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

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You should consider carefully the risks and uncertainties described below, together with all ~~of~~ the other information in this Annual Report on Form 10- K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and / or prospects. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant losses since our inception. These operating losses are expected to continue, and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability. We are a small, non- diversified medical device company with a history of limited revenue and significant operating losses **,** and our prospects must be evaluated considering the uncertainties, risks, expenses, and difficulties frequently encountered by similarly situated companies. The Company has generated net losses in all periods since the commencement of our operations. The operating losses were $ **7. 1 million and $** 8. 8 ~~million and $ 7. 4~~ million, for the years ended December 31, **2023, and** 2022, ~~and 2021,~~ respectively ~~. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we undertake to commercialize our CompuFlo Epidural System~~ . Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets, and stockholders' equity. Because of the risks and uncertainties associated with product acceptance, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability. Even if we do generate profits from operations, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to generate profits from operations, and to become and remain profitable, could impair our ability to raise capital, expand our business, and maintain our commercial efforts or continue our operations. A decline in the value of our company could also cause our shareholders to lose all or part of their investment **.** We ~~may require~~ **anticipate that we will need** additional funding **for our operations** and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate **parts of the** commercialization efforts of our CompuFlo Epidural Computer Controlled Anesthesia System. Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, **2023 and** 2022 ~~and 2021~~ , net cash flow used in operations was approximately $ ~~6~~ **5** . ~~0~~ **3** million and approximately $ ~~4~~ **6** . 0 million, respectively. We expect to continue to spend substantial amounts on commercialization and marketing activities, including the continued commercialization and marketing of our FDA- approved CompuFlo Epidural Computer Controlled Anesthesia System. Until such time, if ever, as we can generate **enough** ~~a sufficient amount of~~ product revenue and achieve positive cash flow, we expect to seek to finance future cash needs through equity financings or corporate collaboration and licensing arrangements and may seek the sale of non- medical assets. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock. Almost all our ~~69~~ **75** , ~~306~~ **881** , ~~497~~ **840** outstanding shares of common stock on December 31, ~~2022~~ **2023** , as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either freely or pursuant to Rule 144 under the Securities Act of 1933, as amended. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock ~~. ● In February 2019, we issued 6, 282, 400 shares and 1, 570, 600 warrants to purchase common shares under our S- 3 registration statement. During 2019 the Company issued 639, 375 shares associated the warrants issued in February 2019. Since the year ended December 31, 2019, the Company issued 675, 000 shares of common stock for warrants exercised at $ 0. 50 for proceeds of $ 337, 500. ● In February 2019, in a private placement we issued 714, 286 restricted common shares and 178, 571 warrants to purchase common stock. ● In April 2020, we completed a Common Stock offering generating gross proceeds of approximately $ 5. 1 million (5, 420, 000 common shares and 2, 710, 000 warrants). The combined price of the shares and warrants was $ 0. 95 per share. The warrants are exercisable at a price of $ 1. 20 per share and have an expiration of three (3) years from the issue date. ● In June 2020, we completed a second Common Stock offering generating gross proceeds of approximately $ 14. 6 million (6, 770, 000 common shares and 3, 749, 000 warrants). The combined price of the shares and warrants was $ 2. 15 per share. The warrants are exercisable at $ 2. 60 and expire three (3) years from the issue date~~ . Raising additional capital by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish proprietary rights. To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements or the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Recent developments in financial institutions could adversely affect our current and projected business operations, financial condition and results of operations. Recent events involving limited liquidity, defaults, non- performance and other adverse developments that affect financial institutions have led to market- wide liquidity concerns. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. On March 12, 2023, Signature Bank and Silvergate Capital Corp. were also placed into receivership. Future increases of the borrowing rate by the Federal Reserve Board, to slow inflation or for other reasons, may expose other financial

institutions to greater interest rate risk and exacerbate liquidity and other adverse developments affecting such institutions. The Company currently keeps more than $ 250, 000, the maximum amount insured by the Federal Deposit Insurance Corporation (" FDIC "), in its current bank depositary. The Company may experience delayed access or a loss of its uninsured deposits or other financial assets should its existing financial institution experience financial distress. While the U. S. Department of Treasury, FDIC and Federal Reserve Board have provided access to uninsured funds in connection with the Silicon Valley Bank crisis, there is no guarantee that these institutions will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. The Company is currently evaluating its banking relationships with the intent of increasing the amount of deposits that are fully insured or invested in risk - free instruments. The results of events or concerns that involve non- performance by