwide COVID-19 global pandemic. The award is an expenditure-type TIA, whereby the U.S. government will make payments to the Company for the Company’s expenditures for equipment and supplies in carrying out the expansion of the Company’s domestic production. The Company’s contributions under the terms of the TIA to enhance domestic capacity of pandemic-essential

technology include providing facilities, technical expertise, labor, and maintenance of the TIA-funded equipment for a ten-year term.

As of December 31, 2020, the Company has negotiated contracts for the purchase of automated assembly equipment, molds, and molding equipment, as well as portions of auxiliary equipment, for approximately \$41.5 million. As of March 2021, the Company has substantially completed construction of expanded facilities consisting of approximately 27,800 square feet of additional controlled environment within existing properties and is expected to complete approximately 55,000 square feet of new warehouse space within the second quarter of 2021. The estimated cost of the controlled environment within existing properties is \$6.4 million. The increase from the original \$6 million estimate is due to change orders and an expedited completion date in order to receive certain manufacturing equipment at an earlier date. The new warehouse space is estimated to cost \$5.8 million. The cost of the controlled environment will be funded by the U.S. government under the TIA, while the cost of the new warehouse will be funded by the Company.

23. SUBSEQUENT EVENTS

The Department of Health and Human Services entered into a contract with the Company on February 12, 2021 to supply low dead space safety syringes. The base price for the contract and purchase order is \$54,217,800 for the five-month base period of performance from February 15, 2021 to July 14, 2021. Such price includes both the fixed price for the products as well as cost reimbursement for freight. The terms of the contract allow for extensions at the option of the U.S. government for up to seven additional one-month periods. If all option periods are exercised, the value of the contract could increase by an additional \$92,772,680, including the price of the products and freight reimbursement.

On March 16, 2021, the Company approved the 2021 Stock Option Plan (the “Plan”) and set aside and reserved 2,000,000 shares of Common Stock for issuance pursuant to the Plan. The Plan is subject to shareholder approval at the May 11, 2021 shareholder meeting. The Plan provides for the granting of incentive stock options and non-qualified stock options at a price equal to at least 100% of the fair market value of the Company’s Common Stock as of the date of grant. Participants in the Plan may include employees, consultants, and non-employee Directors. On March 16, 2021, the Company approved option grants to purchase 1,000,000, 250,000, and 100,000 shares of Common Stock to the Company’s chief executive officer, general counsel, and chief financial officer, respectively. These shares will vest in their entirety three years from the grant date. No award shall be exercisable unless and until the Plan has been approved by the shareholders.

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, John W. Fort III (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, 2020, 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, 2020, 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 2020 or subsequent to December 31, 2020, which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information in the sections “Proposal – The Election of Three Class 1 Directors” and “Corporate Governance” in the 2021 proxy statement is incorporated herein by reference.

Item 11. Executive Compensation.

The information in the section [“Compensation”](#) in the 2021 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 2021 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 2021 proxy statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information in the section [“Accounting Matters”](#) in the 2021 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, 2020, 2019, and 2018:

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Provision for Inventories				
Fiscal year ended 2018	\$ 594,939	\$ —	\$ 297,731	\$ 297,208
Fiscal year ended 2019	\$ 297,208	\$ —	\$ —	\$ 297,208
Fiscal year ended 2020	\$ 297,208	\$ —	\$ —	\$ 297,208
Provision for Accounts Receivable				
Fiscal year ended 2018	\$ 101,872	\$ 47,793	\$ —	\$ 149,665
Fiscal year ended 2019	\$ 149,665	\$ —	\$ 3,283	\$ 146,382
Fiscal year ended 2020	\$ 146,382	\$ 125,000	\$ 65,560	\$ 205,822
Deferred Tax Valuation				
Fiscal year ended 2018	\$ 5,825,954	\$ 325,444	\$ —	\$ 6,151,398
Fiscal year ended 2019	\$ 6,151,398	\$ —	\$ 1,121,560	\$ 5,029,838
Fiscal year ended 2020	\$ 5,029,838	\$ —	\$ 5,029,838	\$ —

	Balance at beginning of period	Additions	Deductions	Balance at end of period
		(A)	(B)	(C)
Provision for Rebates				
Fiscal year ended 2018	\$ 4,794,193	\$ 24,372,111	\$ 24,579,457	\$ 4,586,847
Fiscal year ended 2019	\$ 4,586,847	\$ 24,212,830	\$ 24,526,108	\$ 4,273,569
Fiscal year ended 2020	\$ 4,273,569	\$ 26,104,612	\$ 26,566,256	\$ 3,811,925

(A) Represents estimated rebates deducted from gross revenues.

