Risk Factors Comparison 2025-03-28 to 2024-03-29 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 ~~While we~~ **Operations May Be Affected by Foreign Trade PolicyWe** are ~~committed~~ **subject** to **risks associated with foreign trade policy** ~~decreasing our reliance on imported products,and decreasing the negative financial impact such tariffs carry,there is no guarantee that our efforts will be successful~~ . **In 2023** ~~To the extent possible~~ ,we ~~are working~~ **used Chinese manufacturers** to ~~increase~~ **produce 88.4 % of** our ~~domestic production~~ **products** ~~capacity and efficiency to be cost- competitive with our international manufacturers on a pre- tariff basis~~ .In the event that we become unable to purchase product from our Chinese manufacturers ~~or produce those products domestically~~ ,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 ~~derived~~ . We Are Concerned that Our Stock Price is Not Correlated with ~~Value~~ **ValueAs** ~~As~~ of December ~~29~~ **31** , ~~2023~~ **2024** , our market capitalization was $ ~~33~~ **20** . ~~2~~ **7** million (based on a $ ~~1~~ **0** . ~~11~~ **69** per share closing price) and total stockholders' equity was $ ~~99~~ **87** . ~~3~~ **2** million. Our stock price reached a low of $ 0. ~~95~~ **57** per share in ~~2023~~ **2024** despite our strong balance sheet **. We are therefore concerned that our stock price is not correlated with our value** . Our Customers Have Excess Product In Inventory and We Cannot Predict When It Will Be ~~Depleted~~ **DepletedWe** ~~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. **The extent to which surplus product still exists, and the potential impact it may have on future orders, is uncertain.** We Are Challenged by Uncertainties in Obtaining and Enforcing Intellectual Property ~~Rights~~ **RightsOur** ~~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. Syringes comprised ~~78~~ **68** . ~~3~~ **5** % of sales in ~~2023~~ **2024** . 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~~ **TechnologiesBecause** ~~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~~ **ResourcesOur** ~~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. 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 ~~2023~~ **2024** annual report indicated that the company had 2, ~~200~~ **100** employees, as compared to our workforce of **227** ~~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...... materially adversely impact our operations. We **7We** ~~cannot predict the impact of potential changes to U. S. foreign trade policy. Additionally, we derived 20. 6 % of our revenues in 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 ShareholderThomas J. Shaw, our President and Chief Executive Officer, has investment or voting power over a total of ~~50~~ **53** . ~~8~~ **3** % of the outstanding Common Stock as of March ~~11~~ **10** , ~~2024~~ **2025** . 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 TakeoversOn

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 ~~50~~ **53** . ~~8~~ **3** % of our stock and Chairman of the Board, Mr. Shaw has considerable influence on all business combination decisions. Supply Chain Disruptions Could Negatively Impact our ProfitabilityOur operations ~~are~~ **have historically been** dependent ~~upon~~ **on** timely delivery of finished goods from our Chinese manufacturers and timely delivery of sufficient quantities of components and raw materials for domestic manufacturing. **As mentioned earlier, we are shifting our production operations away from China to our domestic facility. With this change of production venue, we will face increased reliance on our domestic supply chain for raw materials and components parts. We expect this reliance to continue to increase as our domestic production output increases.** 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. ~~7Inflationary~~ **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 **. The full impact of greater domestic production on our sourcing materials through our supply chain is not yet known and difficult to estimate. We expect that as we increase our materials acquisition levels for domestic production, we will be able to achieve economies of scale and greater volume- purchasing agreements with our suppliers, but there is no guarantee such benefits will materialize. 8Vaccine Hesitancy Could Impact DemandOverall demand may be affected by public sentiment and acceptance of the safety and efficacy of vaccinations. While some products in our catalog of products are unrelated to the administration of vaccines, changes in the acceptance of vaccinations could have a material impact on our business** . We Face Inherent Product Liability RisksAs 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. **Since the initiation of the voluntary recall, all reasonable efforts have been made to remove EasyPoint Needle lot K220402 from the market in accordance with the recall strategy. We believe the recall is complete and we have requested termination of the voluntary recall from the FDA. The Medical Devices and Radiological Health Risk Mitigation and Response Branch has: confirmed our request for termination, notified us that the division is currently experiencing a severe backlog of termination requests which are being processed in the order they are received and informed us that once the termination process begins, they will follow up with us concerning any additional questions they may have.** Our Business May Be Affected by Changes in the Health Care Regulatory EnvironmentIn 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 AccountOur 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 ~~19~~ **25** . ~~3~~ **1** % 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. Health Crises Could Have an Adverse Effect on Our BusinessIn 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. **9** ~~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~~