financial institutions could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry, or delayed access or loss of uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution by our customers or vendors, could lead to losses or defaults by companies with whom we do business, which in turn could have a material adverse effect on our current and / or projected business operations, results of operations and financial condition. In addition, other companies could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Risks Related to Sales and Distribution of Milestone Scientific Products ~~Changes in our distribution arrangements exposes us to risks of interruption of marketing efforts and building new marketing channels. Effective December 31, 2022, the Company' s termination of its U. S. distribution agreement with Henry Schein became effective. The goal of changing our marketing plan from a sole exclusive distributor in the United States and Canada, to a large number of non- exclusive distributors and an e- commerce platform, may not be seamless or uninterrupted. Returns under our Distribution and Supply Agreement with Henry Schein, Inc. could have a material adverse effect on our business, financial condition, and results of operations. Under our Distribution and Supply Agreement with Henry Schein, Henry Schein has a right to return our products for full credit against the purchase price paid by them in accordance with such agreement, including but not limited to, returns due to shipment error by us or factory defect. On December 31, 2022, such non- exclusive distribution arrangement terminated, subject to certain post- termination rights and obligations of the parties, all in accordance with such agreement. Milestone Scientific' s International Operations Subject it to Certain Business Risks. A substantial amount of~~ Milestone Scientific' s sales ~~come~~ **and marketing efforts in the United Stated rely upon its E- Commerce platform. Milestone Scientific believes that a significant portion of its sales will continue to be** from its **E- Commerce platform launched in January 2023, for the foreseeable future. We have exposure to risks of** ~~operations~~ **operating in** ~~outside the United States and~~ **an** ~~we intend~~ **E- commerce platform: ● Refunds and customer disputes due** to ~~continue to pursue growth opportunities outside of the United States~~ **issues like wrong product delivery or defective items can impact your business . ● Online security breaches and cyberattacks ● Poor search engine visibility affects traffic and sales. ● Unexpected changes in political or regulatory environments; If** Milestone Scientific **is unable** ~~' s international operations subject it~~ to **maintain** ~~certain risks relating to, among other things, fluctuations in foreign currency exchange, local economic and political conditions, competition from local companies, increases in trade protectionism, United States relations with the governments of the foreign countries in which Milestone Scientific operates, foreign regulatory requirements or changes in such requirements, changes in local healthcare payment systems and healthcare delivery systems, local product preferences and requirements, longer payment terms for~~ **or expand its E- Commerce platform its sales may be negatively affected** ~~account receivables than we experience in the United States, difficulty in establishing and managing foreign operations, weakening or loss of the protection of intellectual property rights in some countries and import or export licensing requirements~~ . We are exposed to the risks inherent in international sales. In ~~2022~~ **2023** , export sales outside of the United States made up approximately ~~63~~ **45** % of our total sales, and we sell our products to customers in approximately ~~30~~ **41** countries and U. S. territories. We have exposure to risks of operating in many foreign countries, including: ● fluctuations in foreign currency exchange rates, could increase the end user cost for instruments ~~;~~ **.** ● restrictions on, or difficulties and costs associated with, the currency exchange from foreign countries to obtain U. S. dollars; ● difficulties and costs associated with complying with a wide variety of complex laws, treaties, and regulations; ● unexpected changes in political or regulatory environments; ● political and economic instability; ● import and export restrictions and other trade barriers; and ● difficulties in obtaining approval for significant transactions. If physicians do not accept nor use our CompuFlo Epidural System, our ability to generate revenue from sales will be materially impaired. Although the FDA has cleared our application to begin marketing the CompuFlo Epidural System, this is no assurance that physicians, hospitals, clinics, and other health care providers will accept and use it. Acceptance and use of the CompuFlo Epidural System will depend on many factors including: ● perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product ~~;~~ **.** ● cost- effectiveness of our product relative to competing products and systems; ● convenience, ease of use and reliability of our product relative to competing products and systems ~~;~~ ● patient satisfaction; ● product availability as well as, manufacturer warranty, maintenance, and customer and technical support; ● availability of reimbursement for our product from government or other healthcare payers; and ● effectiveness of marketing and distribution efforts by us and our licensees and distributors. Because we expect sales of the CompuFlo Epidural Computer Controlled Anesthesia System to generate substantially all our medical product revenues in the near- term, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing or make such financing difficult to obtain on favorable terms, if at all. ~~Milestone Scientific' s sales and marketing efforts rely upon independent distributors that are free to market products that compete with Milestone Scientific' s products, and if Milestone Scientific is unable to maintain or expand its network of independent distributors, its business could be materially adversely affected. Milestone Scientific believes~~

