

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023

Or
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to
Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

Delaware 13-3545623
State or other jurisdiction of incorporation or organization (I.R.S. Employer Identification No.)
425 Eagle Rock Avenue, Roseland, NJ 07068
(Address of principal executive offices)

Registrant's telephone number, including area code: 973-535-2717.

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

| <u>Title of each class</u> | <u>Symbol</u> | <u>Name of each exchange on which registered</u> |
|---|---------------|--|
| Common Stock, par value \$0.001 per share | MLSS | NYSE American |

Securities registered pursuant to section 12(g) of the Act: NONE.

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

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

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

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

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

Large, accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

As of June 30, 2023, the last business day of the registrants most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the issuer was \$40,047,188. This amount is based on the closing price of \$0.87 per share of the registrant's common stock as of such date, as reported on the NYSE American.

As of March 29, 2024, the registrant has a total of 76,602,116 shares of Common Stock, par value \$0.001 per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE
None

MILESTONE SCIENTIFIC INC.
Form 10-K Annual Report
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FORWARD-LOOKING STATEMENTS

When used in this Annual Report on Form 10-K, the words "may", "will", "should", "expect", "believe", "anticipate", "continue", "estimate", "project", "intend" and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") regarding events, conditions and financial trends that may affect Milestone Scientific's future plans of operations, business strategy, results of operations and financial condition. Milestone Scientific wishes to ensure that such statements are accompanied by meaningful cautionary statements pursuant to the safe harbor established in the Private Securities Litigation Reform Act of 1995. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Milestone Scientific's plans and objectives are based, in part, on assumptions involving the continued expansion of its business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific. Although Milestone Scientific believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. Considering the significant uncertainties inherent in the forward-looking statements included herein, our history of operating losses that are expected to continue, requiring additional funding which we may be unable to raise capital when needed (which may force us to delay, curtail or eliminate commercialization efforts of our CompuFlo Epidural Computer Controlled Anesthesia System), the early stage operations of and relative lack of acceptance of our medical products, relying exclusively on two third parties to manufacture our products, changes to our distribution arrangements exposes us to risks of interruption of marketing efforts and building new marketing channels, changes in our informal manufacturing arrangements made by the manufacturer of our products and disruptions at the manufacturing facility of our manufacturers, including shortages of or delays in obtaining chips and other components, exposes us to risks that may harm our business, raising additional funds 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, if physicians do not accept nor use our CompuFlo Epidural Computer Controlled Anesthesia System, our ability to generate revenue from sales will be materially impaired, exposure to the risks inherent in international sales and operations, including China, and developments by competitors may render our products or technologies obsolete or non-competitive, the inclusion of such information should not be regarded as a representation by Milestone Scientific or any other person that the objectives and plans of Milestone Scientific will be achieved. Prospective investors are cautioned that any forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties and the actual results may differ materially from those included within the forward-looking statements because of various factors. Except as required by the federal securities laws, Milestone Scientific undertakes no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise, to reflect events or circumstances occurring after the date of this Annual Report on Form 10-K. Milestone Scientific is the owner of the following registered U.S. trademarks: CompuDent®; CompuMed®; CompuFlo®; DPS Dynamic Pressure Sensing technology ®; Milestone Scientific ®; CathCheck®; the Milestone logo ®; SafetyWand®; STA Single Tooth Anesthesia Device ®; and The Wand ®.

PART I

All references in this report to "Milestone Scientific," "us," "our," "we," the "Company" or "Milestone" refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., and Milestone Innovation, unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent®; CompuFlo®; DPS Dynamic Pressure Sensing technology®; Milestone Scientific®; CathCheck®; the Milestone logo®; SafetyWand®; STA Single Tooth Anesthesia System®; and The Wand®.*

Item 1. Business

Overview

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, revolutionary, computer-controlled anesthetic delivery device, its DPS Dynamic Pressure Sensing Technology® System, to meet the needs of various subcutaneous drug delivery injections and fluid aspiration – enabling healthcare practitioners to achieve multiple unique benefits that cannot currently be accomplished with the 160-year-old manual syringe. Our proprietary DPS Dynamic Pressure Sensing technology is our technology platform that advances the development of next-generation devices. It regulates flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, used in various dental and medical injections. It has specific medical applications for epidural space identification in regional anesthesia procedures and intra-articular joint injections.

Our device, using The Wand®, a single use disposable handpiece, is marketed in dentistry under the trademarks *CompuDent®* and *STA Single Tooth Anesthesia System®*, and is suitable for all dental procedures that require local anesthetic. The dental devices are currently sold in the United States, Canada and in over 41 other countries. Milestone Scientific also has 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the *CompuFlo®* Epidural Computer Controlled Anesthesia System in the lumbar thoracic and cervical thoracic junction of the spinal region. In addition, we have obtained CE mark approval for certain medical devices, which can be marketed and sold in most European countries.

DPS Dynamic Pressure Sensing Technology: Our Proprietary Core Technology Platform

Given our experience and established brand awareness within the dental industry beginning with our first commercial product, the first computer-controlled local anesthesia delivery (C-CLAD) system marketed as the *Wand®* and re-branded as the *CompuDent®* System, now the market leader in dental injection technology, we elected to focus our product development efforts on improving the patient experience and making the device more versatile and precise for the practitioner.

Our next significant intellectual property advancement was an improvement over our *CompuDent®* System – the development of our proprietary *CompuFlo®* Computer-Controlled Drug Delivery System with *DPS Dynamic Pressure Sensing Technology*, an advanced and FDA-approved technology for the painless and accurate delivery of drugs, anesthetics, and other medicaments into all tissue types, as well as for the aspiration of bodily fluids or previously injected substances. Its regulation and control of the flow rate continues to provide painless delivery benefits, while its innovative dynamic pressure sensing capability provides visual and audible in-tissue pressure feedback, identifying tissue types to the healthcare provider. This pressure feedback extends the benefit of painlessness from anesthetics with known viscosities to a wide range of liquid drugs and other medicaments with varying viscosities and flow rates. Such pressure feedback, part of our *DPS Dynamic Pressure Sensing Technology*, also allows the healthcare provider to know when certain types of tissues have been penetrated and permits the healthcare provider to inject medicaments precisely at the desired location. Thus, real-time continuous pressure feedback can prevent the injection of tissue outside the intended target area, an important characteristic in the injection of chemotherapeutics and other toxic substances. In addition to the ability to determine exit pressure *in-situ* (in the injection site tissue) at the tip of the needle, minimizing tissue damage (and eliminating the pain of the injection) because the flow rate and pressure of the injection are precisely controlled, *CompuFlo®* computer-controlled Drug Delivery Systems features a proprietary algorithm, which allow for the measurement of the exit pressure. *CompuFlo®* technology also enables devices to provide a digital record of the time and volume of anesthetic or medicament injected.

Each Wand/STA System also includes a disposable injection handpiece that is extremely comfortable, light, and easy to use, providing for precise tactile control during the injection, an electro-mechanical (computer-controlled) fluid delivery instrument and the ability to record data from the injection event. The pencil grip used with the handpieces provides the practitioner with enhanced tactile sense and accurate control and allows bi-directional rotation, eliminating needle deflection, resulting in greater accuracy and success. The handpiece is vibration-free because it does not have a motor or electrical component in it and, since the handpiece does not look like a typical syringe, we believe it also reduces patient anxiety and offers the possibility of curing dental phobia of which an estimated 40 million Americans suffer.

As confirmed by numerous noted medical and dental experts within academia and the clinical practice arenas, *CompuFlo* Systems using *DPS* Dynamic Pressure Sensing technology have the potential to greatly increase the safety and efficacy of many drug delivery procedures that currently rely upon the over 160-year-old hypodermic syringe technology and the tactile senses and delivery expertise of the administrator.

Devices using *DPS* Dynamic Pressure Sensing Technology such as the *CompuFlo* System can be used to inject a wide variety of liquid medicaments as well as anesthetics. We believe our *CompuFlo* System avoids the negative side effects from the use of traditional hypodermic drug delivery injection devices, which are well documented in dental and medical literature and include risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications. Pain and tissue damage often result from uncontrolled flow rates and pressure created during the administration of drug solutions into human tissue. While several technologies can control the flow rate, we believe our patented *DPS* Dynamic Pressure Sensing technology and *CompuFlo* Systems provide the control of pressure during the injection as well accurately and precisely deliver the drug.

CompuFlo Epidural Computer Controlled Anesthesia System

The *CompuFlo* Epidural Computer Controlled Anesthesia System (or the *CompuFlo* Epidural System) is one such platform extension of our *DPS* Dynamic Pressure Sensing Technology platform, providing anesthesiologists and other healthcare providers the ability, for the first time, to quantitatively determine and document the pressure at the needle tip in real-time for proper needle placement in epidural procedures used for labor/delivery and back pain management. Our proprietary *DPS* Dynamic Pressure Sensing Technology allows the *CompuFlo* Epidural System to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify and confirm placement in the epidural space.

Our *CompuFlo* Epidural System provides an objective tool that we believe consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the intrafilamentary tissue. In studies, the *CompuFlo* Epidural System with *DPS* Dynamic Pressure Sensing Technology has been shown to be effective in correctly identifying the epidural space. Knowing the precise location of a needle tip during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes. In the absence of fluoroscopy, identifying the epidural space by relying on the subjective perception of loss of resistance to saline requires a very long education period and learning curve and could result in morbidity and lack of efficacy. During back pain management epidural procedures, where fluoroscopy is commonly used, the *CompuFlo* Epidural System allows the clinician to locate the epidural space, without using fluoroscopy, thereby protecting the patient and clinician from unnecessary exposure to radiation along with significantly reducing capital and operating costs.

Wand/STA Dental Product

Since its market introduction in early 2007, the STA Single Tooth Anesthesia System and prior C-CLAD devices have been used to deliver over 92 million safe, effective, and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

Medical Market Product

In June 2017, we received FDA regulatory clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for epidural injections.

In May 2022, the Company received a chronology-specific CPT Code for the Company's technology by the American Medical Association, which marks an important milestone that could increase the potential number of anesthesia pain management clinics adopting the *CompuFlo* instrument. Effective January 1, 2023, this temporary tracking code allows clinicians to submit claims to healthcare insurance providers using the Company's technology for Epidural Sterile Injections in the lumbar, thoracic, cervical thoracic junction of the spinal region for reimbursement. A CPT code expands the potential for reimbursement of epidural procedures in pain management utilizing the *CompuFlo* Epidural System, which can accelerate the commercial roll-out of *CompuFlo* in the United States.

On February 27, 2023, the Company announced that its *CompuFlo*® Epidural System has received 510(k) FDA clearance for use in the thoracic region of the spine, including the cervical thoracic junction. This approval expands upon the Company's prior approval of *CompuFlo* for use within the lumbar region of the spine, where the focus has been epidural analgesia during labor and delivery procedures.

Other Possible Products

The Company is reviewing the use of *CompuFlo's DPS Dynamic Pressure Sensing Technology* for less painful injections for use in rhinoplasty, colorectal surgery, podiatry, and other disciplines. In the self-injectable market, there are many injectable drugs routinely self-administered in a home or office setting using spring loaded automatic injection devices by people who suffer from long-term chronic conditions such as multiple sclerosis, rheumatoid arthritis, and other diseases of the auto immune system. We believe *CompuFlo's DPS Dynamic Pressure Sensing Technology*, using pressure sensing capabilities, can serve as a less painless subcutaneous injection method for these self-administered drugs. However, there can be no assurance that we will be able to successfully develop any such products, or that if developed, that we will be able to obtain FDA approval to market any such products, or even if we do obtain such FDA approval, that any such products will generate any revenue for us or be a commercial success.

European Conflicts

Sanctions imposed by the United States and other western democracies, because of the conflicts throughout Europe, and any expansion thereof, is likely to have unpredictable and wide-ranging effects on the domestic and global economy and financial markets, which could have an adverse effect on our business and results of operations. As direct impact from the conflict, we have experienced a decrease in international sales to Ukraine and halted all sales to Russia. We will continue to monitor the situation carefully and, if necessary, take action to protect our business, operations, and financial condition.

Patents and Intellectual Property

Milestone Scientific and its subsidiaries currently hold approximately 245 U.S. and foreign patents, and many patent applications. The Company's patents and patent applications relate to drug delivery methodologies, drug flow rate measurement, pressure/force computer-controlled drug delivery with exit pressure, dynamic pressure sensing, automated rate control, automated charging, drug profiles, audible and visual pressure/force feedback, tissue identification, drug delivery injection unit, drug drive unit for anesthetic, handpiece, and injection device. Milestone Scientific and its subsidiaries also currently hold approximately 36 registered U.S. and foreign trademarks, including *CompuDent®*, *CompuFlo®*, *DPS Dynamic Pressure Sensing technology®*, *Safety Wand®*, *STA Single Tooth Anesthesia System®*, and *The Wand®*

Milestone Scientific relies on a combination of patent, copyright, trade secret and trademark laws and employee and third-party non-disclosure agreements to protect its intellectual property rights. Despite the precautions taken by Milestone Scientific to protect its IP rights, unauthorized parties may attempt to reverse engineer, copy, or obtain and use products and information that Milestone Scientific regards as proprietary, or may design products serving similar purposes that do not infringe on Milestone Scientific's patents. Milestone Scientific's failure to protect its proprietary information and the expenses of doing so could have a material adverse effect on our business, financial condition, and results of operations.

If Milestone Scientific's products infringe upon patent or proprietary rights of others, we may be required to modify processes or to obtain licenses. There can be no assurance that Milestone Scientific would be able to do so in a timely manner, on acceptable terms and conditions, or at all. The failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

Manufacturing

Milestone Scientific has informal arrangements with an U.S. manufacturer of the *Wand/STA System*, and epidural devices. Pursuant to these informal arrangements, our third-party manufacturer manufactures the *Wand/STA System* under specific purchase orders without minimum purchase commitments, and at prices to be agreed upon in each such purchase order.

Our agreement with the principal manufacturer of dental handpieces includes pricing terms. 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 dental handpieces since 2003. The manufacturer of our dental handpieces is in the People's Republic of China and the manufacturer of the *Wand/STA System* is in the United States. Refer to Item 1A. Risk Factors.

Changes to pricing of the *Wand/STA* System instruments by the manufacturer could have a material adverse effect on our financial condition, business, and results of operations. Termination of the manufacturing relationship with any of these third-party manufacturers could significantly and adversely affect our ability to produce and sell the products.

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 "burn in" and other manufacturing and quality control software re-produced. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of supply, whether because of the inability of a supplier to meet our product delivery needs or termination of the relationship, would have a material adverse effect on our financial condition, business, and results of operations.

Distribution and Marketing

Dental Products

The Company uses a combination of exclusive and non-exclusive distributors to sell its dental products. In 2022, the Company began a process of identifying, qualifying and signing non-exclusive dental distribution arrangements with dental distributors in specific geographical locations in the United States and Canada. As of December 31, 2023, there is one non-exclusive dental distributor engaged in Canada and no non-exclusive dental distributors in the United States

As of January 3, 2023, the Company launched an E-Commerce platform, selling and shipping STA Single Tooth Anesthesia Systems® (STA) and handpieces, directly to dental offices and dental groups within the United States. Our E-commerce portal accepts online payments via credit and debit cards. The cost of delivery is charged to the customer along with appropriate sales tax. The Company recognizes revenue from product sales at the time the product ships to a customer via a third party.

On the global front, we have granted exclusive marketing and distribution rights for the Wand STA System to select dental suppliers in various regions within Asia, Africa, South America, and Europe. Additionally, the Company is in the process of evaluating its current international distributors and adding new distributors globally as required based on the economics of the region.

Medical Products

The Company markets and sells its medical products in the international markets, including Italy, Switzerland, Greece, Canada and the Middle East, through exclusive distributors. In the United States the medical products are sold by a direct sales team of one full time employee and CTI a medical products distributor covering 22 states.

Competition

As of this filing, there is no subcutaneous drug delivery platform or device on the market regulating the flow rate and pressure of an injection capable of delivering a painless injection at the desired location like Milestone Scientific's proprietary, patented devices having our *DPS* Dynamic Pressure Sensing technology.

Milestone Scientific's devices compete based on their performance characteristics and the benefits provided to the patient, practitioner, and their business operations. Clinical studies have shown that our devices reduce fear, pain and anxiety for many patients, and Milestone Scientific believes that they can reduce practitioner stress levels, as well. Other computer-controlled local anesthesia delivery (C-CLAD) options are the Quicksleeper and SleeperOne, from Dental Hi Tec, Dentapen from Septodont, the Calajet from Aseptico, and the Comfort Control Syringe by Dentsply. In the medical segment, for needle verification and placement the EpiFaith Syringe made its market entry in 2023.

The Quicksleeper was invented in France by Dr. Alain Villette in 1991. It is marketed as the only local anesthetic delivery device in France that allows the ability to perform all intraoral local anesthetic injection techniques, including osteocentral anesthesia, quickly and without failure. The extra feature that gives the Quicksleeper this ability is a built-in motor in the syringe/handpiece that renders the syringe both an injector and a perforator of bone. That is, the handpiece of the Quicksleeper can perform an intraosseous injection via a motor driven perforation of the cortical plate of bone. A standard dental needle that attaches to the syringe spins as the motor rotates the handpiece thus acting as a perforator. However, the handpiece is relatively heavy, weighing 240 g. as compared to a standard syringe that weighs 80 g. Injection speed increases during the injection, but the operator cannot control when the injection speed increases.

The Calajet instrument, manufactured in Europe, has been very slow to grow market acceptance. It recently began marketing in the United States with similar slow acceptance. The instrument is a higher price than the Wand STA and does not provide dynamic pressure sensing technology. Although a competitor, we believe that without a substantial distribution network this instrument will have a difficult time to be successful in the United States.

The Dentapen from Septodont is the newest competitor in the market. This device is manufactured in Europe and began marketing in the United States in 2018. This device is priced like the Wand/STA device, but currently, to our knowledge, it has been slow to attract viable distribution in the United States.

The EpiFaith Syringe claims to assist physicians in entering epidural space. The instrument is introduced at a lower price. Although a potential competitor, we believe that our technology is well documented and is the only pressure sensor guidance system for epidural analgesia assisting the physician over the entire trajectory of epidural needle placement and catheter verification.

Milestone Scientific's proprietary, patented devices with its *DPS* Dynamic Pressure Sensing Technology platform also compete with disposable and reusable syringes that generally sell at lower prices and that use established and well-understood methodologies in both the dental and medical marketplaces.

Technological change and research in the future may affect the market acceptance of our products. Current or new competitors could, at any time, introduce new or enhanced products with features that render our products less marketable or even obsolete. Therefore, Milestone Scientific devoted substantial efforts and financial resources to improve existing products, bring products to market quickly, and develop new products for related markets. In addition, the ability to compete successfully requires that Milestone Scientific maintain an effective distribution network with a strong marketing plan. Any new products must comply with applicable regulatory authorities before they may be marketed. Milestone Scientific cannot assure that it can compete successfully, that competitors will not develop technologies or products that render our products less marketable or obsolete, or, that Milestone Scientific will succeed in improving its existing products, effectively develop new products, or obtain required regulatory approval.

Government Regulation

The manufacture and sale of medical devices and other medical products are subject to extensive regulation by the Food and Drug Administration ("FDA") pursuant to the U.S. Food, Drug and Cosmetic Act ("FD&C Act"), and by other federal, state, and foreign authorities. Under the FD&C Act, medical devices must receive FDA clearance before they can be marketed commercially in the United States. Some medical products must undergo rigorous pre-clinical and clinical testing and an extensive FDA approval process before they can be marketed.

These processes can take many years and require the expenditure of substantial resources. The time required for completing such testing and obtaining such approvals is uncertain, and FDA clearance may never be obtained. Delays or rejections may be encountered based upon changes in FDA policy during the period of product development and FDA regulatory review of each product submitted. Similar delays also may be encountered in other countries. Following the enactment of the Medical Device Amendments to the U.S. Food, Drug and Cosmetic Act in May 1976, the FDA classified medical devices in commercial distribution into one of three classes. This classification is based on the controls necessary to reasonably ensure the safety and effectiveness of medical devices. Class I devices are those devices whose safety and effectiveness can reasonably be ensured through general controls, such as adequate labeling, pre-market notification, and adherence to the FDA's Quality System Regulation ("QSR"), also referred to as "Good Manufacturing Practices" ("GMP") regulations. Some Class I devices are further exempt from some of the general controls. Class II devices are those devices whose safety and effectiveness reasonably can be ensured using special controls, such as performance standards, post-market surveillance, patient registries, and FDA guidelines. Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and effectiveness. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices.

Prior to Pre-market Notification clearance, the manufacturer or distributor may not place the device into commercial distribution until an order is issued by the FDA. By regulation, the FDA has no specific time limit by which it must respond to a 510(k) Pre-market Notification. Currently, the FDA typically responds to the submission of a 510(k) Pre-market Notification within 180 days. The FDA response may declare that the device is substantially equivalent to another legally marketed device and allow the proposed device to be marketed in the United States. However, the FDA may determine that the proposed device is not substantially equivalent or may require further information, such as additional test data, before the FDA is able to decide regarding substantial equivalence. Such a determination or request for additional information could delay market introduction of products. If a device that has obtained 510(k) Pre-market Notification clearance is changed or modified in design, components, method of manufacture, or intended use, such that the safety or effectiveness of the device could be significantly affected, separate 510(k) Pre-market notification clearance must be obtained before the modified device can be marketed in the United States. If a manufacturer or distributor cannot establish that a proposed device is substantially equivalent to a legally marketed device, the manufacturer or distributor will have to seek pre-market approval of the proposed device, a more difficult procedure requiring extensive data, including pre-clinical and human clinical trial data, as well as extensive literature to prove the safety and efficacy of the device.