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

(C) Includes \$3,435,352; \$3,586,726; and \$3,896,341 in Accounts payable for 2020, 2019, and 2018, 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
<u>3(i)</u>	<u>Restated Certificate of Formation with Certificates of Designation, Preferences, Rights and Limitations of Class B Preferred Stock (all Series)</u> ⁽¹⁾
<u>3(ii)</u>	<u>Fourth Amended and Restated Bylaws of RTI</u> ⁽²⁾
<u>4(i)</u>	<u>Restated Certificate of Formation with Certificates of Designation, Preferences, Rights and Limitations of Class B Preferred Stock (all Series)</u> ⁽³⁾
<u>4(vi)</u>	<u>Description of Securities</u> ⁽⁴⁾
<u>10.1</u>	<u>Sample United States Distribution Agreement</u> ⁽⁵⁾
<u>10.2</u>	<u>Sample Foreign Distribution Agreement</u> ⁽⁶⁾
<u>10.3</u>	<u>Employment Agreement between RTI and Thomas J. Shaw dated as of January 1, 2008 (This is a management compensation contract.)</u> ⁽⁷⁾
<u>10.4</u>	<u>Technology License Agreement between Thomas J. Shaw and RTI dated the 23rd day of June, 1995</u> ⁽⁸⁾
<u>10.5</u>	<u>First Amendment to Technology License Agreement between Thomas J. Shaw and RTI dated the 3rd day of July, 2008</u> ⁽⁹⁾
<u>10.6</u>	<u>Second Amendment to Technology License Agreement between Thomas J. Shaw and Retractable Technologies, Inc. dated as of the 7th day of September, 2012</u> ⁽¹⁰⁾
<u>10.7</u>	<u>Retractable Technologies, Inc. First Amended 2008 Stock Option Plan</u> ⁽¹¹⁾
<u>10.8</u>	<u>Voting Agreement Between Thomas J. Shaw and Suzanne August dated November 8, 2006</u> ⁽¹²⁾
<u>10.9</u>	<u>Technology Investment Agreement between RTI and U.S. Department of Defense dated July 1, 2020</u> ⁽¹³⁾

Exhibit No.	Description of Document
<u>10.10</u>	<u>Agreement for the Purchase and Sale of Preferred Stock between RTI and Sovana Cayman Islands dated as of August 31, 2020⁽¹⁴⁾</u>
<u>10.11</u>	<u>U.S. Small Business Administration Note dated April 17, 2020⁽¹⁵⁾</u>
<u>10.12</u>	<u>2021 Stock Option Plan⁽¹⁶⁾</u>
<u>14</u>	<u>Retractable Technologies, Inc. Code of Business Conduct and Ethics⁽¹⁷⁾</u>
<u>31.1</u>	<u>Certification of Principal Executive Officer⁽¹⁸⁾</u>
<u>31.2</u>	<u>Certification of Principal Financial Officer⁽¹⁹⁾</u>
<u>32</u>	<u>Section 1350 Certifications⁽²⁰⁾</u>
101	The following materials from this report, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of December 31, 2020, and 2019, (ii) the Statements of Operations for the years ended December 31, 2020, 2019, and 2018, (iii) the Statements of Changes in Stockholders' Equity for the years ended December 31, 2020, 2019, and 2018, (iv) the Statements of Cash Flows for the years ended December 31, 2020, 2019, and 2018, and (v) Notes to Financial Statements. ⁽²¹⁾
(1)	Filed herewith
(2)	Incorporated herein by reference to RTI's Form 8-K filed on May 13, 2010
(3)	Filed herewith
(4)	Filed herewith
(5)	Incorporated herein by reference to RTI's Registration Statement on Form 10-SB filed on June 23, 2000
(6)	Incorporated herein by reference to RTI's Registration Statement on Form 10-SB filed on June 23, 2000
(7)	Incorporated herein by reference to RTI's Form 10-Q filed on November 14, 2008
(8)	Incorporated herein by reference to RTI's Registration Statement on Form 10-SB filed on June 23, 2000
(9)	Incorporated herein by reference to RTI's Form 10-K filed on March 31, 2009
(10)	Incorporated herein by reference to RTI's Form 10-Q filed on November 14, 2012
(11)	Incorporated herein by reference to RTI's Form 10-Q filed on November 14, 2014
(12)	Incorporated herein by reference to RTI's Schedule TO filed on October 17, 2008
(13)	Incorporated herein by reference to RTI's Form 10-Q filed on November 16, 2020
(14)	Incorporated herein by reference to RTI's Form 8-K filed October 5, 2020
(15)	Incorporated herein by reference to RTI's Form 8-K filed April 22, 2020
(16)	Incorporated herein by reference to RTI's Schedule 14A filed March 31, 2021
(17)	Incorporated herein by reference to RTI's Form 8-K filed on August 17, 2020
(18)	Filed herewith
(19)	Filed herewith
(20)	Filed herewith
(21)	Filed herewith
(c)	Excluded Financial Statement Schedules: None

Item 16. Form 10-K Summary.

None.

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 31, 2021

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/John W. Fort III
JOHN W. FORT III
VICE PRESIDENT, CHIEF FINANCIAL OFFICER,
PRINCIPAL ACCOUNTING OFFICER, TREASURER, AND
DIRECTOR

March 31, 2021

/s/ Amy Mack
AMY MACK
DIRECTOR

March 31, 2021

/s/ Marco Laterza
MARCO LATERZA
DIRECTOR

March 31, 2021

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

March 31, 2021

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

March 31, 2021