~~that a significant portion of its sales will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of its sales to independent distributors could increase. None of Milestone Scientific' s independent distributors in the United States have been required to sell Milestone Scientific products exclusively, and each of them may freely sell the products of Milestone Scientific' s competitors. If Milestone Scientific is unable to maintain or expand its network of independent distributors, its sales may be negatively affected. If any of its key independent distributors were to cease to distribute Milestone Scientific' s products or reduce their promotion of such products as compared to the products of Milestone Scientific' s competitors, Milestone Scientific may need to seek alternative independent distributors or increase its reliance on other independent distributors which alternative arrangements may not be sufficient to prevent a material reduction in sales of its products.~~ Developments by competitors may render our products or technologies obsolete or non- competitive. The medical device industry is intensely competitive and subject to rapid and significant technological change. We expect that other companies (or individuals), whether located in the United States or abroad, will pursue the development of alternative injection- based or imaging- based systems that will compete with our products. Many of these potential competitors have substantially greater capital resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These companies also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations. As a result, we may not be able to compete effectively against these companies or their products. Our ability to commercialize our products will depend in part on the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers. Our ability to generate revenues from our products will be diminished if the products sell for inadequate prices or hospitals or physicians are unable to obtain adequate levels of reimbursement for the cost they incur in connection with the use of the product. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Insurance coverage may not be available, or reimbursement levels may be inadequate ~~,~~ to cover the charges for the use of such **a** product. If **the** government and other healthcare payers do not provide adequate coverage and reimbursement for any of our products, market acceptance of such ~~product~~ **products** could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and price controls. In the United States, where pricing levels for medical products, procedures and services are substantially established by third- party payors, including Medicare, if payors reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue use of the product, to substitute lower cost products even if the alternatives are less effective or to seek additional price- related concessions. These actions could have a negative effect on our financial results. The existence of direct and indirect price controls and pressures on our products could materially adversely affect our financial prospects and performance. We could lose our market advantage earlier than expected. We believe that our products represent a significant improvement over any existing drug delivery injection system in use today. However, this competitive advantage can evaporate quickly if we are not able to commercialize our products quickly. In the medical device industry, **most** ~~the majority~~ of an innovative product' s commercial value is realized during the early stages of commercialization, before competing products are developed. Our market advantage is based, in part, on patent rights and the need for new competing products and systems to obtain regulatory approval before they can be commercialized. The scope of our patent rights may be limited and may also depend on the availability of meaningful legal remedies. Our failure to adequately protect our intellectual property rights, through patents or otherwise, or limitations on the use or loss of such rights, could have a material adverse effect on our ability to prevent the commercialization of competing anesthetic delivery systems. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and / or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable, and the validity and enforceability of patents cannot be predicted with certainty. Risks Related to ~~the Covid- 19 Pandemic The COVID- 19 pandemic has and may continue to adversely affect the Company' s business. Additional factors could exacerbate such negative consequences and / or cause other materially adverse effects. Certain COVID- 19 pandemic- related impacts were experienced by our businesses during 2022 and may continue for an indeterminable period. These included supply chain delays for some of our products which are manufactured in China and supply shortages in key components in our dental products. Future resurgences in COVID- 19 infections or other new viral outbreaks may affect the prioritization of non- acute versus acute healthcare utilization, which may temporarily weaken future demand for certain of our products and increase the demand for other of our products. Also, adverse macroeconomic conditions may worsen if governments impose future restrictions, such as lockdowns or quarantine requirements, in order to control infection rates associated with COVID- 19 or other viruses. Additionally, the pandemic escalated challenges that existed for global healthcare systems prior to the pandemic, including budget constraints and staffing shortages, particularly shortages of nursing staff. Changes in the ways healthcare services are delivered, including the transition of more care from acute to non- acute settings and increased focus on chronic disease management, may place additional financial pressure on hospitals and the broader healthcare system. Healthcare institutions may take actions to mitigate any persistent pressures on their budgets and such actions could impact the future demand for our products. We are experiencing supply delays and shortages due to the disruptions the ongoing COVID- 19 pandemic is having on the global supply chain, especially with respect to goods from China. We are experiencing supply delays and shortages due to the disruptions the ongoing COVID- 19 pandemic is having on the global supply chain, especially with respect to goods from China. The ongoing COVID- 19 pandemic has resulted in significant disruption to the operations of certain suppliers in China and the related transportation of their goods to the United States that are parts of our global supply chain. We have been able to make alternative delivery arrangements for limited quantities of goods, at an increased cost. While we have not yet experienced material shortages in supply as a result of these disruptions and~~

~~our alternative delivery arrangements, if they were to be prolonged or expanded in scope, there could be resulting supply shortages which could impact our ability to have manufactured and delivered our products to the United States and, ultimately to our customers. Accordingly, such supply shortages and delivery limitations could have a material adverse effect on our business, financial condition, results of operations, and cash flows. Risks Related to~~ Employee Matters We may not be able to attract and retain qualified employees. Our future success depends upon the continued service of our executive officer and other key management and technical personnel, and on our ability to continue to identify, attract, retain, and motivate them. Implementing our business strategy requires specialized territory managers and other talent, as our revenues are highly dependent on technological and product innovations. The market for employees in our industry is extremely competitive, **several** ~~a number of~~ such competitors are significantly larger than us and **can** ~~are able to~~ offer compensation **more than** ~~in excess of~~ what we are able to offer. If we are unable to attract and retain qualified employees, our business may be harmed. Risk Related to Our Dependence on Third Parties Relying exclusively on third parties to manufacture our products, changes in our informal manufacturing arrangements made by the manufacturer of our products and disruptions at the manufacturing facility of our manufacturers and failure to maintain existing supply relationships exposes us to risks that may harm our business. We have limited internal experience in manufacturing operations and have not historically established our own manufacturing facilities. We currently lack the internal resources to manufacture any of our products, including our CompuFlo ® Epidural Computer Controlled Anesthesia System. Milestone Scientific has been supplied by the manufacturer of the Wand / STA System and its predecessor, the CompuDent System, since the commencement of production in 1998, and by the manufacturer of its handpieces since 2003. The manufacturer of our handpieces is in the People' s Republic of China and the manufacturer of the Wand / STA System is in the United States. At present, we have an informal arrangement with the manufacturers of our products. Our current arrangement with our manufacturers is on a purchase order- by- purchase order basis. As a result, we do not have price protection or a supply commitment for our devices or handpieces. If either manufacturer insists on a material change in terms or determines to discontinue manufacture of our products, it could have an adverse effect on our financial condition and results of operation. An operational disruption in the facility of the manufacturer of, or their ability to ship, our handpieces or devices could negatively impact our financial results. The occurrence of a natural disaster, such as a hurricane, tropical storm, earthquake, tornado, severe weather, flood, fire, or epidemic, pandemic, or other health emergency, or other unanticipated problems such as labor difficulties, equipment failure or unscheduled maintenance, in each case could cause operational disruptions of varied duration. These types of disruptions could materially adversely affect our financial condition and results of operations to varying degrees dependent upon the facility, the duration of the disruption, our ability to shift business to another facility or find alternative sources of supply. Any losses due to these events may not be covered by our existing insurance policies or may be subject to certain deductibles. Given our current manufacturing relationships, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. Our anticipated future reliance on third- party manufacturers exposes us to the following additional risks: ● We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to develop substantially equivalent processes for production of our products. ● Contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store, and distribute our products. ● Contract manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact their ability to manufacture our products. ● If any third- party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements. Though ~~other~~ alternate sources of supply for dental handpieces exist, Milestone Scientific would need to establish relationships with new suppliers, and with respect to the Wand / STA System recover its existing tools or have new tools produced and " burned in " and other manufacturing and quality control software re- produced. Establishing new manufacturing relationships could involve significant expense and delay. Each of these risks could delay the commercialization of our CompuFlo Epidural Computer Controlled Anesthesia System, limit our available supply of The Wand / STA for dental applications, cause damage to our reputation, result in higher costs and / or deprive us of potential product revenues. Any curtailment or interruptions of the supply, whether **because** ~~as a result~~ of termination of the relationship or otherwise, would have a material adverse effect on our financial condition, business, and results of operations. Our business is exposed to risks associated with the economic, environmental, and political conditions in China because the sole manufacturer of our handpieces is ~~located~~ in China. Because the sole manufacturer of our dental handpieces is ~~located~~ in China, our business is disproportionately exposed to the economic, environmental, and political conditions of the region. China' s political and economic systems are very different from most developed countries in many respects, including, the amount of government involvement, the level of development, the control of foreign exchange and the allocation of resources. Uncertainties may arise with changing governmental policies and measures. China also faces many social, economic, and political challenges that may produce instabilities in both its domestic arena and in its relationship with other countries. These instabilities may significantly and adversely affect our supply of dental handpieces which would in turn adversely affect our financial performance. In addition, as the Chinese legal system develops, there can be no assurance that changes in laws and regulations and their interpretation or their enforcement will not have a material adverse effect on our business relationship with the sole manufacturer of our dental handpieces. Any adverse change in the economic, environmental, and political conditions in China could have a material adverse effect on economic growth and the level of investments and availability of capital in China, which in turn could lead to a reduction in the supply of our dental handpieces

and consequently have a material adverse effect on our businesses. Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products. In general, our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services, and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. **The use** ~~See Item 1; " Government Regulation. " Use~~ of third parties to manufacture our products may increase the risk that we will not have **enough** ~~sufficient quantities~~ of our products or such quantities at acceptable levels of cost and quality, which could impair our commercialization efforts. Milestone Scientific relies on **several** ~~a number of~~ third parties to supply and manufacture the components and raw materials for its products and its does not have long- term supply agreements with suppliers of these component parts and raw materials, and its arrangements with these suppliers are on a purchase- order basis. These products we obtain from suppliers are subject to fluctuations in price and availability attributable to **several** ~~a number of~~ factors, including general economic conditions, commodity price fluctuations, the demand by other companies for the same raw materials and the availability of complementary and substitute materials. While Milestone Scientific works with suppliers to ensure continuity of supply, no assurance can be given that these efforts will be successful. In the event that any of its existing supply arrangements are terminated or there is a reduction or interruption of supply under these existing arrangements, Milestone Scientific expects that it will be able to enter into new arrangements with alternative suppliers, but these new arrangements may be on terms that are less favorable, including with respect to price and volume, and it may be costly or cause delays in our manufacturing process to transition to a new supplier, particularly in cases in which we must comply with regulatory requirements relating to qualification of new suppliers. The termination, reduction or interruption in supply of these raw materials and components could adversely impact Milestone Scientific Scientific' s ability to manufacture and sell certain of its products. Third- party suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints, and environmental factors, any of which could delay or impede their ability to supply the components and raw materials for Milestone Scientific' s products. Any such failure to perform or a reduction or interruption in supply could have a material adverse effect on Milestone Scientific' s business and operations. Risks Related to Regulatory Compliance and Other Legal Matters We are subject to substantial domestic and international government regulation, including regulatory quality standards applicable to our manufacturing and quality processes. Failure by us to comply with these standards could have an adverse effect on our business, financial condition, or results of operations. The FDA regulates the approval, manufacturing and sales and marketing of many of our products in the United States. Significant government ~~regulation~~ **regulations** also ~~exists~~ **exist** in other countries in which we conduct business. As a device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA' s Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European community, we are required to maintain certain ISO certifications to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Failure to comply with current governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages or delays in product manufacturing. Efficacy or safety concerns, an increase in trends of adverse events in the marketplace, and / or manufacturing quality issues with respect to our products could lead to product recalls or related field actions, withdrawals, and / or declining sales. We may be subject, directly, or indirectly, to U. S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties. Our operations are and will continue to be directly, or indirectly through our distributors, customers, and health care professionals, subject to various U. S. federal and state fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute, federal False Claims Act, and the Foreign Corrupt Practice Act of 1977 (" FCPA "). These laws may impact, among other things, our proposed sales, and marketing and education programs. The federal Anti- Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. Several courts have interpreted the statute' s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. The Anti- Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Penalties for violations of the federal Anti- Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment, and possible exclusion from Medicare, Medicaid, and other federal health care programs. An alleged violation of the Anti- Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as the federal False Claims Act. Many states have also adopted laws like the federal Anti- Kickback

Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as " qui tam " actions, can be brought by any individual on behalf of the government and such individuals, commonly known as " relators " or " whistleblowers, " may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and health care companies to have to defend False Claim Act actions. The Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been previously dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws with qui tam provisions. The Affordable Care Act includes provisions known as the Physician Payments Sunshine Act (section 6002), which require manufacturers of drugs, biologics, devices, and medical supplies covered under Medicare and Medicaid to disclose to the Centers for Medicare and Medicaid Services any transfers of value to physicians and teaching hospitals. Manufacturers must also disclose investment interests held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to $ 1 million per year for knowing violations and may result in liability under other federal laws or regulations. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states, such as Massachusetts and Vermont, impose an outright ban on certain gifts to physicians. These laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our products. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, or an administrative action of suspension or exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations **.** In addition, we are subject to the Foreign Corrupt Practices Act (" FCPA ") and other countries' anti- corruption / anti- bribery regimes, such as the U. K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents, or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, results of operations and financial condition. Changes in United States policy regarding international trade, including import and export regulation and international trade agreements, could also negatively impact Milestone Scientific' s business. The United States has imposed tariffs and export controls on certain goods and products imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Additional tariffs imposed by the United States on a broader range of imports, or further retaliatory trade measures taken by China or other countries in response, could result in an increase in supply chain costs that Milestone Scientific may not be able to offset or that otherwise adversely impact its results of operations. In addition, political tensions between the United States and China have escalated in recent years. Rising political tensions could reduce trade, investment and other economic activities between the two major economies. Any of these factors could have a material adverse effect on Milestone Scientific' s business, prospects, financial condition **,** and results of operations. Certain modifications to Milestone Scientific' s products may require new 510 (k) clearances or other marketing authorizations and may require Milestone Scientific to recall or cease marketing its products. Once a medical device is permitted to be legally marketed in the United States pursuant to a 510 (k) clearance, a manufacturer may be required to notify the FDA of certain modifications to the device. Manufacturers determine in the first instance whether a change to a product requires a new 510 (k) clearance or premarket submission, but the FDA may review any manufacturer' s decision. The FDA may not agree with Milestone Scientific' s decisions regarding whether new clearances are necessary. Milestone Scientific has made modifications to its products in the past and has determined based on its review of the applicable FDA regulations and guidance that in certain instances new 510 (k) clearances or other premarket submissions were not required. Milestone Scientific may make similar modifications or add additional features in the future that it believes ~~does~~ **do** not require a new 510 (k) clearance. If the FDA disagrees with Milestone Scientific' s determinations and requires it to submit new 510 (k) notifications, Milestone Scientific may be required to cease marketing or to recall the modified product until it obtains clearance, and it may be subject to significant regulatory fines or penalties. Milestone Scientific may be subject to enforcement actions if it engages in improper marketing or promotion of its products. Milestone Scientific' s promotional materials and training methods must comply with applicable laws, regulations and regulatory authority' s rules and guidelines, including the FDA and the Federal Trade Commission (the " FTC "). If the FDA, the FTC or another regulatory agency determines that Milestone Scientific' s promotional or training material constitutes off- label, false or misleading, unfair or deceptive promotion of its products, it could request that Milestone Scientific modify its training or promotional materials or subject Milestone Scientific to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might **act** ~~take action~~ if they consider Milestone Scientific' s promotional or training materials to constitute off- label, false or misleading, unfair or deceptive promotion of its products, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement, and reputational harm. Changes in laws and regulations over which we have no

control can significantly affect our business and results of operations. Any governmental entity that regulates our operations in the country in which they are located may enact new legislation or adopt new laws and regulations or policies at any time, and new judicial decisions may change the interpretation of existing legislation or regulations at any time in any of the countries in which our operations or projects are located. We have no control over any such changes. Any new laws or regulations governing our operations could have an adverse impact on our business, results of operations and prospects. Risks Related to Milestone Scientific Common Stock Milestone Scientific is effectively controlled by a limited number of stockholders. Milestone Scientific Scientific' s principal stockholders, Leonard Osser and Gian Domenico Trombetta control approximately ~~25~~ **20** % of the issued and outstanding shares of common stock. As a result, they can exercise substantial control over our affairs and corporate actions requiring stockholder approval, including electing directors, selling all or substantially all our assets, merging with another entity, or amending our certificate of incorporation. This control could delay, deter, or prevent a change in control and could adversely affect the price that investors might be willing to pay in the future for Milestone Scientific' s securities. In addition, because of the concentration of ownership of our shares of common stock, our stockholders may from time to time ~~,~~ observe instances where there may be less liquidity in the public markets for our securities. Failure to implement effective internal controls required by the Sarbanes- Oxley Act of 2002 could result in material misstatements in our financial statements, cause investors to lose confidence in the Company' s reported financial information and have a negative effect on the trading price of our common stock. Section 404 of the Sarbanes- Oxley Act of 2002 requires **the** management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company' s annual and interim financial statements will not be prevented or detected on a timely basis. Any failure to complete the Company' s assessment of its internal controls over financial reporting or to remediate any material weaknesses that management may identify could harm the Company' s operating results, cause the Company to fail to meet its reporting obligations or result in material misstatements in the Company' s financial statements. Inadequate disclosure controls and procedures and internal controls over financial reporting could also cause investors to lose confidence in the Company' s public disclosures and reported financial information, which could have a negative effect on the trading price of our common stock. The market price of our common stock may be volatile and may fluctuate significantly, and stockholders could lose all or part of their investment in Milestone Scientific Our stock price may experience substantial volatility because of many factors, including: ● our failure to meet analysts' expectations; ● sales or potential sales of substantial amounts of our common stock; ● delay or failure in initiating our strategy to commercialize our CompuFlo Epidural System; ● the success of our strategy to commercialize our CompuFlo Epidural System; ● announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions that could adversely impact the market acceptance or competitive advantages of our CompuFlo Epidural System; ● developments concerning our licensors or product manufacturers; ● litigation and other developments relating to our patents or other proprietary rights or those of our competitors; ● our ability to successfully develop and commercialize products and services for the healthcare industry; ● conditions in the medical device industry; ● ~~governmental regulation and legislation; ●~~ variations in our anticipated or actual operating results; and ● change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations. Many of these factors are beyond our control. The stock markets in general, and the market for small, medical device companies ~~, in particular,~~ have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance. We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain. We have never paid cash dividends on any of our capital stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Provisions in our certificate of incorporation, our by- laws and Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock. Provisions of our certificate of incorporation, our by- laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include: ● the inability of stockholders to call special meetings; ● the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors; and ● limitations on filling of vacancies. All of which could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company. In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The existence of the forgoing provisions and anti- takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition. If we fail to adhere to the strict listing requirements of NYSE American, we may be subject to delisting. As a result, our stock price may decline, and our common stock may be de- listed. If

our stock were no longer listed on NYSE American, the liquidity of our securities likely would be impaired. Our common stock currently trades on the NYSE American under the symbol " MLSS ". If we fail to adhere to NYSE American' s strict listing criteria, including with respect to stock price, our market capitalization and stockholders' equity, our stock may be de- listed. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. Any failure at any time to meet the continuing NYSE American listing requirements could have an adverse impact on the value of and trading activity in our common stock. Your percentage of ownership in Milestone Scientific may be diluted in the future **.** In the future, your percentage ownership in Milestone Scientific may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including any equity awards that Milestone Scientific will grant to its directors, officers, employees and consultants. Such awards will have a dilutive effect on outstanding share count which could adversely affect the market price of Milestone Scientific' s common stock. Risks Related to Our Intellectual Property If we are unable to adequately protect our patents, trade secrets and other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged. Intellectual property rights, including patents, trade secrets, confidential information, trademarks, trade names and trade address, are important to our business. We will endeavor to protect our intellectual property rights in key jurisdictions in which our products are produced or used and in jurisdictions into which our products are imported. Our success will depend to a significant degree upon our ability to protect and preserve our intellectual property rights. However, we may be unable to obtain or maintain protection for our intellectual property in key jurisdictions. Although we own and have applied for patents and trademarks throughout the world, we may have to rely on judicial enforcement of our patents and other proprietary rights. Our patents and other intellectual property rights may be challenged, invalidated, circumvented, and rendered unenforceable or otherwise compromised. A failure to protect, defend or enforce our intellectual property could have an adverse effect on our financial condition and results of operations. Similarly, third parties may assert claims against us and our customers and distributors alleging our products infringe upon third party intellectual property rights. We believe that the intellectual property underlying our products is a competitive advantage. We rely on a combination of patent rights, trade secrets and nondisclosure and non- competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patents, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over- broad or otherwise invalidated in subsequent proceedings before courts or the U. S. Patent and Trademark Office. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and / or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies resulting from such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, nondisclosure and non- competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors, or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. If we must take legal action to protect, defend or enforce our intellectual property rights, any suits or proceedings could result in significant costs and diversion of our resources and our management' s attention, and we may not prevail in any such suits or proceedings. A failure to protect, defend or enforce our intellectual property rights could have an adverse effect on ~~our~~ **the** results of operations. Third parties could obtain patents that may require us to negotiate licenses to commercialize our technologies, and we cannot assure you that the required licenses would be available on reasonable terms or at all. Third parties may claim that one or more aspects of our technologies or products may infringe on their intellectual property rights. Our computer- controlled anesthesia systems are complex systems and numerous U. S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of drug delivery systems. In addition, many companies have employed intellectual property litigation as a strategy to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the U. S. and in foreign jurisdictions. If any of our computer- controlled anesthesia systems are found to infringe third party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology unless we obtain a license under the applicable third- party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign the system to avoid infringement. Even if we can redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or costlier product. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. ~~These~~ **This** ~~damages~~ **damage** could be substantial and could harm our reputation, business, financial condition, and operating results. A court also could enter orders that temporarily, preliminary, or permanently prohibit us, our licensees, if

any, and our customers from making, using, selling, offering to sell, or importing one or more of our products or using our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results, and financial condition. General Business Risks ~~Continued instability in the credit and financial markets may negatively impact our ability to commercialize our products. Financial markets in the United States, Canada, Europe, and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be reduced. As a small medical device company, we rely on third parties for several important aspects of our business, including contract manufacturing of products, distribution of our products and sales and marketing. These third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued volatility in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of any adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.~~ Our business and operations would suffer in the event of cybersecurity or other system failures. Despite the implementation of security measures, our internal computer systems, and those of any third parties with which we partner are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any cybersecurity or system failure, accident or breach to date, if an event were to occur, it could result in a material disruption of our operations, substantial costs to rectify or correct the failure, if possible, and potentially violation of HIPAA and other privacy laws applicable to our operations. If any disruption or security breach resulted in a loss of or damage to our data or applications or inappropriate disclosure of confidential or protected information, we could incur liability, further development of our products could be delayed, and our operations could be disrupted, any of which could severely harm our business and financial condition. ~~Issues with~~ **In general, our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services, and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters,** product **recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a** quality ~~could have a material adverse effect upon our~~ **or safety issue in** ~~business, subject us to regulatory actions and~~ **an effective and timely manner may also** cause **negative publicity,** a loss of customer confidence in us or our **current or future products, which may result in the loss of sales and difficulty in successfully launching new** products. Insurance coverage may be inadequate or unavailable to cover any product liability losses we incur. Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing, inspection, and sale of dental and medical devices. We are subject to product liability lawsuits alleging that component failures, manufacturing flaws, manufacturing defects, negligence in manufacturing, design defects, negligence in design, or inadequate disclosure of product- related risks, warnings, or product- related information resulted in an unsafe condition, injury, or death to customers. The risk of one or more product liability claims or lawsuits may be even greater after we launch new products with new features or enter new markets where we have no prior experience selling our products and rely on newly - hired staff or new independent distributors or contractors to provide new customer training and customer support. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, regardless of any available insurance coverage, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could have a material adverse effect on our business, financial condition and operating results.