The FDA cleared the Wand, our *CompuDent* System, and its disposable handpieces, for marketing in the United States for dental applications in July 1996; the *CompuMed®* System for marketing in the United States for medical applications in May 2001; the *Safety Wand®* for marketing in the United States for dental applications in September 2003; the *Wand/STA* System for dental applications in August 2006; and our *CompuFlo* Epidural System in June 2017.

For us to commercialize other products in the United States, Milestone Scientific would have to submit and have cleared additional 510(k) applications to the FDA. In 2017, the FDA reduced the barrier to marketing clearance for certain dental devices. As a result, other manufacturers of injection devices could more easily enter the dental market. However, we believe that any new device will be very limited in sales volume without a significant distributor in the dental market.

Though certain dental and medical devices have received FDA marketing clearance, there can be no assurance that any of the other medical devices under development will obtain the required regulatory clearance in a timely manner, or at all. If regulatory clearance of a product is granted, such clearance may entail limitations on the indicated uses for which the product may be marketed. In addition, modifications may be made to the products to incorporate and enhance their functionality and performance based upon new data and design review. There can be no assurance that the FDA will not request additional information relating to product improvements; that any such improvements would not require further regulatory review, thereby delaying the testing, approval, and commercialization of product improvements; or that ultimately any such improvements will receive FDA clearance.

Compliance with applicable regulatory requirements is subject to continual review and is monitored through periodic inspections by the FDA. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions, and criminal prosecution.

Milestone Scientific is subject to pervasive and continuing regulation by the FDA, whose regulations require manufacturers of medical devices to adhere to certain QSR requirements as defined by the FD&C Act. QSR compliance requires testing, quality control and documentation procedures. Failure to comply with QSR requirements can result in the suspension or termination of production, product recall or fines and penalties. Products also must be manufactured in registered establishments. In addition, labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. The export of devices is also subject to regulation in certain instances.

Human Capital

The Company has a total of 17 full-time employees, including one executive officer. Milestone Scientific also has a consultant who serves as a Director of Clinical Affairs. None of our employees are subject to a collective bargaining agreement and we believe our employee relations are good.

Corporate Information

We were organized in August 1989 under the laws of the State of Delaware. Our principal executive office is located at 425 Eagle Rock Avenue, Roseland, New Jersey 07068. Our telephone number is (973) 535-2717.

Item 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all 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, for the years ended December 31, 2023, and 2022, respectively.

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 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, net cash flow used in operations was approximately \$5.3 million and approximately \$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 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 75,881,840 outstanding shares of common stock on December 31, 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.

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

Milestone Scientific's sales and marketing efforts in the United States 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 operating in an E-commerce platform:

- Refunds and customer disputes due to 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 to maintain or expand its E-Commerce platform its sales may be negatively affected.

We are exposed to the risks inherent in international sales.

In 2023, export sales outside of the United States made up approximately 45% of our total sales, and we sell our products to customers in approximately 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.

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 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 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 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 such competitors are significantly larger than us and can offer compensation more than 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 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 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 in China.

Because the sole manufacturer of our dental handpieces is 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 of third parties to manufacture our products may increase the risk that we will not have enough of our products or such quantities at acceptable levels of cost and quality, which could impair our commercialization efforts.

Milestone Scientific relies on several third parties to supply and manufacture the components and raw materials for its products and it 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 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'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 regulations also 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.

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 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 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's principal stockholders, Leonard Osse and Gian Domenico Trombetta control approximately 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;
- 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 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 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. This 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

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 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.

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.

Item1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity.

Governance Related to Cybersecurity Risks

Our board of directors, as a whole and through its committees, holds overall oversight responsibility for our risk management processes, including in relation to risks from cybersecurity threats. Our board of directors exercises its oversight function through the audit committee, which oversees the management of risk exposure across various areas, including cybersecurity risks, in accordance with its charter. The audit committee receives quarterly reports from our Management on the status of our cybersecurity program. The Chair of the audit committee provides a quarterly report to the board of directors, which includes any key updates on cybersecurity matters, as applicable.

Our management team is responsible for the day-to-day administration and management of our cybersecurity program, under the direct supervision of our Chief Executive Officer currently we also work with external security service providers to support our security monitoring and threat detection capabilities and have implemented a process to report relevant findings to the Chair of audit committee where appropriate.

Cybersecurity Risk Management and Strategy

We maintain a cybersecurity program, which includes processes for identification, assessment, and management of cybersecurity risks. We conduct periodic risk assessments, including with support from external vendors, to assess our cyber program, identify potential areas of enhancement, and develop strategies for the mitigation of cyber risks. We have implemented a process to periodically conduct security awareness training for employees.

Our team is informed about and monitor the prevention, detection, mitigation, and remediation of cybersecurity risks through various means, including by leveraging a managed security service provider and other third-party security software and technology services. In addition, we use third-party security solutions, monitoring, and alerting tools and resources, designed to monitor, identify, and address risks from cybersecurity threats. We also have implemented processes and technologies for network monitoring and data loss prevention procedures, and from time to time review such processes and technologies.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems. See Item 1A "Risk Factors" in this Annual Report on Form 10 K for more information.

Item 2. Description of Property

The headquarters for Milestone Scientific is located at 425 Eagle Rock Avenue, Roseland, New Jersey 07068, and our telephone number is (973) 535-2717. In August 2019, the Company signed a seven-year lease for a facility in Roseland, New Jersey (the "Roseland Facility"). The Roseland Facility carries monthly lease payments of \$9,275, commencing April 1, 2021. The Company is also responsible for electric charges equal to \$2.00 per square foot, which is equal to \$11,130 annually, payable in equal monthly installments of \$928. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises more than the new base year amounts. A third-party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

Milestone Scientific does not own or intend to invest in any real property. Milestone Scientific currently has no policy with respect to investments or interests in real estate, real estate mortgages or securities of, or interests in, persons primarily engaged in real estate activities.

Item 3. Legal Proceedings

Milestone Scientific is not involved in any material litigation.

Item 4. Mine Safety Disclosure

Not applicable.

PART II

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

Market Information

Since June 1, 2015, our common stock has been listed on the NYSE American under the symbol "MLSS". The following table sets forth the high and low sales prices of Milestone's common stock for the periods presented.

| 2023 | High | Low | 2022 | High | Low |
|----------------|---------|---------|----------------|---------|---------|
| First Quarter | \$ 1.00 | \$ 0.46 | First Quarter | \$ 2.20 | \$ 1.13 |
| Second Quarter | \$ 1.22 | \$ 0.72 | Second Quarter | \$ 1.60 | \$ 0.75 |
| Third Quarter | \$ 1.35 | \$ 0.81 | Third Quarter | \$ 1.27 | \$ 0.71 |
| Fourth Quarter | \$ 1.00 | \$ 0.56 | Fourth Quarter | \$ 0.87 | \$ 0.45 |

Holders

As of March 29, 2024, we had approximately 97 stockholders of record of our common stock. We believe that, in addition to the record owners, we have approximately 3,318 beneficial owners of our common stock.

Dividends

The holders of common stock are entitled to receive such dividends as may be declared by Milestone Scientific's Board of Directors. Milestone Scientific has not paid and does not expect to declare or pay any dividends in the foreseeable future.

Sales of Unregistered Securities

Not applicable.

ITEM 6. Selected Financial Data

Milestone Scientific is a "smaller reporting company" as defined by Regulation S-K and as such, is not required to provide the information contained in this item pursuant to Regulation S-K.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussions of the financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this annual report. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Exchange Act, which involve risks and uncertainties. The actual results may differ materially from those anticipated in these forward-looking statements. See "Risk Factors" elsewhere in this Form 10-K.

OVERVIEW

Milestone Scientific is a biomedical technology company that patents, designs, develops and commercializes innovative diagnostic and therapeutic injection technologies and devices for medical and dental use. Since our inception, we have engaged in pioneering proprietary, innovative, computer-controlled injection technologies, and solutions for the medical and dental markets. We believe our technologies are proven and well established. Our common stock was initially listed on the NYSE American on June 1, 2015, and trades under the symbol "MLSS".

We have focused our resources on redefining the worldwide standard of care for injection techniques by making the experience more comfortable for the patient by reducing the anxiety and stress of receiving injections from the healthcare provider. Our computer-controlled injection devices make injections precise, efficient, and virtually painless.

We have developed a proprietary, revolutionary, computer-controlled anesthetic delivery device, our DPS Dynamic Pressure Sensing Technology® System, to meet the needs of various subcutaneous drug delivery injections and fluid aspiration – enabling healthcare practitioners to achieve multiple unique benefits that cannot currently be accomplished with the 160-year-old manual syringe. Our proprietary DPS Dynamic Pressure Sensing technology is our technology platform that advances the development of next-generation devices. It regulates flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, used in various dental and medical injections. It has specific medical applications for epidural space identification in regional anesthesia procedures.

Our device, using The Wand®, a single use disposable handpiece, is marketed in dentistry under the trademark CompuDent®, and STA Single Tooth Anesthesia System® and is suitable for all dental procedures that require local anesthetic. The dental devices currently are sold in the United States, Canada and in over 41 other countries. Milestone Scientific also has 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the CompuFlo® Epidural Computer Controlled Anesthesia System in the lumbar, thoracic and cervical thoracic junction of the spine region. In addition, Milestone Scientific has obtained CE mark approval and can be marketed and sold in most European countries.

Our recent receipt of chronology-Specific CPT Code for the Company's technology by the American Medical Association marks an important milestone, that could increase the potential number of anesthesia pain management clinics adopting the CompuFlo instrument. A CPT code expands the potential for reimbursement of epidural procedures in pain management utilizing the CompuFlo Epidural System., which should help accelerate the commercial roll-out of CompuFlo in the U.S

Milestone Scientific and its subsidiaries currently hold over 245 U.S. and foreign patents, and many patents pending and patent applications. The Company's patents and patent applications relate to drug delivery methodologies, Peripheral Nerve Block, drug flow rate measurement, pressure/force computer-controlled drug delivery with exit pressure, dynamic pressure sensing, automated rate control, automated charging, drug profiles, audible and visual pressure/force feedback, tissue identification, identification of a target region drug delivery injection unit, drug drive unit for anesthetic, handpiece, and injection device.

Milestone Scientific remains focused on advancing efforts to achieve the following three primary objectives:

- Establishing Milestone's DPS Dynamic Pressure Sensing technology platform as the standard-of-care in painless and precise drug delivery, providing for the first time, objective visual and audible in-tissue pressure feedback, and continuing to expand platform applications;
- Following obtaining successful FDA clearance of our first medical device, Milestone Scientific is transitioning from a research and development organization to a commercially focused medical device company; and
- Expanding our global footprint of our CompuFlo Epidural and CathCheck System by utilizing a targeted field sales force and partnering with distribution companies worldwide.

Our dental devices have been used to administer over 92 million injections worldwide. Each of our devices has a related single use disposable handpiece, leading to a continuing revenue stream following the sale of the device. At present, we sell disposable handpieces unique to our legacy product (the Wand and CompuDent) to users who have not upgraded to our current dental product, the STA Single Tooth Anesthesia System.

Building on the success of our proprietary, core technology platform for dental injections, and desiring to pursue other growth opportunities, we have begun to expand the uses and applications of our proprietary, patented technologies to achieve greater operational efficiencies, enhanced patient safety and therapeutic adherence, patient satisfaction, and improved quality of care across a broad range of medical specialties.

We intend to continue to expand the uses and applications of our *DPS* Dynamic Pressure Sensing technology. We believe that we and our technology solutions are recognized by key opinion leaders (i.e., academics, anesthesiologists and practicing dentists whose opinions are widely respected), industry experts and medical and dental practitioners as a leader in the emerging, computer-controlled injection industry.

The Single Tooth Anesthesia System (Dental)

Since its market introduction in early 2007, the STA Single Tooth Anesthesia System and prior C-CLAD devices have been used to deliver over 92 million safe, effective, and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

Medical Market Product

In June 2017, we received FDA regulatory clearance to sell the CompuFlo Epidural Computer Controlled Anesthesia System in the United States for epidural injections.

In May, 2022, the Company received a chronology-specific CPT Code for the Company's technology by the American Medical Association, which marks an important milestone that could increase the potential number of anesthesia pain management clinics adopting the CompuFlo instrument. Effective January 1, 2023, this temporary tracking code allows clinicians to submit claims to healthcare insurance providers using the Company's technology for Epidural Sterile Injections in the lumbar, thoracic, and cervical thoracic junction of the spinal region for reimbursement. A CPT code expands the potential for reimbursement of epidural procedures in pain management utilizing the CompuFlo Epidural System, which should help accelerate the commercial roll-out of CompuFlo in the United States.

On February 27, 2023, the Company announced that its CompuFlo® Epidural System has received 510(k) FDA clearance for use in the thoracic region of the spine, including the cervical thoracic junction. This approval expands upon the Company's prior approval of CompuFlo for use within the lumbar region of the spine, where the focus has been epidural analgesia during labor and delivery procedures.

The following table shows a breakdown of Milestone Scientific's product sales (net), domestically and internationally, by business segment product category:

| | 2023 | | |
|-------------------------------------|----------------------------|-------------------------|----------------------------|
| | Dental | Medical | Grand Total |
| Domestic: US | | | |
| Instruments | \$ 1,002,697 | \$ 1,000 | \$ 1,003,697 |
| Handpieces | 4,270,898 | 12,000 | 4,282,898 |
| Accessories | 75,285 | - | 75,285 |
| Grand Total | <u>\$ 5,348,880</u> | <u>\$ 13,000</u> | <u>\$ 5,361,880</u> |
| International: Rest of World | | | |
| Instruments | \$ 1,251,354 | \$ 25,000 | \$ 1,276,354 |
| Handpieces | 2,845,734 | 28,000 | 2,873,734 |
| Accessories | 45,476 | - | 45,476 |
| Grand Total | <u>\$ 4,142,564</u> | <u>\$ 53,000</u> | <u>\$ 4,195,564</u> |
| International: China | | | |
| Instruments | \$ 270,000 | \$ - | \$ 270,000 |
| Handpieces | - | - | - |
| Accessories | - | - | - |
| Grand Total | <u>\$ 270,000</u> | <u>\$ -</u> | <u>\$ 270,000</u> |
| Total Product Sales | <u><u>\$ 9,761,444</u></u> | <u><u>\$ 66,000</u></u> | <u><u>\$ 9,827,444</u></u> |
| | 2022 | | |
| | Dental | Medical | Grand Total |
| Domestic: US | | | |
| Instruments | \$ 524,715 | \$ 7,500 | \$ 532,215 |
| Handpieces | 2,653,914 | 25,250 | 2,679,164 |
| Accessories | 78,493 | - | 78,493 |
| Grand Total | <u>\$ 3,257,122</u> | <u>\$ 32,750</u> | <u>\$ 3,289,872</u> |
| International: Rest of World | | | |
| Instruments | \$ 1,413,525 | \$ - | \$ 1,413,525 |
| Handpieces | 3,391,748 | 20,000 | 3,411,748 |
| Accessories | 60,797 | - | 60,797 |
| Grand Total | <u>\$ 4,866,070</u> | <u>\$ 20,000</u> | <u>\$ 4,886,070</u> |
| International: China | | | |
| Instruments | \$ 270,000 | \$ - | \$ 270,000 |
| Handpieces | 359,964 | - | 359,964 |
| Accessories | - | - | - |
| Grand Total | <u>\$ 629,964</u> | <u>\$ -</u> | <u>\$ 629,964</u> |
| Total Product Sales | <u><u>\$ 8,753,156</u></u> | <u><u>\$ 52,750</u></u> | <u><u>\$ 8,805,906</u></u> |

Current Product Platform

See Item 1. Description of Business.

Summary of Critical Accounting Estimates

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, Milestone Scientific evaluates its estimates, including those related inventory valuation and cash flow assumptions regarding evaluations for going concern considerations. Milestone Scientific bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not clear from other sources. Actual results may differ from those estimates under different assumptions or conditions.

Our accounting policies are more fully described in Note C of the financial statements to this Annual Report on Form 10-K. As disclosed in Note C, the preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following discussion addresses our most critical accounting estimates, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

Assessment of our Ability to Continue as a Going Concern

In accordance with ("ASC") 205-40, "Presentation of Financial Statements – Going Concern", the Company continually evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception.

The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company has incurred total losses since inception of \$123.3 million. The operating losses were \$7.1 million and \$8.8 million, for the years ended December 31, 2023, and 2022, respectively. On December 31, 2023, Milestone Scientific had cash and cash equivalents and marketable securities of approximately \$6.0 million and working capital of approximately \$7.7 million. For the twelve months ended December 31, 2023 and 2022, we had cash flows used in operating activities of approximately \$5.3 million and \$6.0 million, respectively.

Management has prepared cashflow forecasts covering a period of 12 months from the date of issuance of these financial statements. These forecasts include several revenue and operating expense assumptions which indicate that the Company's current cash and liquidity is sufficient to finance the operating requirements for at least the next 12 months. Additionally, the Company was approved on September 12, 2023 to sell Net Operating Losses through the New Jersey Technology Business Tax Certificate Transfer Program ("NJ NOL Program"), a program administered by the New Jersey Economic Development Authority ("NJEDA"). Management believes this program will generate positive cash flow in the near future. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses. However, the Company's continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability, if ever.

Inventories

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or net realizable value. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirement and regulations.

Results of Operations

The following table sets forth the consolidated results of operations for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Year end December 31, 2023, compared to year ended December 31, 2022.

| | December 31, 2023 | December 31, 2022 |
|--|-----------------------|-----------------------|
| Operating results: | | |
| Product sales, net | \$ 9,827,444 | \$ 8,805,906 |
| Cost of products sold | 3,034,832 | 3,905,092 |
| Gross profit | <u>6,792,612</u> | <u>4,900,814</u> |
| Operating expenses: | | |
| Selling, general and administrative expenses | 13,135,796 | 12,514,323 |
| Research and development expenses | 701,378 | 1,150,209 |
| Depreciation and amortization expense | 61,912 | 63,755 |
| Total operating expenses | <u>13,899,086</u> | <u>13,728,287</u> |
| Loss from operations | (7,106,474) | (8,827,473) |
| Other income, and interest net | 125,527 | 54,607 |
| Net loss | (6,980,947) | (8,772,866) |
| Net loss attributable to noncontrolling interests | (51,843) | (66,735) |
| Net loss attributable to Milestone Scientific Inc. | <u>\$ (6,929,104)</u> | <u>\$ (8,706,131)</u> |

Net sales for year ended December 31, 2023, compared to year ended December 31, 2022

| | 2023 | 2022 | Change |
|------------------|---------------------|---------------------|---------------------|
| Dental | \$ 9,761,444 | \$ 8,753,156 | \$ 1,008,288 |
| Medical | 66,000 | 52,750 | \$ 13,250 |
| Total sales, net | <u>\$ 9,827,444</u> | <u>\$ 8,805,906</u> | <u>\$ 1,021,538</u> |

Consolidated revenue for the years ended December 31, 2023 and 2022 was approximately \$9.8 million and \$8.8 million, respectively, an increase of approximately \$1.0 million. As of January 3, 2023, the Company launched an E-Commerce platform, selling and shipping the STA Single Tooth Anesthesia System® (STA) and handpieces directly to end users, including dental offices and dental groups, within the U.S. E-commerce revenue for the year ended December 31, 2023 was approximately \$4.8 million. The Company ended the agreement with its major United States distributor, Henry Schein, as of December 31, 2022.

The Company recorded no revenue from Henry Schein for the year ended December 31, 2023, compared to approximately \$2.6 million recorded for the year ended December 31, 2022. Revenue from other U.S. distributors was approximately \$485,000 for the year ended December 31, 2023, a decrease of \$97,000 compared to December 31, 2022. The Company terminated all non-exclusive agreements with other distributors in the US in September 2023. For the year ended December 31, 2023, international revenue was approximately \$4.1 million, a decrease of \$724,000 compared to December 31, 2022. For the year ended December 31, 2023, the Company reported approximately \$270,000 revenue from China, a decrease of approximately \$356,000.

Gross Profit for years ended December 31, 2023, and 2022 were as follows:

| | 2023 | 2022 | Change |
|---------------------------|---------------------|---------------------|-----------------------|
| Dental | \$ 7,030,018 | \$ 5,446,175 | \$ 1,583,843 |
| Medical | (237,406) | (545,361) | \$ 307,955 |
| Total gross profit | \$ 6,792,612 | \$ 4,900,814 | \$ (1,891,798) |

Consolidated gross profit for the year ended December 31, 2023 increased by approximately 1.9 million or 40%, compared to the same period in 2022. The increase was due to higher margins in sales associated with the launch of E-Commerce platform. The Company recorded approximately \$258,000 and \$550,000 allowance for medical inventory that was obsolete and or expired for the years ended December 31, 2023 and 2022, respectively.

Selling, general and administrative expenses for years ended December 31, 2023, and 2022 were as follows:

| | 2023 | 2022 | Change |
|---|----------------------|----------------------|-------------------|
| Dental | \$ 4,330,219 | \$ 3,225,032 | \$ 1,105,187 |
| Medical | 3,381,551 | 4,183,983 | (802,432) |
| Corporate | 5,424,026 | 5,105,308 | 318,718 |
| Total selling, general and administrative expenses | \$ 13,135,796 | \$ 12,514,323 | \$ 621,473 |

Consolidated selling, general and administrative expenses for the years ended December 31, 2023 and 2022 were approximately \$13.1 million and \$12.5 million, respectively. The increase of approximately \$621,000 is due to several factors. Employee salaries and benefits expenses increased approximately \$44,000 for the year ended December 31, 2023 compared to the same period in 2022. The Company decreased quality control, regulatory, and travel expenses by approximately \$367,000 compared to the same period in 2022. The Company increased professional fees, and royalties' expenses by approximately \$317,000 compared to the same period in 2022. With the launch of the E-Commerce platform marketing and warehousing expense increased for the year ended December 31, 2023, by approximately \$320,000 compared to the same period in 2022. The Company recorded an increase in other selling, general and administrative expenses of approximately \$306,000 for the year ended December 31, 2023, compared to the same period in 2022 due to the launch of E-Commerce.

Research and Development for years ended December 31, 2023, and 2022 were as follows:

| | 2023 | 2022 | Change |
|---------------------------------------|-------------------|---------------------|---------------------|
| Dental | \$ 567,357 | \$ 1,095,523 | \$ (528,166) |
| Medical | 86,426 | 54,686 | 31,740 |
| Corporate | 47,595 | - | 47,595 |
| Total research and development | \$ 701,378 | \$ 1,150,209 | \$ (448,831) |

Consolidated research and development expenses for the years ended December 31, 2023 and 2022 were approximately \$701,000 and \$1.2 million respectively. The decrease of approximately \$449,000 is related to the Company's near completion in developing the next generation STA Single Tooth Anesthesia System, offset by an increase in medical cost for the epidural consumables.

Profit (Loss) from Operations for 2023 and 2022 were as follows:

| | 2023 | 2022 | Change |
|-----------------------------------|-----------------------|-----------------------|---------------------|
| Dental | \$ 2,128,199 | \$ 1,121,815 | \$ 1,006,384 |
| Medical | (3,708,170) | (4,788,105) | 1,079,935 |
| Corporate | (5,526,503) | (5,161,183) | (365,320) |
| Total loss from operations | \$ (7,106,474) | \$ (8,827,473) | \$ 1,720,999 |

The loss from operations was approximately \$7.2 million and \$8.8 million for the years ended December 31, 2023 and 2022, respectively, a decrease of approximately \$1.7 million. As stated above, the decrease in the loss from operations is driven by higher dental sales, and increased margins, which offset the higher selling, general and administrative expenses during period.

Liquidity and Capital Resources

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

| | 2023 | 2022 | Change |
|---|-----------------------|-----------------------|-------------------|
| Cash flows used in operating activities | \$ (5,326,129) | \$ (6,031,996) | \$ 705,867 |
| Cash flows used in investing activities | (2,972,172) | (8,527) | (2,963,645) |
| Cash flows provided by (used in) financing activities | 2,560,735 | (8,544) | 2,569,279 |
| Total | \$ (5,737,566) | \$ (6,049,067) | \$ 311,501 |

Operating Activities

Cash flows used in operating activities decreased \$0.7 million from \$6.0 million for the year ended December 31, 2022 compared to \$5.3 million for the year ended December 31, 2023. The decrease was driven by an increase of \$0.8 million in cash used in work capital activities offset by employees paid in common stock of \$0.1 million.

Investing Activities

Cash flows used in investing activities increased \$3.0 million for the year ended December 31, 2023 compared to an immaterial amount for the year ended December 31, 2022. The increase in cash used in investing activities was driven by the Company's purchase of marketable securities of \$7.9 million, offset by the sale of \$5.0 million of marketable securities during the current year.

Financing Activities

Cash flows provided by financing activities increased \$2.6 million for the year ended December 31, 2023, compared to an immaterial amount for the year ended December 31, 2022. The increase in cash used in financing activities was the result of gross proceeds of approximately \$3.0 million received from a public offering of common stock, offset by \$0.4 million of offering costs associated with the public offering during the current year.

Consideration of Company's ability to continue as a going concern.

The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company has incurred total losses since inception of \$123.3 million. The operating losses were \$7.1 million and \$8.8 million, for the years ended December 31, 2023, and 2022, respectively. On December 31, 2023, Milestone Scientific had cash and cash equivalents and marketable securities of approximately \$6.0 million and working capital of approximately \$7.7 million. For the twelve months ended December 31, 2023 and 2022, we had cash flows used in operating activities of approximately \$5.3 million and \$6.0 million, respectively. Additionally, the Company was approved on September 12, 2023 to sell Net Operating Losses through the New Jersey Technology Business Tax Certificate Transfer Program ("NJ NOL Program"), a program administered by the New Jersey Economic Development Authority ("NJEDA"). Management believes this program will generate positive cash flow in the near future.

Management has prepared cashflow forecasts covering a period of 12 months from the date of issuance of these financial statements. These forecasts include several revenue and operating expense assumptions which indicate that the Company's current cash and liquidity is sufficient to finance the operating requirements for at least the next 12 months. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses. However, the Company's continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability, if ever.

Contractual Obligations

The impact of the consolidated contractual obligations on December 31, 2023, expected on the liquidity and cash flows in future periods, is as follows:

| Payments Due by Period | Total | Less than | | |
|-----------------------------|---------------------|---------------------|---------------------|-------------|
| | | 1 Year | 1-3 Years | 3-5 Years |
| Operating lease obligations | \$ 1,055,975 | \$ 144,300 | \$ 911,675 | \$ - |
| Purchase obligations (1) | \$ 2,382,630 | \$ 1,782,333 | \$ 600,297 | \$ - |
| Total | <u>\$ 3,438,605</u> | <u>\$ 1,926,633</u> | <u>\$ 1,511,972</u> | <u>\$ -</u> |

Recent Accounting Pronouncements

See "Note C - Summary of Significant Accounting Policies" to the consolidated financial statements for explanation of recent accounting pronouncements impacting Milestone Scientific.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Milestone Scientific is a "smaller reporting company" as defined by Regulation S-K and, as such, is not required to provide the information required by this item.

Item 8. Financial Statements

The financial statements of Milestone Scientific required by this Item are set forth beginning on page F-1.

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

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer, and Principal Accounting Officer, concluded that, as of December 31, 2023, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

We routinely review our internal control over financial reporting and from time to time make changes intended to enhance the effectiveness of our internal control over financial reporting. For the year ended December 31, 2023 we made no changes to our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that we believe materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure regarding Foreign Jurisdiction that Prevent Inspections.

None.

PART III**Item 10. Directors, Executive Officers, Promoters and Control Persons and Corporate Governance; Compliance with Section 16 (a) of the Exchange Act**

| NAME | AGE | POSITION | DIRECTOR SINCE |
|---------------------------------|-----|--|----------------|
| Neal Goldman (1) (2) (3) | 80 | Chairman of the Board | 2019 |
| Leonard Osser | 76 | Vice Chairman of the Board | 1991 |
| Jan Adriaan (Arjan) Haverhals | 61 | President, Chief Executive Officer, and Director | 2023 |
| Benedetta Casamento (1) (2) (3) | 54 | Director | 2022 |
| Gian Domenico Trombetta | 63 | Director | 2014 |
| Michael McGeehan (1) (2) (3) | 58 | Director | 2017 |
| Dr. Didier Demesmin | 55 | Director | 2023 |

1. Member of the Audit Committee
2. Member of the Compensation Committee
3. Member of the Nominating and Corporate Governance Committee

Neal Goldman, Chairman of the Board

Neal Goldman has been a director of Milestone Scientific since 2019 and has served as Chairman of the Board since January 2023. Mr. Goldman is the President and Founder of Goldman Capital Management, Inc., a family office since 2018, which was previously an investment advisory firm founded in 1985. He was First Vice President of Research at Shearson Lehman Hutton. He has also held senior positions as a money manager and research analyst with a variety of firms including Neuberger Berman, Moseley Hallgarten Estabrook and Weeden, Bruns Nordeman, and Russ and Company. Mr. Goldman serves as Chairman of Charles & Colvard, Ltd. since 2016 and served on the board of Imageware Systems, Inc. until November 2020. He also serves on the board of Deep-Down Inc. Prior to their respective acquisitions, he served on the boards of Blyth Industries and IPASS Corporation. Mr. Goldman received his B.A. degree in Economics from The City University of New York (City College). Mr. Goldman's professional experience and financial background have given him the expertise needed to serve as one of our directors.

Leonard Osser, Vice Chairman of the Board

Leonard Osser has been a director of Milestone Scientific since 1991 and has served as Milestone Scientific's Vice Chairman of the Board since May 2021. Mr. Osser had been Interim Chief Executive Officer from December 2017 until May 2021. From July 2017 to December 2017, he had been Managing Director –China Operations. Prior to that, he served as Milestone Scientific's Chairman from 1991 until September 2009, and during that time, from 1991 until 2007, was also Chief Executive Officer of Milestone Scientific. In September 2009, he resigned as Chairman of Milestone Scientific, but remained director, and assumed the position of Chief Executive Officer. From 1980 until the consummation of Milestone Scientific's public offering in November 1995, Mr. Osser is the Managing Member of U.S. Asian Consulting Group, LLC, a New Jersey-based provider of consulting services specializing in distressed or turnaround situations in both the public and private markets. Mr. Osser also serves as a special consultant to the board of directors of Nexalin Technology, Inc. where he is also Managing Director of China Operations. Mr. Osser's knowledge of our business and background with us since 1980 provides the Board with valuable leadership skills and insight into our business and accordingly, the expertise needed to serve as one of our directors.

Jan Adriaan (Arjan) Haverhals, President, Chief Executive Officer and Director

Arjan Haverhals has been Milestone Scientific's President since September 2020, Chief Executive Officer since May 2021 and has served as the President and Chief Executive Officer of Milestone Scientific's Dental Division (Wand Dental Inc.) since June 2020. In January 2023, Mr. Haverhals was appointed to the Board. He brings more than 30 years of sales, marketing, product development, and international expansion experience within the medical device, pharmaceutical, and other industries. Prior to joining Wand Dental and Milestone Scientific, Mr. Haverhals was senior vice president of sales at Xcentric Mold & Engineering from 2019 until 2020 where he was instrumental in increasing sales productivity and efficiency for the company's prototype injection molding services, which included leading healthcare company clients.

From 2012 until 2018, Mr. Haverhals worked at Straumann, LLC, a global leader in manufacturing medical and dental devices, where he held a series of senior sales and marketing roles including vice president of customer marketing & education, where he oversaw all product franchises and led the launch of more than 30 products in the North American market. He also served as senior vice president for the Nordic Region at Straumann AB, senior vice president of global sales digital solutions, which included oversight of the strategic acquisition of Etkon; and served as vice president of the Prosthetics Business Unit, where he introduced a new implant and prosthetics product line within a new market segment.

He also served as senior vice president for the Nordic Region at Straumann AB, senior vice president of global sales digital solutions, which included oversight of the strategic acquisition of Etkon; and served as vice president of the Prosthetics Business Unit, where he introduced a new implant and prosthetics product line within a new market segment. He also served as vice president of global marketing & sales at Elkem AS, one of Norway's largest industrial companies. Previously, Mr. Haverhals served as executive vice president of marketing & sales at Cresco Ti Systems Sàrl, a global dental implant company, where he was responsible for turning around and managing global sales, marketing, international business. Mr. Haverhals holds an MS in Pharmacy from the University of Leyden in the Netherlands. Mr. Haverhals' knowledge of Milestone Scientific's day-to-day operations gives him the expertise needed to serve as one of our directors.

Benedetta I. Casamento, Director

Benedetta Casamento has served as a director of the Company since April 2022. Since August 2017, Ms. Casamento has served as a Retail Consultant specializing in finance, business operations, and financial planning and analysis. Ms. Casamento previously served as Chairman and President of Allyke, Inc., an artificial intelligence company creating digital imagery insights for retail and other industries, from June 2016 to August 2017. From December 2014 to April 2016, she served as Chief Executive Officer of Calypso St. Barth, a luxury boutique retailer of women's apparel and accessories. Prior to her role as CEO at Calypso St. Barth, Ms. Casamento served as a consultant to private equity firms with portfolio interests in retail and fashion from July 2012 to December 2014. Ms. Casamento previously served as Executive Vice President, Finance & Operations of The Talbots, Inc. ("Talbots"), a specialty retailer and direct marketer of women's apparel, accessories, and shoes, from March 2009 to July 2012. Prior to joining Talbots, Ms. Casamento served in various leadership roles within Liz Claiborne Inc. from February 1999 to November 2008, culminating in her position as President of Liz Claiborne Brands. Ms. Casamento started her career at Saks Fifth Avenue. Our Board has determined that Ms. Casamento's extensive business experience, as well as her background in accounting and finance, qualifies her to serve on the Board.

Gian Domenico Trombetta, Director

Gian Domenico Trombetta has been a director of Milestone Scientific since May 2014 and served as the President and Chief Executive Officer of Milestone Scientific's Dental Division (Wand Dental Inc.) from October 2014 until May 2020. He founded Innovest S.p.A, headquartered in Milan, Italy, in 1993, a special situation firm acting in development and distressed capital investments. He has been its President and Chief Executive Officer since its inception. He served as the Chief Executive Officer or a board member of several private commercial companies in different industries including both industrial (e.g. IT, media, web, and fashion) and holding companies. Before founding Innovest, Mr. Trombetta was Project Manager for Booz Allen & Hamilton Inc., a management consulting firm from 1988 to 1992. Mr. Trombetta holds a degree in business administration from the Luiss University in Rome, Italy, and an MBA degree from INSEAD-Fontainbleau-France. Mr. Trombetta's business background and experience has given him the expertise needed to serve as one of our directors.

Michael McGeehan, Director

Michael McGeehan has been a director of Milestone Scientific since October 2017. Mr. McGeehan is a business consultant with 30 years of experience in a variety of business domains, including financial services, medical and healthcare products, consumer package goods and the software technology industry. Mr. McGeehan started his career at Metaphor Computer Systems in 1988 and then went to work at Microsoft Corporation in 1991. In 1995, Mr. McGeehan left Microsoft and founded Forefront Information Strategies, an information technology consulting firm. In 2002, Mr. McGeehan returned to Microsoft where he worked until 2017, when he returned to and re-started Forefront. Mr. McGeehan was on the Board of Directors of Wand Dental. Mr. McGeehan has a master's in business administration from Pace University and a Bachelor of Science in Electrical Engineering and Computer Science from Marquette University. Mr. McGeehan's professional experience and background have given him the expertise needed to serve as one of our directors.

Dr. Didier Demesmin, Director

Dr. Demesmin is currently the Chief Executive Officer and Medical Director of University Pain Medicine Center, a position he has held since 2007. Since March 2006, Dr. Demesmin has held the position of Director of the Pain Management Department at St. Peter's University Hospital. He is also a physician in the Departments of Pain Medicine at JFK Medical Center (since March 2007), Robert Wood Johnson University Hospital (since January 2008), Somerset Medical Center (since February 2009), Hudson Regional Hospital (since December 2010), and Saint Barnabas Hospital (since November 2013). Dr. Demesmin is also a Clinical Instructor in the Department of Medicine at Rutgers Robert Wood Johnson Medical School (since August 2006), a Clinical Assistant Professor in the Department of Physical Medicine and Rehabilitation at Rutgers Robert Wood Johnson Medical School (since July 2013), the Medical Director in the Physical Medicine and Rehabilitation and Sports Medicine Institute at St. Peter's University Hospital (since December 2013), and an Assistant Fellowship Program Director in the Multidisciplinary Interventional Pain Medicine Fellowship at JFK Johnson Rehabilitation Institute (since November 2013). Dr. Demesmin has been a member of the Board of Trustees of the New Jersey Society of Interventional Pain Physicians, since September 2010, and the Middlesex County Medical Society of New Jersey, since January 2010, where he held the positions of President Elect, from June 2011 to June 2012, and President, from June 2012 to June 2014. Dr. Demesmin received a BA in Psychology from Rutgers University in 1994, a Medical Degree from the University of Medicine and Dentistry of New Jersey in 2000, and an MBA from the Kellogg School of Management of Northwestern University in 2018. Mr. Demesmin's medical healthcare background in the field of interventional pain management and business background has given him the expertise needed to serve as one of our directors.

Board Leadership Structure

The Board believes that the segregation of the roles of Board Chairman and the Chief Executive Officer ensures better overall governance of the Company and provides meaningful checks and balances regarding its overall performance. This structure allows our Chief Executive Officer to focus on developing and implementing the Company's business plans and supervising the Company's day-to-day business operations and allows our chairman to lead the Board in its oversight and advisory roles. Because of the many responsibilities of the Board and the significant time and effort required by each of the Chairman and the Chief Executive Officer to perform their respective duties, the Company believes that having separate persons in these roles enhances the ability of each to discharge those duties effectively and enhances the Company's prospects for success. The Company also believes that having separate positions provides a clear delineation of responsibilities for each position and fosters greater accountability of management. For the foregoing reasons, the Board has determined that its leadership structure is appropriate and in the best interest of stockholders.

The Board's Oversight of Risk Management

The Board recognizes that companies face a variety of risks, including China operation risk, liquidity/capital accessibility risk, medical product acceptance risk, and operational risk. The Board believes an effective risk management system will (1) timely identify the material risks that we face; (2) communicate necessary information with respect to material risks to senior executives and, as appropriate, to the Board or relevant Board committee; (3) implement appropriate and responsive risk management strategies consistent with the Company's risk profile; and (4) integrate risk management into the Company's decision-making. The Board encourages, and management promotes, a corporate culture that incorporates risk management into the Company's corporate strategy and day-to-day business operations. The Board also continually works, with the input of management and executive officers, to assess and analyze the most likely areas of future risk for the Company.

Committees of the Board

The Board has standing audit, compensation, and nominating and corporate governance committees (respectively, the "Audit Committee," the "Compensation Committee," and the "Nominating Committee.")

Compensation Committee

The Compensation Committee reviews and recommends to the Board the compensation and benefits of all officers of the Company, reviews general policy matters relating to compensation and benefits of employees of the Company and administers the issuance of stock options to the Company's officers, employees, directors, and consultants. It also provides recommendations to the Board with respect to non-employee director compensation. The Compensation Committee may not delegate its authority to any other person, other than to a subcommittee. The Compensation Committee is comprised of three members, Benedetta Casamento (Chairman), Neal Goldman and Michael McGeehan. A copy of the Compensation Committee Charter has been posted on our website at www.milestonescientific.com. For additional discussion of the Compensation Committee executive compensation objectives, see Item 11, "Objective of Executive Compensation Program."

Audit Committee

The Audit Committee meets with management and the Company's independent accountants to determine the adequacy of internal controls and other financial reporting matters. The Audit Committee's purpose is to: (A) assist the Board in its oversight of: (i) the integrity of our financial statements; (ii) our compliance with legal and regulatory requirements; (iii) our independent auditors' qualifications and independence; (iv) the performance of our internal audit function and independent auditors to decide whether to appoint, retain or terminate our independent auditors; and (v) the preparation of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Annual Report"); and (B) to pre-approve all audit, audit-related and other services, if any, to be provided by the independent auditors. The members of the Audit Committee are comprised of Benedetta Casamento (Chairman), Neil Goldman and Michael McGeehan, all of whom are independent as defined in the listing standards of the NYSE American and Section 10A(m)(3) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). A copy of the Audit Committee Charter has been posted on our website at www.milestonescientific.com.

Audit Committee Financial Expert

The Board has determined that Benedetta Casamento is an "audit committee financial expert," as that term is defined in Item 407(d)(5) of Regulation S-K, and "independent" for purposes of the listing standards of the NYSE American and Section 10A(m)(3) of the Exchange Act.

Nominating Committee

The Nominating Committee identifies potential director nominees and evaluates their suitability to serve on the Board. Based on its evaluation, it recommends to the Board the director nominees for Board membership. In addition, the Nominating Committee also evaluates each existing Board member's suitability for continued service as a director. The members of the Nominating Committee are Michael McGeehan (Chairman), Benedetta Casamento, and Neal Goldman. A copy of the Nominating Committee Charter has been posted on our website at www.milestonescientific.com.

The Nominating Committee believes that the minimum qualifications for service as a director of the Company are that a nominee possess an ability, as demonstrated by recognized success in his or her field, to make meaningful contributions to the Board's oversight of the business and affairs of the Company and an impeccable reputation of integrity and competence in his or her personal or professional activities. The Nominating Committee's criteria for evaluating potential candidates include the following: an understanding of the Company's business environment; and the possession of such knowledge, skills, expertise and diversity of experience so as to enhance the Board's ability to manage and direct the affairs and business of the Company including, when applicable, to enhance the ability of committees of the Board to fulfill their duties and/or satisfy any independence requirements imposed by law, regulation or listing requirements.

The Nominating Committee considers director candidates recommended by stockholders. In considering candidates submitted by stockholders, the Committee will take into consideration the needs of the Board and the qualifications of the candidate. The Nominating Committee may also take into consideration the number of shares held by the recommending stockholder and the length of time that such shares have been held. To have a candidate considered by the Nominating Committee, a stockholder must submit the recommendation in writing and must include the following information: the name of the stockholder and evidence of the person's ownership of Company stock, including the number of shares owned and the length of time of ownership; the name of the candidate, the candidate's resume or a listing of his or her qualifications to be a director of the Company; and, the person's consent to be named as a director if selected by the Nominating Committee and nominated by the Board.

The Nominating Committee may also receive suggestions from current Board members, the Company's executive officers or other sources, which may be either unsolicited or in response to requests from the Nominating Committee for such candidates. The Nominating Committee also, from time to time, may engage firms that specialize in identifying director candidates.

Once a person has been identified by the Nominating Committee as a potential candidate, it may collect and review publicly available information regarding the person to assess whether the person should be considered further. If the Nominating Committee determines that the candidate warrants further consideration, the Chairman or another member of the Nominating Committee may contact the person. Generally, if the person expresses a willingness to be considered and to serve on the Board, the Nominating Committee may request information from the candidate, review the person's accomplishments and qualifications and may conduct one or more interviews with the candidate. The Nominating Committee may consider all such information considering information regarding any other candidates that it might be evaluating for membership on the Board. In certain instances, Nominating Committee members may contact one or more references provided by the candidate or may contact other members of the business community or other persons that may have greater first-hand knowledge of the candidate's accomplishments. The Nominating Committee's evaluation process does not vary based on whether a candidate is recommended by a stockholder, although, as stated above, the Board may take into consideration the number of shares held by the recommending stockholder and the length of time that such shares have been held.

Director Independence

The Board has determined that Michael McGeehan, Benedetta Casamento, and Neal Goldman (the "Independent Directors") are independent, as that term is defined in the listing standards of the NYSE American. In determining director independence, the Board also considered all equity awards, if any, to the Independent Directors for the year ended December 31, 2023, disclosed in "Director Compensation" below, and determined that such awards were compensation for services rendered to the Board and therefore did not impact their ability to continue to serve as Independent Directors.

Stockholder Communication with the Board

The Board has established a process to receive communications from stockholders. Stockholders and other interested parties may contact any member (or all members) of the Board, or the non-management directors as a group, any Board committee, or any chair of any such committee by mail or electronically. To communicate with the Board, any individual director or any group or committee of directors, correspondence should be addressed to the Board or any such individual directors or group or committee of directors by either name or title. All such correspondence should be sent "c/o Corporate Secretary" at 425 Eagle Rock Ave., Suite 403, Roseland, New Jersey 07068. All communications received as set forth in the preceding paragraph will be opened by the Corporate Secretary of the Company for the sole purpose of determining whether the contents represent a message to our directors. Any contents that are not in the nature of advertising, promotions of a product or service, patently offensive material or matters deemed inappropriate for the Board will be forwarded promptly to the addressee. In the case of communications to the Board or any group or committee of directors, the Company's Corporate Secretary will make sufficient copies of the contents to send to each director who is a member of the group or committee to which the envelope is addressed.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and person who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten-percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. Based solely on review of the copies of such forms furnish to us, or written representations that no Forms 5 were required, we believe that all Section 16(a) filing requirements applicable to our officers and director were complied with during the fiscal year ended December 31, 2023.

Insider Trading Arrangements and Policies

We have adopted an insider trading compliance policy governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, and employees that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us. The insider trading policy prohibits the use of material non-public information about the Company when making decisions to purchase, sell, give away or otherwise trade in the Company's securities or to provide such information to others outside the Company. We have established black-out periods to which covered persons are subject related to the filing of our regular reports with the Securities and Exchange Commission. The Company may impose additional black-out periods from time to time as other types of material non-public information occur when material non-public events or disclosures are pending. Covered persons are permitted to trade in the Company's securities only when there is no black-out period in effect and such trade has been pre-cleared by the appointed Company officer, or when a qualified 10b5-1 plan has been established in accordance with federal securities laws. No covered person has adopted or terminated a Rule 10b5-1 trading plan during the last fiscal quarter of the fiscal year to which this report relates.

Code of Ethics

Milestone Scientific has adopted a code of ethics that applies to its directors, principal executive officer, principal financial officer and other people performing similar functions. This code of ethics is posted on Milestone Scientific's web site at www.milestonescientific.com. Milestone Scientific will also provide a copy of the Code of Ethics to any person without charge, upon written request addressed to the Chairman of the Board, Neal Goldman, at the Company's principal executive office, located at 425 Eagle Rock Avenue Roseland, NJ 07068.

Clawback Policy

Our Board has adopted a written policy to recover "excess" compensation that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure. The compensation includes both cash-based and equity-based incentives. The compensation covered includes incentive awards awarded to any individuals (including former employees) who served as an executive officer during the three most recently completed fiscal years preceding the date on which the preparation of an accounting restatement is required, provided that the executive officers were awarded more incentive awards than they would have received if the financial statements had been prepared correctly. The recovery will include an executive incentive award even if the executive was not involved in preparing the financial statements or did not commit misconduct that led to the restatement. Restatements attributable to an inadvertent error also will subject executive officers to the recovery of previously received incentive awards.

Item 11. Executive Compensation

SUMMARY COMPENSATION TABLE

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2023 and 2022 by Milestone Scientific's (i) chief executive officer and (ii) two most highly compensated executive officers, other than the chief executive officer, who were serving as executive officers at the end of the 2023 fiscal year and whose salary as determined by Regulation S-K, Item 402, exceeded \$100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the "Named Executive Officers").

| Name and Principal Position | Year | Salary | Bonuses | Option Awards (3) | Other Compensation | Total |
|--|------|------------|------------|-------------------|--------------------|------------|
| Jan Adriaan (Arjan) Haverhals (1) Chief Executive Officer and President of Milestone Scientific Inc. | 2023 | \$ 350,000 | \$ 281,853 | \$ - | \$ 48,412 | \$ 680,265 |
| President of Wand Dental Inc | 2022 | \$ 350,000 | \$ 246,603 | \$ 216,385 | \$ 28,153 | \$ 841,141 |
| Peter Milligan (2) Chief Financial Officer | 2023 | \$ 70,000 | \$ 100,000 | \$ - | \$ - | \$ 170,000 |

1. Arjan Haverhals was awarded \$281,000 in a discretionary performance bonus for the year ended December 31, 2023. Other compensation represents payments made for health insurance coverage of approximately \$34,000 and car allowance of approximately \$14,000. During 2022 he was awarded \$246,000 in a discretionary performance bonus for the year ended December 31, 2022. Other compensation represents payments made for health insurance coverage of approximately \$14,000 and car allowance of approximately \$14,000.
2. Peter Milligan was appointed as the Chief Financial Officer of the Company February 1, 2023. He was awarded a \$100,000 bonus for joining the company to be paid in shares of stock. On August 24, 2023 the Company announced that Peter Milligan resigned from the Company effective September 1, 2023.
3. The amounts in this column reflect the fair value of the options on the date of grant. For details used in the assumption calculating the fair value of the option reward, see Note C to the Financial Statements for the year ended December 31, 2023, which is located on pages F-9 through F-12 of the Company's 2023 Annual Report on Form 10-K. Compensation cost is generally recognized over the vesting period of the award. See the table below entitled Outstanding Equity Awards on December 31, 2023.

Pay versus Performance Table

As required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and Item 402(v) of Regulation S-K, we are providing the following information about the relationship between executive compensation actually paid (as defined by SEC rules) and certain financial performance metrics of the Company. For further information concerning the Company's compensation philosophy and how the Company aligns executive compensation with the Company's performance, refer to "—Compensation Philosophy and Objectives" and "—Compensation Elements".

| | (a) | (b) | (c) | (d) | (e) |
|------|--|---------------------------------------|--|---|---|
| | Summary Compensation Table Total for PEO(\$) | Compensation Actually Paid to PEO(\$) | Average Summary Compensation Table Total for Non-PEO NEO's(\$) | Average Compensation Actually Paid to Non-PEO NEO's(\$) | Value of Initial Fixed \$100 Investment Based on: |
| Year | | | | | |
| 2023 | 680,265 | 680,265 | n/a | n/a | 150.00 |
| 2022 | 841,141 | 649,824 | n/a | n/a | 22.86 |

Calculation of Compensation Actually Paid to PEO (column b)

Total Summary Compensation Paid Table (SCT) - column (a)

Less: value reported under stock awards in the SCT

Add: FV of unvested equity awards at year end 2022

Add: FV of vested awards as of the vesting date

Compensation actually paid

| | 2023 | 2022 |
|--|----------------|----------------|
| Total Summary Compensation Paid Table (SCT) - column (a) | 680,265 | 735,024 |
| Less: value reported under stock awards in the SCT | - | (85,200) |
| Add: FV of unvested equity awards at year end 2022 | - | - |
| Add: FV of vested awards as of the vesting date | - | - |
| Compensation actually paid | 680,265 | 649,824 |

- (a) The amounts reported in this column are the amounts of total compensation reported for Mr. Haverhals, Chief Executive Officer, for each corresponding year in the "Total" column of the Summary Compensation Table ("SCT") on page 12 of this proxy statement.
- (b) The amounts reported in this column represent the amount of compensation actually paid ("CAP") Mr. Haverhals as computed in accordance with Item 402(v) of Regulation S-K, but do not reflect the actual amount of compensation earned by or paid to Mr. Haverhals during the applicable year. The determination of CAP begins with the total compensation reported in the SCT, which is then adjusted by equity-based and other compensation as set forth in the following table. For equity-based awards made during the year, the recorded grant date value is replaced with the estimated year-end value. For equity-based awards made in prior years that remain unvested at year-end, the estimated change in value from the beginning to the end of the year is included. For equity-based awards made in prior years, but vested during the year, the estimated change in value from the beginning of the year to the date of vesting is included.
- (c) The amounts reported in this column represent the average of the amounts reported for the Company's Non-CEO named executive officer's ("NEOs") as a group in the "Total" column of the SCT in each applicable year. There were no NEO's at the company during 2023 and 2022, respectively.
- (d) The amounts reported in this column represent the average amount of CAP to the Non-CEO NEOs as a group, as computed in accordance with Item 402(v) of Regulation S-K. Since there were no adjustments to be made for these NEO's, the amounts actually paid are equal to the SCT amounts calculated in the previous column.
- (e) This represents the year-end value of an initial \$100 investment made at the beginning of the period.

Employment Contracts

On March 2, 2021, the Company entered into a Royalty Sharing Agreement with Leonard Osser, pursuant to which Mr. Osser sold, transferred and assigned to the Company all of his rights in and to a certain patent application as to which he is a co-inventor with Mark Hochman, a consultant to the Company, and the Company agreed to pay to Mr. Osser, beginning May 9, 2027, half of the royalty (2.5%) on net sales that would otherwise be payable to Mark and Claudia Hochman under their existing Technology Sale Agreement, dated January 1, 2005 and amended from time to time, with the Company. In connection with the Royalty Sharing Agreement, the Hochman's agreed with the Company, pursuant to an addendum to such Technology Sale Agreement dated February 25, 2021, to reduce from 5% to 2.5% the payments due to them under their Technology Sale Agreement beginning on May 9, 2027, and thereafter with respect to dental products embodying the invention.

As part of the Succession Plan of the Company, Mr. Osser agreed, pursuant to an agreement dated April 6, 2021 (the "Succession Agreement"), to restructure certain of his existing agreements with the Company, which provide for additional and broader executive support, and at such time as he elects to step down as Interim Chief Executive Officer of the Company, to become the Vice Chairman of the Board of the Company. With respect to Mr. Osser's July 2017 Employment Agreement and July 2017 Consulting Agreement (each as previously disclosed), the compensation under the Employment Agreement was modified to reduce the overall compensation by \$100,000 to \$200,000, split equally between a cash amount and an amount in shares, and the compensation under the Consulting Agreement was increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares, which shares were formerly payable under the Employment Agreement. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term. In connection with his acceptance of the Vice Chairman position and in consideration of his services as a member of the Board and agreement to provide certain additional general consulting services, Mr. Osser was granted options to purchase 2,000,000 shares of common stock, exercisable at the fair market value of the common stock on the date of grant, vesting over the five-year period after he steps down as Interim Chief Executive Officer of the Company or ten years from the date of grant, whichever shall end first. The Company believes that the effect of such existing agreements and the Succession Agreement, all of which relate to the period after such time Mr. Osser steps down as Interim Chief Executive Officer of the Company, collectively expand Mr. Osser's consulting to and support of the Company beyond its Chinese operations to also include its medical and other products, while enhancing the retention aspects of the Company's relationship with Mr. Osser. On May 19, 2021, Mr. Osser resigned as Interim Chief Executive Officer of the Company and assumed the role of Vice Chairman of the Board.

Compensation under the Employment Agreement and the Consulting Agreement is payable for 9.5 years from May 19, 2021. The Company recorded expenses of \$200,000 related to the Employment Agreement for each of the years ended December 31, 2023 and 2022, respectively. The Company recorded expenses of \$200,000 and \$200,000 related to the Consulting Agreement for each of the years ended December 31, 2023 and 2022, respectively.

On January 1, 2022, the Company entered into an employment agreement with Mr. Arjan Haverhals. The employment term ends December 31, 2024, unless extended by mutual written agreement. Mr. Haverhals will serve as the President and Chief Executive Officer of the Company and such other senior executive positions as accepted and determined by the Board reasonably requests. As an executive, notwithstanding the fact that he is a director, Mr. Haverhals has board observer rights. The agreement calls for a base salary of \$350,000 and bonus compensation of up to \$400,000 per year, comprise of three separate performance based bonuses each up to \$100,000 per year, based upon the Company's achievement of three (3) performance or financial goals, as established by the Compensation Committee in its reasonable discretion; and (ii) a discretionary bonus up to \$100,000, as determined by the Compensation Committee, in its sole discretion. Satisfaction of bonus goals will be determined by the Compensation Committee from time to time in its reasonable discretion. Bonus compensation, if any, shall be payable annually in arrears thirty-three percent (33%) in cash and sixty-seven percent (67%) in shares of the Company's common stock. Mr. Haverhals will also be entitled to reimbursement of expenses, four weeks paid vacation, a car allowance and participation in company retirement plans and health insurance reimbursement. The agreement provides for the typical termination provisions. If Mr. Haverhals is terminated for other than for cause or termination by him for good reason, he will be paid as severance, his base compensation and certain other benefits, as provided in the employment agreement, for two years after termination.

Objective of Executive Compensation Program

The primary objective of the executive compensation program is to attract and retain qualified, energetic managers who are enthusiastic about the mission and culture of Milestone Scientific. A further objective of the compensation program is to provide incentives and reward each manager for their contribution. In addition, Milestone Scientific strives to promote an ownership mentality among key leadership and the Board of Directors.

The Compensation Committee reviews and approves, or in some cases recommends for the approval of the full Board, the annual compensation procedures for the Named Executive Officers.

The compensation program is designed to reward teamwork, as well as each manager's individual contribution. In measuring the Named Executive Officers' contribution, the Compensation Committee considers numerous factors including the growth strategic business relationships and financial performance. Regarding most compensation matters, including executive and director compensation, management provides recommendations to the Compensation Committee; however, the Compensation Committee does not delegate any of its functions to others in setting compensation. Milestone Scientific does not currently engage any consultant to advise on executive and/or director compensation matters.

Stock price performance has not been a factor in determining annual compensation because the price of Milestone Scientific's common stock is subject to a variety of factors outside of Milestone Scientific's control. Milestone Scientific does not have an exact formula for allocating between cash and non-cash compensation.

Annual CEO compensation consists of a base salary component, a bonus component (payable in a mix of cash and stock) and periodic stock option grants. It is the Compensation Committee's intention to set totals for the CEO for cash compensation sufficiently high enough to attract and retain a strong motivated leadership team, but not so high that it creates a negative perception with the other stakeholders. The CEO receives stock option grants under the stock option plan. The number of stock options granted to the executive officer is made on a discretionary rather than a formula basis by the Compensation Committee.

The CEO's current and prior compensation is considered in setting future compensation. To some extent, the compensation plan is based on the market and the companies that compete for executive management. The elements of the plan (e.g., base salary, bonus, and stock options) are like the elements used by many companies. The exact base pay, stock option grant, and bonus amounts are chosen to balance the competing objectives of fairness to all stakeholders and attracting and retaining executive managers.

Outstanding Equity Awards on December 31, 2023

| Name | Number of Securities Underlying Vested Options (#) Exercisable (1) | Number of Securities Underlying Nonvested Options (#) | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units of Stock that have not vested (#) (2) | Market Value of Number of Shares or Units of Stock that have not vested (#) (3) |
|-------------------------------|--|---|----------------------------|-------------------------------------|---|---|
| Jan Adriaan (Arjan) Haverhals | 40,000 119,676 | - 96,620 | \$ 2.13 \$ 1.52 | 12/23/2024 3/30/2025 | 319,546 | \$ 220,487 |
| Total | 159,676 | 96,620 | | | 319,546 | \$ 220,487 |
| Leonard Osse | 703,518 800,000 24,882 | - 1,200,000 7,293 | \$ 1.99 2.47 \$ 3.11 | 12/22/2025 4/23/2031 2/9/2026 | 2,272,713 | \$ 1,568,172 |
| Total | 1,528,400 | 1,207,293 | | | 2,272,713 | \$ 1,568,172 |
| Grand Total | 1,688,076 | 1,303,913 | | | 2,592,260 | \$ 1,788,659 |

The following table includes certain information with respect to all unexercised stock options and unvested shares of common stock of Milestone Scientific outstanding owned by the Named Executive Officers on December 31, 2023.

1. Represents stock option grants at fair market value on the date of grant.
2. Issuance of the shares of common stock have been deferred until the termination of employment with Milestone Scientific in accordance with the terms of respective employment arrangements.
3. Based on the closing price per share of \$0.69 as reported on the NYSE American on December 31, 2023

Director Compensation

| | Fees Earned paid in cash\$ | Stock Awards \$ | Options Award \$ | Non-Equity Incentive Plan Compensation \$ | Change in pension value and nonqualified deferred compensation earnings \$ | All other Compensation | Fees Earned paid in cash\$ | Total \$ | Fees Earned paid in cash\$ |
|-------------------------|----------------------------|-----------------|------------------|---|--|------------------------|----------------------------|----------|----------------------------|
| Neal Goldman | - | 120,000 | - | - | - | - | - | 120,000 | - |
| Benedetta Casamento | - | 120,000 | - | - | - | - | - | 120,000 | - |
| Leonard Osser | - | 100,000 | - | - | - | - | - | 100,000 | - |
| Dr. Didier Demesmin | - | - | - | - | - | - | - | - | - |
| Michael McGeehan | - | 110,000 | - | - | - | - | - | 110,000 | - |
| Gian Domenico Trombetta | - | 100,000 | - | - | - | - | - | 100,000 | - |

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

The following table, together with the accompanying footnotes, sets forth information, as March 15, 2024 regarding stock ownership of all persons known by Milestone Scientific to own beneficially more than 5% of Milestone Scientific's outstanding common stock, Named Executives, all directors, and all directors and executive officers of Milestone Scientific as a group:

| Names of Beneficial Owner (1) | Shares of Common Stock Beneficially Owned (2) | Percentage |
|---|---|------------|
| Executive Officers and Directors | | |
| Jan Adriaan (Arjan) Haverhals (3) | 319,546 | 0.42% |
| Neal Goldman (4) | 2,112,834 | 2.77% |
| Benedetta Casamento (5) | 269,659 | 0.35% |
| Michael McGeehan (6) | 505,407 | 0.66% |
| Leonard Osser (7) | 5,166,428 | 6.78% |
| Dr. Didier Demesmin | - | -% |
| Gian Domenico Trombetta (8) | 10,484,597 | 13.76% |
| All directors & executive officers as group (7 persons) | 18,858,472 | 24.75% |

1. The addresses of the persons named in this table are as follows: Leonard Osser, Jan Adriaan (Arjan) Haverhals, Gian Domenico Trombetta, Neal Goldman, Michael McGeehan, Benedetta Casamento and Dr. Didier Demesmin are at 425 Eagle Rock Avenue, Roseland, New Jersey 07068.
2. A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 15, 2024, as applicable, upon the exercise of options and warrants or conversion of convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants and convertible securities that are held by such person (but not held by any other person) and that are exercisable or convertible within 60 days from March 15, 2024, have been exercised or converted. Except as otherwise indicated, and subject to applicable community property and similar laws, each of the persons named has sole voting and investment power with respect to the shares shown as beneficially owned. The percentages for each beneficial owner are determined based on dividing the number of shares of common stock beneficially owned by the sum of the outstanding shares of common stock on March 15, 2024 and the number of shares underlying options exercisable and convertible securities convertible within 60 days from March 15, 2024 held by the beneficial owner.
3. Includes 319,546 shares to be issued at the termination of Mr. Haverhals employment agreement, and 98,424 vested stock options to purchase common stock of the Company.
4. Includes 2,112,834 shares held by Mr. Goldman.
5. Includes 269,659 shares held by Mrs. Casamento.
6. Includes 505,407 shares held by Mr. McGeehan and 21,250 shares subject to common stock warrants to purchase common stock of the Company.
7. Includes 2,744,947 shares held by Mr. Osser or his family, 2,272,713 shares to be issued at the termination of his employment agreement, and 1,279,975 vested stock options to purchase common stock of the Company.
8. Includes 608,835 shares held by Mr. Trombetta directly, 178,571 shares subject to warrants to purchase common stock of the Company in the name of Bp4 Sr. I, and 9,875,763 shares held directly by BP4 U.R.L. ("BP4") of which 5,982,906 shares were issued upon the conversion of \$7 million of preferred stock at \$1.17 per share, as adjusted to date. Innovest S.p.A. ("Innovest") is the controlling shareholder of BP4 and Mr. Trombetta is a controlling shareholder and director of Innovest, and, as such, is deemed to have voting and investment power over the securities held by BP4. Mr. Trombetta disclaims beneficial ownership of all securities held by BP4.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information (as of December 31, 2023)

| | Number of Securities to be issued upon exercise of outstanding options | Weighted-average exercise price of outstanding options | Number of securities remaining available for future issuance under equity compensation plan |
|---|--|--|---|
| Equity compensation plan approved by stockholders | | | |
| Grants under our 2020 Equity Incentive Plan (4) | 3,128,652 | \$ 2.30 | 9,174,520 |
| Total | 3,128,652 | \$ - | 9,174,520 |

1. The 2020 plan, as amended and restated in 2021 and amended during 2023, provides for awards of restricted common stock and options to purchase up to a maximum of 11,500,000 shares of common stock and expires in December 2030. Options may be granted to employees, directors, and consultants of Milestone Scientific for the purchase of shares of common stock at a price not less than the fair market value of common stock on the date of grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. During the year ended December 31, 2023, 9,174,520 options and shares were issued.

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

United Systems

Milestone Scientific has a supply agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal supplier of its handpieces, pursuant to which it procures manufactured products under specific purchase orders, but without minimum purchase commitments. Purchases from this supplier were approximately 2.3 million and \$3.4 million for the twelve months ended December 31, 2023, and 2022, respectively. As December 31, 2023, and December 31, 2022, Milestone Scientific owed this supplier approximately \$402,000 and \$819,000, respectively, which is included in accounts payable and accrued expenses related party on the consolidated balance sheets. In June 2021, the Company signed a ten-year agreement with United Systems for supplier of the handpieces.

Other

In December 31, 2023 and 2022 the Company had approximately \$270,000 and \$630,000 sales to Milestone China or agents of Milestone China, an entity in which the Company formerly had an ownership interest terminating in 2021.

Consulting Agreements

K. Tucker Andersen, a significant stockholder of Milestone Scientific, has an agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$100,000 for years ended December 31, 2023 and 2022, respectively.

The Director of Clinical Affairs' royalty fee was approximately \$485,000 and \$442,000 for the years ended December 31, 2023 and 2022, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$156,000 and \$154,000 for the year ended December 31, 2023 and 2022, respectively. As of December 31, 2023, and 2022, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$114,000 and \$120,000, respectively, which is included in accounts payable, related party and accrued expense, related party, in the consolidated balance sheet.

Employment Contracts

On March 2, 2021, the Company entered into a Royalty Sharing Agreement with Leonard Osser, pursuant to which Mr. Osser sold, transferred and assigned to the Company all of his rights in and to a certain patent application as to which he is a co-inventor with Mark Hochman, a consultant to the Company, and the Company agreed to pay to Mr. Osser, beginning May 9, 2027, half of the royalty (2.5%) on net sales that would otherwise be payable to Mark and Claudia Hochman under their existing Technology Sale Agreement, dated January 1, 2005 and amended from time to time, with the Company. In connection with the Royalty Sharing Agreement, the Hochman's agreed with the Company, pursuant to an addendum to such Technology Sale Agreement dated February 25, 2021, to reduce from 5% to 2.5% the payments due to them under their Technology Sale Agreement beginning on May 9, 2027, and thereafter with respect to dental products embodying the invention.

As part of the Succession Plan of the Company, Mr. Osser agreed, pursuant to an agreement dated April 6, 2021 (the "Succession Agreement"), to restructure certain of his existing agreements with the Company, which provide for additional and broader executive support, and at such time as he elects to step down as Interim Chief Executive Officer of the Company, to become the Vice Chairman of the Board of the Company. With respect to Mr. Osser's July 2017 Employment Agreement and July 2017 Consulting Agreement (each as previously disclosed), the compensation under the Employment Agreement was modified to reduce the overall compensation by \$100,000 to \$200,000, split equally between a cash amount and an amount in shares, and the compensation under the Consulting Agreement was increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares, which shares were formerly payable under the Employment Agreement. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term. In connection with his acceptance of the Vice Chairman position and in consideration of his services as a member of the Board and agreement to provide certain additional general consulting services, Mr. Osser was granted options to purchase 2,000,000 shares of common stock, exercisable at the fair market value of the common stock on the date of grant, vesting over the five-year period after he steps down as Interim Chief Executive Officer of the Company or ten years from the date of grant, whichever shall end first.

The Company believes that the effect of such existing agreements and the Succession Agreement, all of which relate to the period after such time Mr. Osser steps down as Interim Chief Executive Officer of the Company, collectively expand Mr. Osser's consulting to and support of the Company beyond its Chinese operations to also include its medical and other products, while enhancing the retention aspects of the Company's relationship with Mr. Osser. On May 19, 2021, Mr. Osser resigned as Interim Chief Executive Officer of the Company and assumed the role of Vice Chairman of the Board. Compensation under the Employment Agreement and the Consulting Agreement is payable for 9.5 years from May 19, 2021. The Company recorded expenses of \$200,000 related to the Employment Agreement for each of the years ended December 31, 2023 and 2022, respectively. The Company recorded expenses of \$200,000 related to the Consulting Agreement for each of the years ended December 31, 2023 and 2022, respectively.

On January 1, 2022, the Company entered into an employment agreement with Mr. Arjan Haverhals. The employment term ends December 31, 2024, unless extended by mutual written agreement. Mr. Haverhals will serve as the President and Chief Executive Officer of the Company and such other senior executive positions as accepted and determined by the Board reasonably requests. As an executive, notwithstanding the fact that he is a director, Mr. Haverhals has board observer rights. The agreement calls for a base salary of \$350,000 and bonus compensation of up to \$400,000 per year, comprise of three separate performance based bonuses each up to \$100,000 per year, based upon the Company's achievement of three (3) performance or financial goals, as established by the Compensation Committee in its reasonable discretion; and (ii) a discretionary bonus up to \$100,000, as determined by the Compensation Committee, in its sole discretion. Satisfaction of bonus goals will be determined by the Compensation Committee from time to time in its reasonable discretion. Bonus compensation, if any, shall be payable annually in arrears thirty-three percent (33%) in cash and sixty-seven percent (67%) in shares of the Company's common stock. Mr. Haverhals will also be entitled to reimbursement of expenses, four weeks' paid vacation, a car allowance and participation in company retirement plans and health insurance reimbursement. The agreement provides for the typical termination provisions. If Mr. Haverhals is terminated for other than for cause or termination by him for good reason, he will be paid as severance, his base compensation, and certain other benefits, as provided in the employment agreement, for two years after termination.

Item 14. Principal Accountant Fees and Services

Audit Fees

Milestone Scientific incurred aggregate audit and financial statement review fees of approximately \$295,200 from Marcum for 2023. Milestone Scientific incurred audit and financial statement review fees of approximately \$267,000 from Marcum and Friedman for 2022. These fees include fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Q's or services that are normally provided in connection with statutory and regulatory filings and fees related to registration statements.

Tax Fees

Milestone Scientific incurred aggregate tax fees of approximately \$42,000 from Marcum for 2023. Milestone Scientific incurred tax fees of approximately \$40,000 from Marcum and Friedman for 2022.

Audit Related Fees

Milestone Scientific did not incur audit related fees from Marcum and Friedman in either 2023 or 2022.

All Other Fees

Milestone Scientific did not incur other accounting fees from Marcum or Friedman in either 2023 or 2022.

Audit Committee Administration of the Engagement

The engagements with Friedman and Marcum as the Company's principal accountants were approved in advance by the Board and the Audit Committee. No non-audit or non-audit related services were approved by the Audit Committee in either 2023 or 2022.

Audit Committee Pre-Approval Policies and Procedures

The Audit Committee charter provides that the Audit Committee will pre-approve audit services and non-audit services to be provided by the independent auditors before the accountant is engaged to render these services. The Audit Committee may consult with management in the decision-making process but may not delegate this authority to management. The Audit Committee may delegate its authority to preapprove services to one or more committee members, provided that the designers present the pre-approvals to the full committee at the next committee meeting. All audit and non-audit services performed by the independent accountants have been pre-approved by the Audit Committee to assure that such services do not impair the auditors' independence from us.

PART IV

Item 15. Exhibits and Financial Statement Schedules

a. The following documents are filed as part of this Report:

- 1 Financial Statements. See Index to Financial Statements on page F-1.
- 2 Financial Statement Schedule
- 3 Exhibits

Certain of the following exhibits were filed as Exhibits to previous filings filed by Milestone Scientific under the Securities Act of 1933, as amended, or reports filed under the Securities and Exchange Act of 1934, as amended, and are hereby incorporated by reference.

b. The following documents are filed as exhibits to this Report:

Exhibit Description

| No | Description |
|---------|--|
| 3.1 | Restated Certificate of Incorporation of Milestone filed on September 6, 2013 (1) |
| 3.2 | Form of Certificate of Designation filed on April 18, 2014 (2) |
| 3.3 | Certificate of Correction to the Certificate of Designation filed on May 12, 2014 (3) |
| 3.4 | Amended and Restated By-laws of Milestone filed April 1, 2019 (4) |
| 3.5 | Certificate of Amendment to Restated Certificate of Incorporation (5) |
| 4.1 | Specimen stock certificate (6) |
| 4.5 | Description of Registrant's Securities (7) |
| 10.1 | Lease dated November 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (8) |
| 10.2 | Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (9) |
| 10.3 | 2011 Equity Compensation Plan (10) |
| 10.4 | Agreement with Mark Hochman, dated July 2015 (11) |
| 10.5 | Succession Agreement between Leonard Osser and Milestone Scientific Inc. + (12) |
| 10.6 | Amended and Restated 2020 Equity Incentive Plan (13) |
| 10.7 | Employment Agreement, dated and effective as of January 1, 2022, between Arjan Haverhals and Milestone Scientific Inc.+ (14) |
| 10.8 | Underwriting Agreement, dated as of December 10, 2023, between the Company and Maxim Group LLC (15) |
| 10.10 | Amended Employment agreement dated and effective July 5, 2023 between Arjan Haverhals and Milestone Scientific Inc. + * |
| 14.1 | Code of Ethics * |
| 19.1 | Insider Trading Policy* |
| 21.1 | List of Subsidiaries* |
| 23.1 | Consent of Marcum LLP* |
| 31.1 | Rule 13a-14(a) Certification-Chief Executive Officer* |
| 32.1 | Section 1350 Certifications-Chief Executive Officer* / *** |
| 99.1 | Clawback Policy, dated 2023* |
| 101.INS | Inline XBRL Instance Document* |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document* |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document* |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document* |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document* |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document* |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed herewith.

+ Indicates management contract or compensatory plan or arrangement.

*** Furnished, not filed, in accordance with item 601(32) (ii) of Regulations-S-K.

- 1) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2013, Exhibit 3.1.
- 2) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on April 18, 2014, Exhibit 10.2.
- 3) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2015, Exhibit 3.3.
- 4) Incorporated by reference to Milestone Scientific's Form 10-K filed with the SEC on April 1, 2019, Exhibit 3.4.
- 5) Incorporated by reference to Milestone Scientific's Form 10-K/A filed with the SEC on April 2, 2020, Exhibit 3.4.
- 6) Incorporated by reference to Amendment No. 1 to Milestone Scientific's Registration Statement on Form 10-KSB for the year ended May 15, 1995
- 7) Incorporated by reference to Milestone Scientific's Form 10-K filed with the SEC on March 31, 2022, Exhibit 4.6.
- 8) Incorporated by reference to Milestone's Form 10-KSB for the year ended December 31, 1996.
- 9) Incorporated by reference to Milestone Scientific's Form 10-K filed with the SEC on April 4, 2005, Exhibit 10.37
- 10) Filed as Appendix A to Milestone Scientific's Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.
- 11) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2015, Exhibit 10.11
- 12) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on April 7, 2021, Exhibit 10.1
- 13) Incorporated by reference to Milestone Scientific's Proxy Statement on Schedule 14A filed with the SEC on April 30, 2021, Appendix A
- 14) Incorporated by reference to Milestone Scientific's Form 10-Q filed with the SEC on August 15, 2022, Exhibit 10.1.
- 15) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on December 12, 2023, Exhibit 1.1.

Item 16. Form 10-K Summary

None

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Milestone Scientific Inc.

By:

/s/Arjan Haverhals
Chief Executive Officer

Date: March 29, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Date | Title |
|---|----------------|----------------------------|
| <u>/s/ Neal Goldman</u> Neal Goldman | March 29, 2024 | Chairman and Director |
| <u>/s/ Leonard Osser</u> Leonard Osser | March 29, 2024 | Vice Chairman and Director |
| <u>/s/ Gian Domenico Trombetta</u> Gian Domenico Trombetta | March 29, 2024 | Director |
| <u>/s/ Benedetta Casamento</u> Benedetta Casamento | March 29, 2024 | Director |
| <u>/s/ Michael McGeehan</u> Michael McGeehan | March 29, 2024 | Director |
| <u>/s/ Dr. Didier Demesmin</u> Dr. Didier Demesmin | March 29, 2024 | Director |
| <u>/s/ Arjan J. Haverhals</u> Arjan J. Haverhals | March 29, 2024 | Director |

REPORT INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

For the Years Ended December 31, 2023 and 2022

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Milestone Scientific, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Milestone Scientific, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2016

East Hanover, New Jersey
March 29, 2024

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | December 31, 2023 | December 31, 2022 |
|---|-----------------------------|-----------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 2,977,713 | \$ 8,715,279 |
| Marketable securities | 2,976,573 | - |
| Accounts receivable (net of allowance for credit losses of \$ 10K at December 31, 2023 and 2022) | 312,664 | 693,717 |
| Prepaid expenses and other current assets | 517,785 | 443,872 |
| Inventories | 2,638,186 | 1,792,335 |
| Advances on contracts | 1,371,548 | 1,325,301 |
| Total current assets | <u>10,794,469</u> | <u>12,970,504</u> |
| Furniture, fixtures and equipment, net | 10,024 | 18,146 |
| Intangibles, net | 178,636 | 227,956 |
| Right of use assets finance lease | 8,998 | 17,645 |
| Right of use assets operating lease | 355,235 | 443,685 |
| Other assets | 24,150 | 24,150 |
| Total assets | <u><u>\$ 11,371,512</u></u> | <u><u>\$ 13,702,086</u></u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 689,604 | \$ 1,102,729 |
| Accounts payable, related party | 410,512 | 803,492 |
| Accrued expenses and other payables | 1,511,717 | 1,124,839 |
| Accrued expenses, related party | 137,189 | 167,549 |
| Accrued liabilities noncontrolling interests | 214,000 | - |
| Current portion of finance lease liabilities | 10,264 | 9,365 |
| Current portion of operating lease liabilities | 103,427 | 91,701 |
| Total current liabilities | <u>3,076,713</u> | <u>3,299,675</u> |
| Non-current portion of finance lease liabilities | 434 | 10,698 |
| Non-current portion of operating lease liabilities | 281,853 | 385,279 |
| Total liabilities | <u><u>\$ 3,359,000</u></u> | <u><u>\$ 3,695,652</u></u> |
| Commitments (see Note P) | | |
| Stockholders' equity | | |
| Common stock, par value \$.001; authorized 100,000,000 shares; 75,881,840 shares issued and 75,848,507 shares outstanding as of December 31, 2023 shares; 69,306,497 shares issued and 69,273,164 shares outstanding as of December 31, 2022; | 75,881 | 69,306 |
| Additional paid in capital | 132,187,656 | 127,478,325 |
| Accumulated deficit | (123,339,509) | (116,410,405) |
| Treasury stock, at cost, 33,333 shares | (911,516) | (911,516) |
| Total Milestone Scientific, Inc. stockholders' equity | <u>8,012,512</u> | <u>10,225,710</u> |
| Noncontrolling interest | - | (219,276) |
| Total stockholders' equity | <u><u>8,012,512</u></u> | <u><u>10,006,434</u></u> |
| Total liabilities and stockholders' equity | <u><u>\$ 11,371,512</u></u> | <u><u>\$ 13,702,086</u></u> |

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31,

| | 2023 | 2022 |
|---|-----------------------|-----------------------|
| Product sales, net | \$ 9,827,444 | \$ 8,805,906 |
| Cost of products sold | 3,034,832 | 3,905,092 |
| Gross profit | 6,792,612 | 4,900,814 |
| Selling, general and administrative expenses | 13,135,796 | 12,514,323 |
| Research and development expenses | 701,378 | 1,150,209 |
| Depreciation and amortization expense | 61,912 | 63,755 |
| Total operating expenses | 13,899,086 | 13,728,287 |
| Loss from operations | (7,106,474) | (8,827,473) |
| Interest income (expense) | 125,527 | 54,607 |
| Provision for income Taxes | - | - |
| Loss before provision for income taxes | (6,980,947) | (8,772,866) |
| Net loss | (6,980,947) | (8,772,866) |
| Net loss attributable to noncontrolling interests | (51,843) | (66,735) |
| Net loss attributable to Milestone Scientific Inc. | \$ (6,929,104) | \$ (8,706,131) |
| Net loss per share applicable to common stockholders— | | |
| Basic and Diluted | (0.10) | (0.12) |
| Weighted average shares outstanding and to be issued— | | |
| Basic and Diluted | 72,775,781 | 70,607,338 |

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31 2023 AND 2022

| | Common Stock Shares | Common Stock Amount | Additional Paid in Capital | Accumulated Deficit | Noncontrolling Interest | Treasury Stock | Total Stockholder Equity |
|--|---------------------------|---------------------------|----------------------------------|-------------------------|----------------------------|---------------------|--------------------------------|
| Balance January 1, 2022 | <u>68,153,336</u> | <u>68,153</u> | <u>124,915,560</u> | <u>(107,704,274)</u> | <u>(152,541)</u> | <u>(911,516)</u> | <u>16,215,382</u> |
| Stock based compensation | - | - | 1,499,302 | - | - | - | 1,499,302 |
| Common stock issued to be employee for bonus | - | - | 264,385 | - | - | - | 264,385 |
| Common stock issued to employee for compensation | 30,196 | 30 | 39,973 | - | - | - | 40,003 |
| Common stock to be issued for payment of consulting services | 577,074 | 577 | 746,774 | - | - | - | 747,351 |
| Common stock to be issued to employees for bonuses | 147,338 | 147 | (147) | - | - | - | - |
| Common stock issued to board of directors for services | 398,553 | 399 | 12,478 | - | - | - | 12,877 |
| Net loss | - | - | - | (8,706,131) | (66,735) | - | (8,772,866) |
| Balance December 31, 2022 | <u>69,306,497</u> | <u>\$ 69,306</u> | <u>\$127,478,325</u> | <u>\$ (116,410,405)</u> | <u>\$ (219,276)</u> | <u>\$ (911,516)</u> | <u>\$10,006,434</u> |
| Stock based compensation | - | - | 1,467,425 | - | - | - | 1,467,425 |
| Common stock issued in public offering net of issuance cost of \$431,849 | 4,765,000 | 4,765 | 2,565,336 | - | - | - | 2,570,101 |
| Common stock issued to consultants | 1,051,660 | 1,051 | 744,948 | - | - | - | 745,999 |
| Common stock issued to be employee for compensation | - | - | 417,500 | - | - | - | 417,500 |
| Common stock issued to board of directors for services | 758,683 | 759 | (759) | - | - | - | - |
| Repurchase of noncontrolling interest | - | - | (485,119) | - | 271,119 | - | (214,000) |
| Net loss | - | - | - | (6,929,104) | (51,843) | - | (6,980,947) |
| Balance December 31, 2023 | <u>75,881,840</u> | <u>75,881</u> | <u>132,187,656</u> | <u>(123,339,509)</u> | <u>-</u> | <u>(911,516)</u> | <u>8,012,512</u> |

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31,

| | December 31, 2023 | December 31, 2022 |
|---|----------------------|----------------------|
| Cash flows from operating activities: | | |
| Net loss | \$ (6,980,947) | \$ (8,772,866) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | 12,999 | 14,180 |
| Amortization of intangibles | 49,320 | 49,663 |
| Stock based compensation | 1,467,426 | 1,499,302 |
| Inventory Reserve | 258,011 | 582,299 |
| Employees paid in stock | 417,500 | 317,265 |
| Expense paid in stock | 745,999 | 747,351 |
| Unrealized gain on marketable securities | (9,282) | - |
| Bad debt expense | 24,865 | - |
| Amortization of right-of-use asset | 88,450 | 80,533 |
| Changes in operating assets and liabilities: | | |
| Decrease in accounts receivable | 356,188 | 249,555 |
| Increase in inventories | (1,103,861) | (833,121) |
| Increase in advances | (46,246) | (16,041) |
| Increase in prepaid expenses and other current assets | (73,912) | (68,512) |
| (Decrease) increase in accounts payable | (413,125) | 322,300 |
| (Decrease) increase in accounts payable, related party | (392,981) | 407,636 |
| Increase (decrease) in accrued expenses | 386,882 | (292,495) |
| (Decrease) in accrued expenses, related party | (30,361) | (246,692) |
| Decrease operating right of use lease asset | (83,054) | (72,353) |
| Net cash used in operating activities | <hr/> \$ (5,326,129) | <hr/> \$ (6,031,996) |
| Cash flows from investing activities: | | |
| Purchase of furniture, fixtures, and equipment | (4,881) | (8,527) |
| Sale of Marketable securities | 4,966,213 | - |
| Purchase of Marketable securities | (7,933,504) | - |
| Net cash provided by (used in) in investing activities | <hr/> \$ (2,972,172) | <hr/> \$ (8,527) |
| Cash flows from financing activities: | | |
| Net proceeds from issuance of Common Stock | 2,570,101 | - |
| Payments finance lease obligations | (9,366) | (8,544) |
| Net cash provided by (used in) financing activities | <hr/> \$ 2,560,735 | <hr/> \$ (8,544) |
| Net decrease in cash and cash equivalents | (5,737,566) | (6,049,067) |
| Cash and cash equivalents at beginning of period | 8,715,279 | 14,764,346 |
| Cash and cash equivalents at end of period | <hr/> \$ 2,977,713 | <hr/> \$ 8,715,279 |
| Supplemental non-cash disclosure of cash flow information: | | |
| Declared repurchase of noncontrolling interest | 214,000 | - |

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE A — ORGANIZATION AND BUSINESS

All references in this report to "Milestone Scientific," "us," "our," "we," the "Company" or "Milestone" refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., and Milestone Innovations Inc. and Milestone Education LLC (all described below), unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent®; CompuMed®; CompuFlo®; DPS Dynamic Pressure Sensing technology®; Milestone Scientific ®; the Milestone logo ®; SafetyWand®; STA Single Tooth Anesthesia System®; and The Wand ®.*

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery device, using *The Wand®*, a single use disposable handpiece. The device is marketed in dentistry under the trademark *CompuDent®*, and *STA Single Tooth Anesthesia System®* and in medicine under the trademark *CompuMed®*. *CompuDent®* is suitable for all dental procedures that require local anesthetic. *CompuMed®* is suitable for many medical procedures regularly performed in plastic surgery, hair restoration surgery, podiatry, colorectal surgery, dermatology, orthopedics, and many other disciplines. The dental devices are sold in the United States, Canada and in 60 other countries. Certain medical devices have obtained CE mark approval and can be marketed and sold in most European countries. In June 2017, Milestone Scientific received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the *CompuFlo® Epidural Computer Controlled Anesthesia System ("Epidural")*.

We are in the process of meeting with medical facilities and device distributors within the United States, Middle East and Europe. Certain of our medical instruments have obtained European CE mark approval and can be marketed and sold in most European countries.

In 2020, the Company received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) related to its new CompuPulse System, which combines the benefits of our CompuWave technology with a manual syringe. The new CompuPulse System allows one to identify a pulsatile pressure waveform in a variety of applications, thereby improving the reliability and safety of a drug delivery procedure. Importantly, not all procedures require the sophistication of our CompuFlo system, which precisely controls the administration and flow rate of medication as it is being administered. This new technology provides an efficient and low-cost alternative for procedures where a manual syringe may suffice, while still providing the ability to verify needle and subsequent catheter placement.

NOTE B- LIQUIDITY AND UNCERTAINTIES

The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company has incurred total losses since inception of \$123.3 million. The operating losses were \$7.1 million and \$8.8 million, for the years ended December 31, 2023, and 2022, respectively. On December 31, 2023, Milestone Scientific had cash and cash equivalents and marketable securities of approximately \$6.0 million and working capital of approximately \$ 7.7 million. For the twelve months ended December 31, 2023 and 2022, we had cash flows used in operating activities of approximately \$5.3 million and \$6.0 million, respectively.

Management has prepared cashflow forecasts covering a period of 12 months from the date of issuance of these financial statements. These forecasts include several revenue and operating expense assumptions which indicate that the Company's current cash and liquidity is sufficient to finance the operating requirements for at least the next 12 months. Additionally, the Company was approved on September 12, 2023 to sell Net Operating Losses through the New Jersey Technology Business Tax Certificate Transfer Program ("NJ NOL Program"), a program administered by the New Jersey Economic Development Authority ("NJEDA"). Management believes this program will generate positive cash flow in the near future. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses. However, the Company's continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability, if ever.

In addition to its employees, the Company relies on (i) distributors, agents, and third-party logistics providers in connection with product sales and distribution and (ii) raw material and component suppliers in the U.S., Europe, and China. If the Company, or any of these entities encounter any disruptions to its or their respective operations or facilities, or if the Company or any of these third-party partners were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute, pandemic or other public health crises, or other unforeseen disruption, then the Company or they may be prevented or delayed from effectively operating its or their business, respectively.

NOTE C — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1. Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"), and the applicable rules and regulations of the Securities and Exchange Commission (SEC) include the accounts of Milestone Scientific and its wholly owned and majority owned subsidiaries, including, Wand Dental (wholly owned), and Milestone Innovations Inc.(wholly owned). All significant, intra-entity transactions and balances have been eliminated in the consolidation. Ownership interests in consolidated entities that are held by entities other than us are reported as noncontrolling interests in our consolidated balance sheets. Losses attributed to noncontrolling interests are reported separately in our consolidated statements of operations.

During December 2023, the Board of Directors of the Company approved a resolution to repurchase the remaining minority stake of Milestone Medical, Inc. for \$214,000. Concurrently, the Company transferred the net assets of Milestone medical, Inc. to a newly created, wholly-owned subsidiary, Milestone Innovations, Inc., a Delaware corporation.

2. Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the inventory valuation, and cash flow assumptions going concern considerations. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known Actual results could differ from those estimates.

3. Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition, the Company performs the following five steps:

- i. identification of the promised goods or services in the contract;
- ii. determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- iii. measurement of the transaction price, including the constraint on variable consideration;
- iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
- v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606.

The Company derives its revenues from the sale of its products, primarily dental instruments, handpieces, and other related products. The Company sells its products directly to consumers in the United States and through a global distribution network that includes both exclusive and non-exclusive distribution agreements with related and third parties.

Revenue from product sales is recognized upon transfer of control of a product to a customer at a point in time, generally upon date of shipment. The Company has no obligation to product sales for any installation, set-up, or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

E-Commerce

As of January 3, 2023, the Company launched an E-Commerce platform, selling and shipping STA Single Tooth Anesthesia Systems® (STA) and handpieces directly to dental offices and dental groups within the United States. Our E-commerce portal accepts online payments via credit and debit cards. The cost of delivery is charged to the customer along with appropriate sales tax. The Company recognizes revenue from product sales at the time the product ships to a customer via a third party carrier.

Sales Returns

The Company records allowances for product returns as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights and the Company's historical experience with returns and the amount of product in the distribution channel not consumed by end users and subject to return. The Company relies on historical return rates to estimate returns.

The Company terminated its major U.S. distributor contract as of December 31, 2022. That distributor had return rights in connection with this contract termination that extended through March 31, 2023. The Company recorded allowance of approximately \$179,000 for those returns within its December 31, 2022 financial statements. As of December 31, 2023 no returns have been presented, and the Company reversed the allowance for sales returns.

Financing and Payment

The Company's payment terms differ by geography and customer, but payments from distributors are required within 90 days or less from the date of shipment. The E-commerce portal sells directly to end users and accepts online payments via credit and debit cards via a third-party. These payments from the third party are typically settled within two business days.

Disaggregation of Revenue

The Company operates in two operating segments: dental and medical. Therefore, the results of the Company's operations are reported on a consolidated basis for the purposes of segment reporting, consistent with internal management reporting. See Note M for revenues by geographical market, based on the customer's location, and product category for the years ended December 31, 2023 and 2022 respectively.

5. Cash and Cash Equivalents

Milestone Scientific considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2023 and 2022 Milestone Scientific has approximately \$3.0 million and \$8.7 million, respectively, in cash. As of December 31, 2023 and 2022 Milestone Scientific had cash that exceeded the Federal Deposit Insurance Corporation insurance limit of \$250,000.

6. Marketable Securities

The Company's marketable securities are comprised of treasury bills with an original maturity greater than three months from date of purchase. The Company's marketable securities are measured at fair value and are accounted for in accordance with ASU 2016-01. Unrealized holding gains and losses on treasury bills are recorded in interest income on the consolidated statements of operations. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of the marketable securities.

The appropriate classification of marketable securities is determined at the time of purchase and evaluated as of each reporting balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair value is determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Declines in the fair values of equity securities that are considered other-than-temporary, are charged to other income (expense), net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. As of December 31, 2023 the Company held approximately \$3.0 million in U.S. treasury securities, with maturity dates within 3 and 6 months.

7. Accounts Receivable

Milestone Scientific sells a significant amount of its product on credit terms to its major distributors. Milestone Scientific estimates losses from the ability or inability of its customers to make payments on amounts billed. Most credit sales are due within 90 days from invoicing. There have not been any significant credit losses incurred to date. As of December 31, 2023 and 2022, accounts receivable was recorded, net of allowance for doubtful accounts of \$10,000.

9. Inventories

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or net realizable value. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess, slow moving, defective, and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence, and product expiration requirements.

The valuation allowance creates a new cost basis for the inventory, and it is not subsequently marked up through a reduction in the valuation allowance based on any changes in the underlying facts and circumstances. When the valuation allowance is initially recorded, the increase to the allowance is recognized as an increase in cost of sales. The valuation allowance is only reduced if or when the underlying inventory is sold or destroyed, at which time cost of sales recognized would include the previous adjusted cost basis.

10. Furniture, Fixture and Equipment

Equipment is recorded at cost, less accumulated depreciation. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. The costs of maintenance and repairs are charged to operations as incurred.

11. Intangible Assets – Patents and Developed Technology

Patents are recorded at cost to prepare and file the applicable documents with the United States Patent Office, or internationally with the applicable governmental office in the respective country. The costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. Patents and other developed technology acquired from another business entity are recorded at acquisition cost and be amortized at the estimated useful life. Patent defense costs, to the extent applicable, are expensed as incurred.

12. Impairment of Long-Lived Assets

Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company's impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

- significant under performance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends; and
- significant technological changes, which would render the technology obsolete.

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs.

13. Research and Development

Research and development costs, which consist principally of new product development costs payable to third parties, are expensed as incurred.

14. Income Taxes

Milestone Scientific accounts for income taxes under the asset and liability method which requires deferred tax assets and liabilities to be computed for temporary differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

On December 31, 2023 and 2022, we had no uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Consolidated Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2020, 2021, and 2022 years are subject to audit by federal and state jurisdictions.

15. Basic and Diluted Net Loss Per Common Share

Milestone Scientific presents "basic" loss per common share applicable to common stockholders and, if applicable, "diluted" loss per common share applicable to common stockholders pursuant to the provisions of ASC 260, "Earnings per Share". Basic loss per common share is calculated by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding and to be issued common shares of 72,775,781 and 70,607,338 during the years ended December 31, 2023 and 2022, respectively. The calculation of diluted earnings per common share is like that of basic earnings per common share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if all potentially dilutive common shares, such as those issuable upon the exercise of stock options and warrants were issued during the period.

Since Milestone Scientific had net losses in the years ended December 31, 2023 and 2022, the assumed effects of the exercise of potentially dilutive outstanding stock options, unissued restricted stock awards ("RSA") and warrants, were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options, RSA and warrants 3,771,151 and 7,855,160 on December 31, 2023 and 2022, respectively.

16. Fair Value of Financial Instruments

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). The Company required us to classify fair value measurements in one of the following categories.

- Level 1 inputs which are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can access at the measurement date.
- Level 2 inputs which are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.
- Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of an input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels. As of December 31, 2023, the Company has the following assets that were measured at fair value on a recurring basis.

| | Level 1 | Level 2 | Level 3 | Total |
|---|--------------|---------|---------|--------------|
| Marketable Securities December 31, 2023 | \$ 2,976,573 | | | \$ 2,976,573 |

Marketable Securities included US Treasury securities totaling \$2,976,573 that are considered to be highly liquid and easily transferable at December 31, 2023. US Treasury securities are valued using inputs observable in active markets for identical securities and are therefore classified at Level 1 within the Company fair value hierarchy.

The Company had no assets or liabilities that were measured at fair value on a recurring basis as of December 31, 2022.

17. Stock-Based Compensation

Milestone Scientific accounts for stock-based compensation under ASC Topic 718, Share-Based Payment. ASC Topic 718 requires all share-based payments to employees, non-employees, directors, and officers, including grants of employee stock options, to be recognized in the consolidated statements of operations over the service period, as an operating expense, based on the grant-date fair values. The Company accounts for forfeitures as they occur.

18. Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815").

The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether they meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. Management concluded that its warrants qualify for equity accounting treatment.

19. Recent Accounting Pronouncements

Recently Issued Accounting Pronouncement

In November 2023, FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which provides improvements to reportable segment disclosure requirements, primarily through enhanced disclosures around segment expenses. ASU 2023-07 requires us to disclose significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss. ASU 2023-07 also requires that the Company disclose an amount for other segment items by reportable segment, a description of their composition and provide all annual disclosures about a reportable segment's profit or loss and assets pursuant to Topic 280 during interim periods. The Company must also disclose the CODM's title and position, as well as certain information around the measures used by the CODM and an explanation of how the CODM uses the reported measures in assessing segment performance and deciding how to allocate resources. For public entities with a single reportable segment, the entity must provide all the disclosures required pursuant to ASU 2023-07 and all existing segment disclosures under Topic 280. The amendments of ASU 2023-07 are effective for us for annual periods beginning January 1, 2024, and effective for interim periods beginning January 1, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company will evaluate the impact of ASU 2023-07 on our financial statements.

In December 2023, FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide improvements primarily related to the rate reconciliation and income taxes paid information included in income tax disclosures. The Company would be required to disclose additional information regarding reconciling items equal to or greater than five percent of the amount computed by multiplying pretax income (loss) by the applicable statutory tax rate. Similarly, the Company would be required to disclose income taxes paid (net of refunds received) equal to or greater than five percent of total income taxes paid (net of refunds received). Additionally, the Company would be required to disclose income (loss) from continuing operations before income tax expense disaggregated by foreign and domestic jurisdictions, as well as income tax expense disaggregated by federal, state, and foreign jurisdictions. The amendments in ASU 2023-09 are effective January 1, 2025, including interim periods. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company will evaluate the impact of ASU 2023-09 on our financial statements.

Recently Adopted Accounting Pronouncement

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which amends the guidance on measuring credit losses for certain financial assets measured at amortized cost, including trade receivables. The FASB has subsequently issued several updates to the standard, providing additional guidance on certain topics covered by the standard. This update requires entities to recognize an allowance for credit losses using a forward-looking expected loss impairment model, taking into consideration historical experience, current conditions, and supportable forecasts that impact collectability. As January 1, 2023, the Company adopted ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") the adoption of this ASU does not have a material impact on our financial statements.

In November 2019, the FASB issued ASU 2019-10, *Financial Instruments - Credit Losses (Topic, 326), Derivatives and hedging (Topic 815), and Leases (Topic 842): Effective dates*, which deferred the effective date of ASU 2016-13 for the Company. As a result of ASU 2019-10, ASU 2016-13 is effective for all entities with fiscal years beginning after December 15, 2022, including interim periods. As of January 1, 2023, the Company adopted ASU 2019-10, *Financial Instruments - Credit Losses (Topic, 326), Derivatives and hedging (Topic 815), and Leases (Topic 842)* the adoption of this ASU does not have a material impact on our financial statements.

NOTE D — INVENTORIES

| | December 31, 2023 | December 31, 2022 |
|-------------------------------------|-------------------|-------------------|
| Dental finished goods | \$ 2,404,970 | \$ 1,315,263 |
| Medical finished goods | 14,730 | 334,124 |
| Component parts and other materials | 218,486 | 142,948 |
| Total inventories | \$ 2,638,186 | \$ 1,792,335 |

The Company has recorded an allowance on slow moving Medical finished goods due to the slow adoption of the epidural instruments and handpieces for approximately \$258,000 and \$582,000 as of December 31, 2023 and 2022, respectively.

NOTE E — ADVANCES ON CONTRACTS

The advances on contracts represent funding of future dental STA "Single Tooth Anesthesia System" and epidural inventory purchases and epidural replacements parts. The balance of the advances as of December 31, 2023 and 2022 was approximately \$1.4 million and \$1.3 million respectively.

NOTE F— FURNITURE, FIXTURES AND EQUIPMENT

| | December 31, 2023 | December 31, 2022 |
|--------------------------------|-------------------|-------------------|
| Leasehold improvements | \$ 24,734 | \$ 24,734 |
| Office furniture and equipment | 181,745 | 178,058 |
| Molds | 7,200 | 7,200 |
| Trade show displays | 151,462 | 151,462 |
| Computers and software | 281,256 | 280,066 |
| Tooling Safety Wand | 125,022 | 125,022 |
| Tooling equipment-STA & Wand | 11,100 | 11,100 |
| EPI and IA Instruments | 82,363 | 82,363 |
| STA Trials Instruments | \$ 63,752 | \$ 63,752 |
| Total | 928,634 | 923,757 |
| Less accumulated depreciation | (918,610) | (905,611) |
| Total | \$ 10,024 | \$ 18,146 |

Depreciation expenses was \$12,999 and \$14,180 for the years ended December 31, 2023, and 2022, respectively.

NOTE G —INTANGIBLES, NET

| | Cost | Accumulated Amortization | Net |
|--|--------------|--------------------------|------------|
| Patents-foundation intellectual property | \$ 1,377,863 | \$ (1,199,227) | \$ 178,636 |
| Total | \$ 1,377,863 | \$ (1,199,227) | \$ 178,636 |
| | Cost | Accumulated Amortization | Net |
| Patents-foundation intellectual property | \$ 1,377,863 | \$ (1,149,907) | \$ 227,956 |
| Total | \$ 1,377,863 | \$ (1,149,907) | \$ 227,956 |

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was approximately \$49,000 and \$50,000 for the years ended December 31, 2023 and 2022, respectively. The annual amortization expense expected to be recorded for existing intangibles assets for the years 2024 through 2027 is approximately \$34,000, \$28,000, \$28,000 and \$86,000, respectively.

NOTE H — STOCKHOLDERS' EQUITY

PUBLIC OFFERING

On December 10, 2023, the Company completed a public offering for sale of 4,765,000 common stock, at \$0.63 per share which generated net proceeds of approximately \$2.6 million. In addition, the Company granted the Underwriter a 45-day option to purchase up to an additional 714,750 shares of Common Stock at the same price to cover over-allotments. Refer to subsequent event note Q.

NONCONTROLLING INTEREST

During December 2023, the Board of Directors of the Company approved a resolution to merge Milestone Medical, Inc. with and into a newly created, wholly owned subsidiary, Milestone Innovations, Inc., a Delaware corporation, with Milestone Innovations, Inc. as the surviving entity. As a result of such merger, the public stockholders are entitled to receive for their shares traded on the Warsaw Stock Exchange an aggregate of approximately \$214,000, and Milestone Medical, Inc. has been de-listed, no longer requiring reports and other filings in Poland. The Company accounted for the transaction as a transfer between entities under common control pursuant to ASC 805, *Business Combinations* ("ASC 805"). Due to the nature of the transaction, the Company did not remeasure the transferred assets at fair value but recorded them at their carrying basis at the time of transfer pursuant to ASC 805. As the Company was acquiring an additional interest in Milestone Medical, the Company accounted for the transaction as a capital transaction pursuant to ASC 810, *Consolidation*, as the Company retained control of both Milestone Medical, Inc. and Milestone, Innovations, Inc prior to and subsequent to the transaction. As of December 31, 2023, the Company recorded a liability due to the minority shareholder of Milestone Medical. The Company recorded a charge to additional paid in capital of approximately \$485,000 which includes the reclassification of accumulated deficit attributed to the non-controlling interest on the date of the transaction and payable to non-controlling interest holders as a result of this transaction.

WARRANTS

The following table summarizes information about shares issuable under warrants outstanding on December 31, 2023:

| | Warrant shares outstanding | Weighted Average exercise price | Weighted Average remaining life | Intrinsic value |
|---|----------------------------|---------------------------------|---------------------------------|-----------------|
| Outstanding at January 1, 2023 | 4,268,221 | 2.18 | 0.50 | - |
| Issued | - | - | - | - |
| Exercised | - | - | - | - |
| Expired or cancelled | (3,953,649) | - | - | - |
| Outstanding and exercisable at December 31, 2023 | 314,572 | 0.50 | 0.10 | 59,737 |

SHARES TO BE ISSUED

As of December 31, 2023 and 2022, there were 2,571,292 and 2,057,976, respectively shares to be issued whose issuance has been deferred under the terms of an employment agreements with the former Interim Chief Executive Officer, former Chief Financial Officer, and other employees of Milestone Scientific. Such shares will be issued to each party upon termination of their employment.

As of December 31, 2023 and 2022, there were 527,625 and 382,697 respectively shares to be issued to non-employees, that will be issued to non-employees for services rendered. The number of shares was fixed at the date of grant and were fully vested upon grant date.

The following table summarizes information about shares to be issued on December 31, 2023 and 2022.

| | 2023 | 2022 |
|--|------------------|------------------|
| Shares-to-be-issued, outstanding January 1, respectively | 2,440,673 | 2,066,343 |
| Granted in current period | 658,244 | 524,814 |
| Issued in current period | - | (150,484) |
| Shares-to be issued outstanding December 31, respectively | 3,098,917 | 2,440,673 |

NOTE I — STOCK OPTION PLANS

The Milestone Scientific Inc., Amended and Restated 2020 Equity Incentive Plan, provides for awards of restricted common, stock restricted stock units, options to purchase and other awards. On June 28, 2023 the plan was amended and restated (the "2020 Plan") the maximum 4,000,000 common stock share was increased to 11,500,000 shares of common stock. The plan expires in June 2031. Options may be granted to employees, directors, and consultants of Milestone Scientific for the purchase of shares of common stock at a price not less than the fair market value of common stock on the date of grant. Generally, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. As of December 31, 2023 and 2022, the Company had 9,174,520 and 323,190, respectively, remaining options available for grants under the Plan.

Milestone Scientific recognizes compensation expenses over the requisite service period and in the case of performance-based options over the period of the expected performance. For the years ended December 31, 2023 and 2022, Milestone Scientific recognized approximately \$ 0.9 million and \$1.0 million of total employee compensation cost, respectively, recorded in general and administrative expenses on the statement of operations.

As of December 31, 2023, there was \$1.5 million of total unrecognized compensation cost related to non-vested options. Milestone Scientific expects to recognize these costs over a weighted average period of 2.3 years.

A summary of option activity for employees under the plans and changes the year ended December 31, 2023 is presented below:

| | Number of Options | Weighted Averaged Exercise Price \$ | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Options Value \$ |
|---------------------------------------|-------------------|-------------------------------------|---|--------------------------------------|
| Options outstanding January 1, 2023 | 3,059,989 | 2.36 | 6.38 | - |
| Granted during 2023 | - | - | - | - |
| Exercised during 2023 | - | - | - | - |
| Forfeited or expired during 2023 | (23,000) | - | - | - |
| Options outstanding December 31, 2023 | 3,036,989 | 2.29 | 5.41 | - |
| Exercisable, December 31, 2023 | 1,732,084 | 2.21 | 4.34 | - |

There were no options granted to employees during the year ended December 31, 2023.

A summary of option activity for non-employees under the plans and changes during the year ended December 31, 2023 is presented below:

| | Number of Options | Weighted Averaged Exercise Price \$ | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Options Value \$ |
|---------------------------------------|-------------------|-------------------------------------|---|--------------------------------------|
| Options outstanding January 1, 2023 | 91,663 | 1.75 | 2.55 | 1,083 |
| Granted during 2023 | 8,333 | 0.89 | 4.21 | - |
| Exercised during 2023 | (8,333) | 0.75 | - | - |
| Options outstanding December 31, 2023 | 91,663 | 1.76 | 2.25 | 2,833 |
| Exercisable, December 31, 2023 | 83,332 | 1.86 | 1.79 | 2,833 |

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model at the date of grant. For the years ended December 31, 2023 and 2022, Milestone Scientific recognized approximately \$ 19,700 and \$22,900 expense related to non-employee options, respectively.

A summary of restricted stock under the plans and changes during the year ended December 31, 2023 is presented below:

| | Number of Shares | Weighted Average Grant-Date Fair Value per Award |
|---------------------------------|------------------|--|
| Non-vested as January 1, 2023 | 435,293 | 1.18 |
| Granted | 617,978 | 0.89 |
| Vested | (694,658) | - |
| Cancelled | (30,676) | - |
| Non-vested as December 31, 2023 | <u>327,937</u> | <u>0.91</u> |

As of December 31, 2023, there were 18,947 restricted shares granted and deferred under the terms of an employment agreement with the Territory Manager of Milestone Scientific. Such shares will be issued to each party upon completion of 2 years of employment. For the years ended December 31, 2023 and 2022, the Company recognized negative stock compensation expense of approximately (\$ 15,000) and \$(20,000), respectively. As of December 31, 2023, the total unrecognized compensation expense was \$ 2,000 related to unvested restricted stock awards for Territory Managers, which the Company expects to recognize over an estimated weighted-average period of 0.21 years.

As of December 31, 2023, the Company entered into restricted stock agreements with members of the Board of Directors of the Company. The Company granted 617,978 restricted stock awards with a fair market value of \$ 0.89 per share. Such restricted stock vests as follows: 25% on the grant date in June 2023, and 25% quarterly, on the first day of the following months: October 2023, January 2024, and April 2024. These awards vest immediately upon a change of control as defined in the agreements. For the year ended December 31, 2023, the Company recognized approximately \$576,000 for restricted stock expenses recorded in general and administrative expenses on the statement of operation. As of December 31, 2023, the total unrecognized stock compensation expense was approximately \$132,000 related to non-vested restricted stock awards with the members of the Board of Directors, which the Company expects to recognize over an estimated weighted average period of 0.25 years.

NOTE J—EMPLOYMENT CONTRACT AND CONSULTING AGREEMENTS

Consulting Agreements

K. Tucker Andersen, a significant stockholder of Milestone Scientific, has an agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$100,000 for years ended December 31, 2023 and 2022, respectively.

The Director of Clinical Affairs' royalty fee was approximately \$ 485,000 and \$442,000 for the years ended December 31, 2023 and 2022, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$156,000 and \$154,000 for the year ended December 31, 2023 and 2022, respectively. As of December 31, 2023, and 2022, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$114,000 and \$120,000, respectively, which is included in accounts payable, related party and accrued expense, related party, in the consolidated balance sheet.

Employment Contracts

On March 2, 2021, the Company entered into a Royalty Sharing Agreement with Leonard Osser, pursuant to which Mr. Osser sold, transferred and assigned to the Company all of his rights in and to a certain patent application as to which he is a co-inventor with Mark Hochman, a consultant to the Company, and the Company agreed to pay to Mr. Osser, beginning May 9, 2027, half of the royalty (2.5%) on net sales that would otherwise be payable to Mark and Claudia Hochman under their existing Technology Sale Agreement, dated January 1, 2005 and amended from time to time, with the Company. In connection with the Royalty Sharing Agreement, the Hochman's agreed with the Company, pursuant to an addendum to such Technology Sale Agreement dated February 25, 2021, to reduce from 5% to 2.5% the payments due to them under their Technology Sale Agreement beginning on May 9, 2027, and thereafter with respect to dental products embodying the invention.

As part of the Succession Plan of the Company, Mr. Osser agreed, pursuant to an agreement dated April 6, 2021 (the "Succession Agreement"), to restructure certain of his existing agreements with the Company, which provide for additional and broader executive support, and at such time as he elects to step down as Interim Chief Executive Officer of the Company, to become the Vice Chairman of the Board of the Company. With respect to Mr. Osser's July 2017 Employment Agreement and July 2017 Consulting Agreement (each as previously disclosed), the compensation under the Employment Agreement was modified to reduce the overall compensation by \$100,000 to \$200,000, split equally between a cash amount and an amount in shares, and the compensation under the Consulting Agreement was increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares, which shares were formerly payable under the Employment Agreement. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term. In connection with his acceptance of the Vice Chairman position and in consideration of his services as a member of the Board and agreement to provide certain additional general consulting services, Mr. Osser was granted options to purchase 2,000,000 shares of common stock, exercisable at the fair market value of the common stock on the date of grant, vesting over the five-year period after he steps down as Interim Chief Executive Officer of the Company or ten years from the date of grant, whichever shall end first. The Company believes that the effect of such existing agreements and the Succession Agreement, all of which relate to the period after such time Mr. Osser steps down as Interim Chief Executive Officer of the Company, collectively expand Mr. Osser's consulting to and support of the Company beyond its Chinese operations to also include its medical and other products, while enhancing the retention aspects of the Company's relationship with Mr. Osser. On May 19, 2021, Mr. Osser resigned as Interim Chief Executive Officer of the Company and assumed the role of Vice Chairman of the Board.

Compensation under the Employment Agreement and the Consulting Agreement is payable for 9.5 years from May 19, 2021. The Company recorded expenses of \$200,000 related to the Employment Agreement for each of the years ended December 31, 2023 and 2022, respectively. The Company recorded expenses of \$200,000 related to the Consulting Agreement for each of the years ended December 31, 2023 and 2022, respectively.

On January 1, 2022, the Company entered into an employment agreement with Mr. Arjan Haverhals. The employment term ends December 31, 2024, unless extended by mutual written agreement. Mr. Haverhals will serve as the President and Chief Executive Officer of the Company and such other senior executive positions as accepted and determined by the Board reasonably requests. As an executive, notwithstanding the fact that he is a director, Mr. Haverhals has board observer rights. The agreement calls for a base salary of \$350,000 and bonus compensation of up to \$400,000 per year, comprise of three separate performance based bonuses each up to \$100,000 per year, based upon the Company's achievement of three (3) performance or financial goals, as established by the Compensation Committee in its reasonable discretion; and (ii) a discretionary bonus up to \$100,000, as determined by the Compensation Committee, in its sole discretion. Satisfaction of bonus goals will be determined by the Compensation Committee from time to time in its reasonable discretion. Bonus compensation, if any, shall be payable annually in arrears thirty-three percent (33%) in cash and sixty-seven percent (67%) in shares of the Company's common stock. Mr. Haverhals will also be entitled to reimbursement of expenses, four weeks' paid vacation, a car allowance and participation in company retirement plans and health insurance reimbursement. The agreement provides for the typical termination provisions. If Mr. Haverhals is terminated for other than for cause or termination by him for good reason, he will be paid as severance, his base compensation, and certain other benefits, as provided in the employment agreement, for two years after termination.

NOTE K — INCOME TAXES

Milestone Scientific accounts for income taxes under the asset and liability method which requires deferred tax assets and liabilities to be computed for temporary differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

At December 31, 2023 and 2022, we had no uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Consolidated Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2020, 2021, and 2022 years are subject to audit by federal and state jurisdictions.

Due to Milestone Scientific's history of operating losses, a full valuation allowances have been provided for all of Milestone Scientific's deferred tax assets. At December 31, 2023 and 2022, no recognition was given to the utilization of the remaining net operating loss carry forwards in each of these periods.

Deferred tax attributes resulting from differences between financial accounting amounts and tax bases of assets and liabilities at December 31, 2023 and 2022 are as follows:

| | 2023 | 2022 |
|----------------------------------|--------------|--------------|
| Allowance for Doubtful Accounts | 2,000 | \$ 2,000 |
| Warranty Reserve | - | 2,000 |
| Impaired Assets | - | - |
| Capitalized Sec. 174 R&D | 344,000 | 242,000 |
| Inventory Reserve | 300,000 | 242,000 |
| Deferred Officer's Compensation | 689,000 | 428,000 |
| Depreciation and Amortization | (44,000) | (56,000) |
| Right of Use Asset | (86,000) | (108,000) |
| Lease Liability | 93,000 | 116,000 |
| Net Operating Loss Carryforwards | 19,920,000 | 19,315,000 |
| Tax Credits | 558,000 | 688,000 |
| Other | 302,000 | 147,000 |
| Subtotal | 22,080,000 | 21,018,000 |
| Valuation allowance | (22,080,000) | (21,018,000) |
| Non-current deferred tax asset | <hr/> | <hr/> |

As of December 31, 2023 and 2022, federal net operating loss carry-forwards are approximately \$ 74,500,000 and \$71,700,000, respectively. As of December 31, 2023, Milestone Scientific has \$38,100,000 net operating losses generated before December 31, 2017 that will be available to offset future income, if any, through December 2037. Additionally, as of December 31, 2023, Milestone Scientific has \$36,400,000 of net operating losses generated in 2018 or after that can be carried forward indefinitely.

State net operating losses were approximately \$ 63,300,000 and \$60,500,000 for the periods ended December 31, 2023 and 2022, respectively. Net operating losses will be available to offset future taxable income, if any, through December 2041.

The utilization of Milestone Scientific's net operating losses may be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carry forwards before their utilization. Milestone Scientific has established a 100% valuation allowance for all of its deferred tax assets due to uncertainty as to their future realization.

Accounting for uncertainties in income taxes prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure, and transition. No interest and penalties are present for periods open. Tax returns for the 2020, 2021, and 2022 years are subject to audit by federal and state jurisdictions.

A reconciliation of the statutory tax rates for the years ended December 31, is as follows:

| | 2023 | 2022 |
|-------------------------------|---------|---------|
| Statutory Rate | 21.00% | 21.00% |
| State income tax - all states | 0.88% | -2.74% |
| Stock compensation | 0.58% | -2.57% |
| NOL Expiration | -5.05% | -4.69% |
| Return to Provision | -2.21% | 0.00% |
| Other | 0.03% | -0.56% |
| Subtotal | 15.23% | 10.44% |
| Valuation Allowance | -15.23% | -10.44% |
| Effective tax Rate | 0.00% | 0.00% |

NOTE L — SEGMENT AND GEOGRAPHIC DATA

The Company conducts its business through two reportable segments: Dental and Medical. These segments offer different products and services to different customer base. The Company provides general corporate services to its segments; however, these services are not considered when making operating decisions and assessing segment performance. These services are reported under "Corporate Services" below and these include costs associated with executive management, investor relations, patents, trademarks, licensing agreements, new instruments developments, financing activities and public company compliance.

The following tables present information about our reportable and operating segments:

| | Year ended December 31, | |
|---|--------------------------------|-----------------------|
| | 2023 | 2022 |
| Sales | | |
| Net Sales: | | |
| Dental | \$ 9,761,444 | \$ 8,753,156 |
| Medical | 66,000 | 52,750 |
| Total net sales | \$ 9,827,444 | \$ 8,805,906 |
| Operating Income (Loss): | | |
| Dental | \$ 2,128,199 | \$ 1,121,815 |
| Medical | (3,708,170) | (4,788,105) |
| Corporate | (5,526,503) | (5,161,183) |
| Total operating loss | \$ (7,106,474) | \$ (8,827,473) |
| Depreciation and Amortization: | | |
| Dental | \$ 4,243 | \$ 3,805 |
| Medical | 2,787 | 4,075 |
| Corporate | 54,882 | 55,875 |
| Total depreciation and amortization | \$ 61,912 | \$ 63,755 |
| Income (loss) before taxes and equity in earnings of affiliates: | | |
| Dental | \$ 2,127,659 | \$ 1,116,598 |
| Medical | (3,708,170) | (4,794,089) |
| Corporate | (5,400,436) | (5,095,375) |
| Total loss before taxes and equity in earnings of affiliate | \$ (6,980,947) | \$ (8,772,866) |
| Total Assets | December 31, | |
| | December 31, 2023 | 2022 |
| Dental | \$ 4,866,786 | \$ 3,875,978 |
| Medical | 345,194 | 620,373 |
| Corporate | 6,159,532 | 9,205,735 |
| Total assets | \$ 11,371,512 | \$ 13,702,086 |

The following table presents information about our operations by geographic area as of December 31, 2023 and 2022. Net sales by geographic area are based on the respective locations of our subsidiaries.

| | 2023 | | |
|-------------------------------------|---------------------|------------------|---------------------|
| | Dental | Medical | Grand Total |
| Domestic: US | | | |
| Instruments | \$ 1,002,697 | \$ 1,000 | \$ 1,003,697 |
| Handpieces | 4,270,898 | 12,000 | 4,282,898 |
| Accessories | 75,285 | - | 75,285 |
| Grand Total | \$ 5,348,880 | \$ 13,000 | \$ 5,361,880 |
| International: Rest of World | | | |
| Instruments | \$ 1,251,354 | \$ 25,000 | \$ 1,276,354 |
| Handpieces | 2,845,734 | 28,000 | 2,873,734 |
| Accessories | 45,476 | - | 45,476 |
| Grand Total | \$ 4,142,564 | \$ 53,000 | \$ 4,195,564 |
| International: China | | | |
| Instruments | \$ 270,000 | \$ - | \$ 270,000 |
| Handpieces | - | - | - |
| Accessories | - | - | - |
| Grand Total | \$ 270,000 | \$ - | \$ 270,000 |
| Total Product Sales | \$ 9,761,444 | \$ 66,000 | \$ 9,827,444 |
| | 2022 | | |
| | Dental | Medical | Grand Total |
| Domestic: US | | | |
| Instruments | \$ 524,715 | \$ 7,500 | \$ 532,215 |
| Handpieces | 2,653,914 | 25,250 | 2,679,164 |
| Accessories | 78,493 | - | 78,493 |
| Grand Total | \$ 3,257,122 | \$ 32,750 | \$ 3,289,872 |
| International: Rest of World | | | |
| Instruments | \$ 1,413,525 | \$ - | \$ 1,413,525 |
| Handpieces | 3,391,748 | 20,000 | 3,411,748 |
| Accessories | 60,797 | - | 60,797 |
| Grand Total | \$ 4,866,070 | \$ 20,000 | \$ 4,886,070 |
| International: China | | | |
| Instruments | \$ 270,000 | \$ - | \$ 270,000 |
| Handpieces | 359,964 | - | 359,964 |
| Accessories | - | - | - |
| Grand Total | \$ 629,964 | \$ - | \$ 629,964 |
| Total Product Sales | \$ 8,753,156 | \$ 52,750 | \$ 8,805,906 |

NOTE M-- CONCENTRATION

Milestone Scientific has informal arrangements with third-party U.S. manufacturers of the STA, *CompuDent* and *CompuMed* devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current on December 31, 2023 and 2022. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business, and results of operations.

On January 3, 2023, the Company launched an E-Commerce platform selling and shipping STA Single Tooth Anesthesia System® (STA) and handpieces directly to dental offices and dental groups within the U.S. For the year ended December 31, 2023, E-Commerce accounted for 48% of net product. The Company had two distributors that accounted for 32%, and 11% amount of revenue respectively for the year ended December 31, 2022.

We had three distributors that accounted for 39%, 38%, and 15% of accounts receivable, respectively, year ended December 31, 2023. We had two customers that accounted for 33%, and 20% of accounts receivable, respectively as of December 31, 2022.

As of December 31, 2023 we had three vendors that accounted for 37%, and 17% and 12%, respectively, of accounts payable and accounts payable related party. We had one vendor that accounted for 42% of accounts payable and accounts payable related party as of December 31, 2022.

NOTE N -- RELATED PARTY TRANSACTIONS

United Systems

Milestone Scientific has a supply agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal supplier of its handpieces, pursuant to which it procures manufactured products under specific purchase orders, but without minimum purchase commitments. Purchases from this supplier were approximately 2.3 million and \$3.4 million for the twelve months ended December 31, 2023, and 2022, respectively. As December 31, 2023, and December 31, 2022, Milestone Scientific owed this supplier approximately \$402,000 and \$819,000, respectively, which is included in accounts payable and accrued expenses related party on the consolidated balance sheets. In June 2021, the Company signed a ten-year agreement with United Systems for supplier of the handpieces.

Other

In December 31, 2023 and 2022 the Company had approximately \$270,000 and \$630,000 sales to Milestone China or agents of Milestone China, an entity in which the Company formerly had an ownership interest terminating in 2021.

K. Tucker Andersen, a significant stockholder of Milestone Scientific, has an agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$100,000 for years ended December 31, 2023 and 2022, respectively.

Director of Clinical Affairs

The Director of Clinical Affairs' royalty fee was approximately \$485,000 and \$442,000 for the years ended December 31, 2023 and 2022, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$156,000 and \$154,000 for the year ended December 31, 2023 and 2022, respectively. As of December 31, 2023, and 2022, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$114,000 and \$120,000, respectively, which is included in accounts payable, related party and accrued expense, related party, in the consolidated balance sheet.

Director

On March 2, 2021, the Company entered into a Royalty Sharing Agreement with Leonard Osser, pursuant to which Mr. Osser sold, transferred and assigned to the Company all of his rights in and to a certain patent application as to which he is a co-inventor with Mark Hochman, a consultant to the Company, and the Company agreed to pay to Mr. Osser, beginning May 9, 2027, half of the royalty (2.5%) on net sales that would otherwise be payable to Mark and Claudia Hochman under their existing Technology Sale Agreement, dated January 1, 2005 and amended from time to time, with the Company. In connection with the Royalty Sharing Agreement, the Hochman's agreed with the Company, pursuant to an addendum to such Technology Sale Agreement dated February 25, 2021, to reduce from 5% to 2.5% the payments due to them under their Technology Sale Agreement beginning on May 9, 2027, and thereafter with respect to dental products embodying the invention.

As part of the Succession Plan of the Company, Mr. Osser agreed, pursuant to an agreement dated April 6, 2021 (the "Succession Agreement"), to restructure certain of his existing agreements with the Company, which provide for additional and broader executive support, and at such time as he elects to step down as Interim Chief Executive Officer of the Company, to become the Vice Chairman of the Board of the Company.

With respect to Mr. Osser's July 2017 Employment Agreement and July 2017 Consulting Agreement (each as previously disclosed), the compensation under the Employment Agreement was modified to reduce the overall compensation by \$100,000 to \$200,000, split equally between a cash amount and an amount in shares, and the compensation under the Consulting Agreement was increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares, which shares were formerly payable under the Employment Agreement. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term. In connection with his acceptance of the Vice Chairman position and in consideration of his services as a member of the Board and agreement to provide certain additional general consulting services, Mr. Osser was granted options to purchase 2,000,000 shares of common stock, exercisable at the fair market value of the common stock on the date of grant, vesting over the five-year period after he steps down as Interim Chief Executive Officer of the Company or ten years from the date of grant, whichever shall end first. The Company believes that the effect of such existing agreements and the Succession Agreement, all of which relate to the period after such time Mr. Osser steps down as Interim Chief Executive Officer of the Company, collectively expand Mr. Osser's consulting to and support of the Company beyond its Chinese operations to also include its medical and other products, while enhancing the retention aspects of the Company's relationship with Mr. Osser. On May 19, 2021, Mr. Osser resigned as Interim Chief Executive Officer of the Company and assumed the role of Vice Chairman of the Board.

Compensation under the Employment Agreement and the Consulting Agreement is payable for 9.5 years from May 19, 2021. The Company recorded expenses of \$200,000 related to the Employment Agreement for each of the years ended December 31, 2023 and 2022, respectively. The Company recorded expenses of \$200,000 related to the Consulting Agreement for each of the years ended December 31, 2023 and 2022, respectively.

NOTE O — COMMITMENTS

(1) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, CompuDent® and CompuMed® devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. The company entered into a new purchase commitment for the delivery of 2,200 STA CompuDent® instruments. As of December 31, 2023, the purchase order commitment was approximately \$2.3 million, and approximately \$1.3 million was paid and reported in advance on contracts in the consolidated balance sheet. As of December 31, 2022, the purchase order commitment was approximately \$1.7 million, and approximately \$1.2 million was paid and reported in advance on contracts in the consolidated balance sheet. As of December 31, 2023 and 2022 the company also has advances on an open purchase order for long lead items for a future purchase order for the manufacturing of Epidural instrument of approximately \$76,000, respectively.

(2) Leases

Operating Leases

In August 2019, the Company made the decision to not renew its existing office lease for its corporate headquarters located in Livingston, New Jersey and instead signed a new seven-year lease in a new facility located in Roseland, New Jersey (the "Roseland Facility"), which commenced of January 8, 2021. Under the Roseland Facility lease, rent payments commence on April 1, 2021, and the monthly lease payments escalate annually on January 1 of each year, and range from \$9,275 to \$10,898 per month over the lease term. The Company is also required to pay a fixed electric charge equal to \$ 2.00 per square foot which is paid in equal monthly installments over the lease term or \$11,130 annually. These fixed monthly payments have been included in the measurement of the operating lease liability and related operating lease right-of-use asset as the Company has elected the practical expedient to not separate lease and non-lease components for all leases. The Company is also required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises more than new base year amounts, which are accounted for as variable lease expenses.

As of December 31, 2023, total finance right-of-use assets were \$8,998 and total finance liabilities were \$ 10,698 of which \$10,264 and \$434. were classified as current and non-current, respectively. As of December 31, 2023 total operating right-of use assets were \$ 355,235 and total operating lease liabilities were \$385,280, of which \$103,427 and \$281,853 were classified as current and non-current, respectively. As of December 31, 2022, total finance right-of-use assets were \$17,645 and total finance liabilities were \$ 20,063 of which \$9,365 and \$10,698 were classified as current and non-current, respectively. As of December 31, 2022, total operating right-of use assets were \$ 443,685 and total operating lease liabilities were \$ 476,980, of which \$91,701 and \$385,279 were classified as current and non-current, respectively.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company has utilized its incremental borrowing rate based on the long-term borrowing costs of comparable companies in the Medical Device industry.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined lease component, all contract consideration was allocated to the combined lease component.
- The expected lease terms include non-cancellable lease periods. Renewal option periods are not included in the determination of the lease terms as they were not reasonably certain to be exercised.

The components of lease expense were as follows:

| | <u>December 31, 2023</u> | <u>December 31, 2022</u> |
|--|--------------------------|--------------------------|
| Cash paid for operating lease liabilities | \$ 127,526 | \$ 127,995 |
| Cash paid for finance lease liabilities | 10,740 | 10,740 |
| Right-of-use assets obtained in exchange for new operating lease liabilities (1) | | |
| Property and equipment obtained in exchange for new finance lease liabilities | | |
| Weighted Average Remaining Lease Term | | |
| Finance leases (years) | 1.04 years | 2.04 years |
| Operating leases (years) | 3.25 years | 4.25 years |
| Weighted-average discount rate – operating leases | | |
| Weighted-average discount rate – finance leases | | |
| Maturity of lease liabilities as December 31, 2023 | | |
| 2024 | Operating Lease 133,560 | Finance Lease 10,740 |
| 2025 | 136,343 | 433 |
| 2026 | 139,125 | - |
| 2027 | 35,477 | - |
| Less: Interest | 444,505 | 11,173 |
| Present Value of lease liabilities | (59,225) | (475) |
| <hr/> | <hr/> | <hr/> |
| | 385,280 | 10,698 |

NOTE P — BENEFIT PLAN

Milestone Scientific has a Defined Contribution Plan that allows eligible employees to contribute part of their salary through payroll deductions. Milestone Scientific does not contribute to this plan, but does pay the administrative costs of the plan, which were not significant.

NOTE Q — SUBSEQUENT EVENTS

In Connection with the Company's capital raise on December 10, 2023, on January 12, 2024 the underwriter exercised its over-allotment option as to 372,110 shares of common stock for net proceeds after discounts and commission of \$ 216,847.

Since the year ended December 31, 2023, the Company issued 103,500 shares of common stock for warrants exercised at \$ 0.50 for proceeds of \$51,647.

AMENDMENT TO EMPLOYMENT AGREEMENT

RECITALS

WHEREAS, an employment agreement (the "Agreement") was entered into as of January 1, 2022 by and between Arjan Haverhals (the "Executive") and Milestone Scientific Inc. (the "Company" and together with the Executive, the "Parties"); and

WHEREAS, the Parties have agreed to amend the Agreement (this "Amendment").

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the Parties agree that the Agreement shall be amended as follows:

AMENDMENT

Section 1. Section 7(c) of the Agreement is hereby deleted in its entirety and replaced with the following:

"Upon the termination of the Term and the Executive's employment due to a Termination Other Than for Cause or a termination of the Executive's employment by Executive for Good Reason, neither the Executive nor his beneficiary nor his estate shall have any rights or claims against the Company except the right to receive (i) the Accrued Benefits, (ii) any earned but unpaid Bonus Compensation from the prior fiscal year, payable in accordance with the Company's standard payroll practices and on the date that such bonus would otherwise be payable hereunder, (iii) payment of any Bonus Compensation with respect to the then-current fiscal year based on actual performance and pro-rated based on the number of completed months the Executive was employed with the Company in such fiscal year through the date of termination or resignation, as applicable, payable in accordance with the Company's standard payroll practices and on the date that such bonus would otherwise be payable hereunder, (iv) accelerated vesting in full of all unvested Bonus Options held by the Executive as of the date of termination and the unvested portion of any Bonus Compensation deferred pursuant to the terms hereof or the applicable plan and the Executive's elections thereunder, if any, and (v) (A) continued payment for two (2) years (the "**Severance Period**") of Executive's Base Compensation, in accordance with the Company's standard payroll practices and subject to applicable withholding taxes, (B) continued payment for six (6) months of the Car Payments, and (C) for a period of six (6) months, continued provision of the benefits with respect to health, vision and dental pursuant to and to the extent required by Section 5(c) herein ((iv) and (v), collectively, "**Severance**")."

MISCELLANEOUS

Section 2. Except as expressly amended by this Amendment, all of the terms and provisions of the Agreement are and shall remain in full force and effect and are hereby ratified and confirmed by the parties hereto. Without limiting the generality of the forgoing, the amendments contained herein will not be construed as an amendment to or waiver of any other provision of the Agreement. Each reference in the Agreement to "this Agreement", "the Agreement", "hereunder", "hereof", "herein" or words of like import will mean and be a reference to the Agreement as amended by this Amendment.

Section 3. This Amendment shall be governed by and construed in accordance with the laws of the state of New York, without regard to its conflict of laws principles.

Section 4. This Amendment may be executed in several counterparts and all such counterparts shall constitute one agreement, binding on the Parties.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have executed this Amendment to Employment Agreement on the dates indicated below.

Milestone Scientific Inc.

By: /S/ Neal Goldman
Name: Neal Goldman
Title: Chairman of the Board

July 5, 2023
Date

Executive

/S/ Arkam Haverhals
Arjan Haverhals

July 5, 2023
Date

MILESTONE SCIENTIFIC INC. CODE OF BUSINESS CONDUCT AND ETHICS

This Code of Ethics applies to the Board of Directors, officers and employees of Milestone Scientific Inc. (the "Company") and its subsidiaries (collectively, "Milestone Personnel") and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder, as well as the NYSE listing requirements. Accordingly, this Code of Business Conduct and Ethics for Milestone Personnel ("Code of Ethics") provides general guidelines for conducting the business of the Company in accordance with high standards of business conduct. It is designed to deter wrongdoing and to promote honest and ethical conduct, proper disclosure of financial information and compliance with applicable laws, rules, and regulations.

Standards of Conduct

Although laws and customs vary in the countries in which we operate, our basic ethical responsibilities and standards of conduct are universal. Regardless of the situation or local cultural norms, we are committed to conducting business with integrity according to the highest ethical standards.

This means that we are honest and ethical in all our business practices, including the ethical handling of actual or apparent conflicts of interest in personal and professional relationships. We will avoid conflicts of interest and report any material transaction or relationship that reasonably could be expected to give rise to such a conflict. We obey both the letter and spirit of the laws that apply to our business. Most importantly, this means we carry out our business activities with integrity so that if our private business dealings were to become public, we would be proud of the manner in which we have acted.

Even if our competition may behave differently that will never be an excuse for our failing to act according to our standards. We do not compromise our standards regardless of any internal or external pressures, financial or otherwise. We will never authorize anyone, regardless of position, to commit an illegal or improper act or to direct another employee to commit such an act. Milestone Personnel may never justify an illegal, unethical, or improper act by claiming it was necessary to compete in the local business climate, necessary to meet our financial goals or ordered by a superior.

We believe our first responsibility is to our customers and all others who use our products and services. In meeting their needs everything we do will be of high quality. Customers' orders and issues must be serviced promptly and accurately.

We have a responsibility to our employees, the people who work with us wherever located. Everyone will be considered as an individual. We will respect our employees' dignity and recognize their merit. Compensation must be fair and adequate, and working conditions.

clean, orderly, and safe. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement, and their actions must be just and ethical. We have a responsibility to the communities in which we live and work and to the world community as well. We must be good citizens, support good works and charities, and bear our fair share of taxes. We encourage civic improvements and better health and education. We must maintain in good order the property we use, protecting the environment and natural resources.

We have a responsibility to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research will be carried on and innovative programs developed. Accordingly, we will:

- Engage in and promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest in personal and professional relationships.
- Avoid conflicts of interest and report any material transaction or relationship that reasonably could be expected to give rise to such a conflict.
- Provide full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company.
- Act in good faith, responsibly, with due care, competence, and diligence, without misrepresenting material facts or allowing one's own judgment to be subordinated.
- Comply with applicable governmental laws, rules, and regulations as well as the rules and regulations of any self-regulatory organizations of which the Company is a member.
- Take reasonable measures to protect the confidentiality of non-public information about the Company and to prevent the unauthorized disclosure of such information unless applicable law, regulation, or other legal or regulatory process requires such disclosure.

When we operate according to these principles, our stockholders should realize a fair return.

Corporate Opportunities

Milestone Personnel are prohibited from taking for themselves opportunities that are discovered through the use of corporate property, information, or position without the consent of the Board of Directors. No Milestone Personnel may use corporate property, information or position for improper personal gain and no employee may compete with the Company directly or indirectly. Milestone Personnel owe a duty to the Company to advance its legitimate interests whenever possible.

Protection and Proper Use of Company Assets

Milestone Personnel should endeavor to protect the Company's assets and ensure their efficient use. Theft, carelessness, and waste have a direct impact on the Company's profitability. Any suspected incident of fraud or theft should be immediately reported for investigation. The Company's equipment should not be used for non-Company business, though incidental personal use is permitted.

The obligation of Milestone Personnel to protect the Company's assets includes its proprietary information. Proprietary information includes intellectual property such as trade secrets, patents, trademarks, and copyrights, as well as business, marketing and service plans, engineering and manufacturing ideas, designs, databases, records, salary information and any unpublished financial data and reports. Unauthorized use or distribution of this information would violate Company policy. It could also be illegal and result in civil or criminal penalties.

Reporting Violations

Milestone Personnel must promptly report any possible violation of this Code of Ethics, including transactions or relationships that reasonably could be expected to give rise to a violation, to the Board of Directors. The Company prohibits any retaliation against anyone who, in good faith, reports known or suspected violations. Individuals may choose to remain anonymous in reporting any violations of this Code of Ethics through the process as described in the Standards of Business Conduct and Ethics. Please contact the Corporate Compliance Officer with any questions about compliance with this Code.

Accountability and Adherence

The Board of Directors or a committee thereof will investigate any reported violations of this Code of Ethics and will determine appropriate disciplinary actions, up to and including termination of employment. Such disciplinary actions will be based on the facts and circumstances of each particular case and reasonably designed to deter wrongdoing and to promote accountability for adherence to the Code. Violations of this Code of Ethics may also constitute violations of law, which may result in criminal or civil penalties.

Waivers or Amendments

Waivers of or amendments to this Code of Ethics must be approved by the Board of Directors or a committee thereof. Waivers will be granted on a case-by-case basis in the sole discretion of the Board of Directors or a committee thereof, and any such waiver or amendment shall be publicly disclosed as required by the Securities and Exchange Commission.

Conclusion

This Code of Ethics and the matters contained herein are neither a contract of employment nor a guarantee of continuing Company policy. The Company reserves the right to amend, supplement or discontinue this Code of Ethics and the matters addressed herein, without prior notice, at any time. All of us have the responsibility for nurturing a culture in which compliance with our policies and applicable laws is at the very core of our business activities. It is, and must be, the way we work.

As a company and individuals, we will display the characteristics of Honesty, Ethics, Responsibility and Openness. This is our code of ethics, and it applies to all Milestone Personnel. In addition, we expect our vendors, suppliers, and customers to support and comply with our guidelines.

Insider Trading Policy

Under United States securities laws, it is a crime to buy or sell securities of a company (including stocks or bonds) while in possession of material, non-public information about the company. Furthermore, it is a crime to pass on such information to others who use it for personal profit if the information was obtained in the course of one's employment and disclosure violates a duty (of confidentiality or otherwise) owed to the employer. Corporations and "controlling persons" can also be criminally liable unless they take precautions to prevent violations of these laws.

Responsibilities

If a director, officer, or any employee has material non-public information relating to Milestone Scientific Inc. (together with any subsidiaries, the "Company"), it is the Company's policy, consistent with the law, that neither that person nor any related person may buy or sell securities of the Company or engage in any other action to take advantage of that information or to pass it on to others. This policy also applies to information obtained in the course of employment relating to any other company, including customers, suppliers, or other companies with whom the Company is considering a transaction. Such information is the property of the Company, and use for personal gain, or disclosure to others who use it for personal gain, is a conversion of Company property for personal use. As such, that improper use of Company property is strictly prohibited. There are no exceptions for transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure).

Disclosure of Information to Others

The Company is required under Regulation FD of the Federal securities laws to avoid the selective disclosure of material non-public information. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of the information immediately upon its release. No director, officer or employee should, therefore, disclose information to anyone outside the Company, including family members and friends, or discuss the Company or its business on any internet message board, chat room or any similar or other forum, other than as expressly permitted by the Company.

Definition of Material Information

Always remember that "material information" is broadly defined to include any information that a reasonable investor would consider important in a decision to buy, hold, or sell securities (in short, any information that could reasonably be expected to affect the price of the securities). Common examples of information that is frequently regarded as material are: projections of future earnings or losses that differ from market expectations; news of a pending or proposed merger, acquisition or tender offer; news of a significant sale of assets or the disposition of a subsidiary; changes in dividend policies, the declaration of a new stock split or the offering of additional securities; changes in management; significant new products or services offerings; or the gain or loss of a substantial customer or supplier. Either positive or negative information may be material.

Twenty-Twenty Hindsight

If securities transactions become the subject of scrutiny they will be viewed after the fact with the benefit of twenty-twenty hindsight. As a result, before engaging in any transaction involving the Company's securities, any director, officer, or employee should carefully consider how the transaction would be viewed in hindsight if a marked increase or decrease in the stock price occurs after the transaction.

Transactions by Family Members

The very same restrictions apply to family members and others living with any of such persons. Each director, officer and other employee will also be held responsible for their actions and for the actions of their immediate families and personal households. If a relative living outside such person's home trades, and thereafter there is a marked increase or decrease in the stock price because of a Company transaction or event, the relative's trades, and such person's actions, will be subject to strict scrutiny. For example, in that type of circumstance the Securities and Exchange Commission ("SEC") frequently begins investigations into whether directors, officers or employees of the company involved tipped the relative who traded.

Tipping Information to Others

Whether the information is proprietary information about the Company, information that could have an impact on the Company's stock price, or non-public information about another company learned in the course of employment, none of such information should be passed on to others.

The same legal penalties apply whether or not the distributor of the information, or tipper, actually benefits from another's actions. The SEC has often successfully asserted substantial penalties against employees who told others about pending transactions even though those employees did not actually trade or profit from their tutees' trading. When Information is Public It is also improper for a director, officer, or employee to enter a trade immediately after the Company has made a public announcement of material information, including earnings releases. Because the Company's shareholders and the investing public must be afforded the time to receive the information and act upon it, as a general rule no director, officer or employee should engage in any transactions until two full business days have elapsed after the information has been released. Thus, if a public announcement is made before the markets open on a Monday, Wednesday generally would be the first day on which such persons could trade. Similarly, if an announcement were made after the close on a Thursday, the following Tuesday generally would be the first day. Obviously, these guidelines are meant to ensure only that the public announcement has been adequately disseminated and, even if the specified time periods following a public announcement have passed, any desired transactions by directors, officers or employees will remain subject to all of the other provisions of this policy.

Additional Prohibited Transactions

Because it is also illegal for certain Company personnel to engage in short-term or speculative transactions involving Company securities, it is the Company's policy that directors, officers, and employees should not engage in any of the following activities with respect to securities of the Company:

1. Trading in securities on a short-term basis.
 - a. All employees. The Company encourages (but does not require) that all Company securities purchased by an employee (other than an Insider (as defined below)) should be held for a minimum period of six months before any subsequent resale.
 - b. Insiders. The Company requires that any director, officer, or other employee designated as an insider by the Board or Chief Financial Officer from time to time (collectively, "Insiders") refrain from selling any Company securities for a period of six months after the purchase of any Company securities. Similarly, any Insider must refrain from purchasing any Company securities for a period of six months after the sale of any Company securities. (Note that the SEC's short-swing profit rule similarly prevents Insiders from selling any securities within six months of any purchase and from purchasing any securities within six months after any sale.) Insiders of the Company may vary from time to time and will typically include, in addition to the directors and executive officers of the Company, those persons who, because of the nature of their responsibilities, are or are likely to become aware of important Company information.
 - c. Exceptions. These restrictions do not apply to stock option exercises because option exercises are not regarded as purchases of securities. The restrictions do apply, however, to sales of shares received upon the exercise of an option.
 - d. Therefore, an Insider may exercise a stock option and immediately sell the option shares. However, if an Insider has purchased other Company shares within the six months prior to the option exercise, he or she may not sell the option shares until the purchased shares have been held for at least six months.
 - e. These restrictions also do not apply to share grants received pursuant to an election to receive equity in payment of a portion of a bonus or other award pursuant to any incentive compensation plan of the Company. Share grants received pursuant to such a plan are subject to contractual restrictions on resale as set forth in the applicable compensation plan or award agreement.
2. Short sales. No Insiders or other employees should ever engage in short sales of Company securities.
3. Buying or selling puts or calls. No Insiders or other employees should ever engage in the purchase or sale of a put or call option, or any other derivative or hedging transaction, in respect of Company securities.

Company Assistance

Any person who has any questions about specific transactions may obtain additional guidance from the Company's Chief Financial Officer. Remember, however, that the ultimate responsibility for adhering to this Policy and avoiding improper transactions rests with the individual. In this regard, it is imperative that good judgment is used at all times.

Pre-Clearance of All Trades by Insiders

To provide assistance in preventing inadvertent violations and avoiding even the appearance of an improper transaction (which could result, for example, where any director, officer or other employee engages in a trade while unaware of a pending major development), the following procedures will apply:

Except as otherwise set forth below, all transactions in Company securities (acquisitions, dispositions, transfers, etc.) by Insiders must be pre-cleared by the Company's Chief Financial Officer. If an employee has not been previously designated as an Insider and the Company determines that he or she is or may become aware of potentially material information nonetheless, such employee will be notified of his or her Insider status and the rules relating to trading by Insiders will apply to such employee until further notice.

Those persons required to pre-clear transactions should contact the Chief Financial Officer at least two business days in advance of a proposed trade. The Chief Financial Officer will make appropriate inquiries and review and as soon as possible advise whether or not the Company will permit a trade under the circumstances. The Chief Financial Officer is under no obligation to approve a trade submitted for pre-clearance and may determine not to permit the trade. This pre-clearance requirement does not apply to stock option exercises but does cover sales of option shares (that is, the sale of the shares received when an option is exercised). Once pre-cleared, a trade must be initiated within two business days. If a transaction is not initiated within that period, it cannot thereafter be initiated without a second advance clearance.

Blackout Periods

The Company's announcement of its annual and quarterly financial results almost always has the potential to have a material effect on the market for the Company's securities. Therefore, Insiders can anticipate that, to avoid even the appearance of trading while aware of material non-public information, they will not be pre-cleared to trade in Company securities for periods surrounding the preparation and filing of these results. