

Risk Factors Comparison 2024-03-29 to 2023-03-30 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

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 Concerned that Our Stock ~~May Be Manipulated~~ **Price is Not Correlated with Value** As previously disclosed, we are concerned there may be manipulation of our stock. We engaged an independent, highly reputable economic consulting firm in 2021 at the expense of approximately \$ 640 thousand which analyzed millions of trades in our stock in recent years. The resulting in-depth analysis confirmed that there were statistically significant anomalies in the market's reaction to our positive disclosures, meaning that our stock price would often react negatively or in a statistically insignificant way following positive earnings reports and press releases. We presented evidence of the anomalies to the U. S. Securities and Exchange Commission. In late November 2022, the SEC informed us that it would not pursue the matter further from an enforcement perspective. As such, there is a risk that an investment in our stock will continue not to track our operational performance. In our April 2022 press release describing the lack of correlation between the stock price and our economic performance, we noted that the then-current market capitalization was less our asset value at that time. This remains true. As of December 31-29, 2022-2023, our market capitalization was \$ 49-33. +2 million (based on a \$ 1. 64-11 per share closing price) and total stockholders' equity was \$ 108-99.3 million. **Our stock price reached a low of \$ 0. 95 per share in 2023 despite our strong balance sheet**. Our Customers Have Excess Product In Inventory and We Cannot Predict When It Will Be Depleted We believe domestic customers have retained Retractable products **(as well as competitive products)** purchased or provided for vaccination purposes in inventory, leading to a decrease in demand for our products. It is unclear when the excess inventory surplus will clear. Until the inventory is depleted, we expect domestic demand to continue to be depressed. 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~~ **Syringes** comprised 91-78. 5-3 % of sales in 2022-2023. 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~~ **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. For instance, Becton. Dickinson and Company (" BD "), a global company which we had previously considered our primary competitor, spun off a portion of its syringe, needle, and injection product division as Embecta Corp. (" Embecta ") in April 2022. Though newly formed, Embecta licenses existing BD intellectual property and has continued to use the BD branding on its products and is provided with certain other services by BD. Embecta's 2022-2023 annual report indicated that the company had 1-2, 900-200 employees, as compared to our workforce of less than 200 employees. With resources greatly in excess of our own, we expect Embecta will be a formidable competitor. Operations May Be Affected by Foreign Trade Policy We are subject to risks associated with foreign trade policy. In 2022-2023, we used Chinese manufacturers to produce 91-88. 6-4 % of our products. In the event that we become unable to purchase product from our Chinese manufacturers, we may 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 derived 44-20. 9-6 % of our revenues in 2022-2023 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 51-50. 4-8 % of the outstanding Common Stock as of March 10-11, 2023-2024. 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. The concentration of ownership may likewise influence Mr. Shaw's continued employment and position as President, CEO, and Chairman of the Board. Mr. Shaw's rights under the Technology License Agreement, as the owner of the technology we produce, present similar conflicts of interest. Defensive Measures to Deter Hostile Takeovers

On November 16, 2021, we and Mr. Shaw entered into the Third Amendment to Technology License Agreement (the "Amendment"). The Amendment expands the scope of the Technology License Agreement and provides additional protection to the parties in the event of a Hostile Takeover, as defined by the Amendment. Under the Amendment, under certain conditions, Mr. Shaw is granted the unilateral right to terminate the Technology License Agreement or cancel or convert a license thereunder from exclusive to nonexclusive following a Hostile Takeover. Additionally, as a public Texas corporation, we are generally prohibited from entering into a business combination with a person who acquires twenty percent or more of our stock for three years unless either: (1) the combination or acquisition is pre-approved by our Board; or (2) the combination is approved by affirmative vote of the shareholders of at least two-thirds of the outstanding voting shares entitled to vote, excluding the affiliated shareholder. As such, independent of the rights granted to Mr. Shaw under the Amendment, as beneficial owner of ~~51.50~~ **48** % of our stock and Chairman of the Board, Mr. Shaw has considerable influence on all business combination decisions.

~~7~~ **Supply** - **Supply** Chain Disruptions Could Negatively Impact our Profitability Our operations are dependent upon timely delivery of finished goods from our Chinese manufacturers and timely delivery of sufficient quantities of components and raw materials for domestic manufacturing. Any disruption in our suppliers' operations or timely availability of shipments from our third-party freight carriers, could disrupt our ability to provide product to our customers in a timely manner, which could materially and adversely affect our results of operations and cash flows.

~~Inflationary~~ **Inflationary** Price Pressures and Uncertain Availability of Commodities, Raw Materials, Utilities, Labor or Other Inputs Used by us and our Suppliers, or Instability in Logistics and Related Costs, Could Negatively Impact our Profitability Increases in the price of commodities, raw materials, utilities, labor or other inputs that we or our suppliers use in manufacturing and supplying products, components and parts, along with logistics and other related costs, may lead to higher production and shipping costs for our products, parts, and components. Further, increasing global demand for, and uncertain supply of, such materials could disrupt our or our suppliers' ability to obtain such materials in a timely manner to meet our supply needs and / or could lead to increased costs. A material increase in the cost of inputs to our production could lead to higher costs for our products and could negatively impact our operating results.

~~Our Stock Has Recently Experienced Significant Price Fluctuation~~ **Our stock price experienced significant fluctuation during 2022 and may continue to be unpredictable. Our stock price fluctuated in 2022 from a high in January of \$ 7.37 per share to a low price in December of \$ 1.61. As of March 10, 2023, the stock price was \$ 1.79 per share. We entered into a private stock repurchase effective December 2022 for the purchase of three million shares of our Common Stock at \$ 1.60 per share. We purchased 558,976 shares of our common stock in 2022 at an average price of \$ 5.01 per share pursuant to our stock repurchase plan established in June 2021 which plan was terminated in April 2022.** 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. **As disclosed in a Current Report on Form 8-K on February 16, 2024, we initiated a voluntary recall on February 5, 2024 of our EasyPoint Needle lot number K220402 which was shipped within the U. S. between July 20, 2022 and September 20, 2023. The recall was due to the possible detachment of the needle cannula from the needle holder, which could result in serious injury. The possible defect increases our risk of liability in connection with those units.** 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 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 ~~15-19~~ **23** % of our total 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.

~~8~~ **Health** - **Health** Crises Could Have an Adverse Effect on Our Business In any future health crisis, 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. In the event of a resurgence of COVID-19 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. Travel and import restrictions may also disrupt our ability to manufacture or distribute our products. 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.

~~8~~ **Our key personnel and other employees could be affected by COVID-19 or any future pandemic, which could affect our ability to operate efficiently. 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 giving away 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. 9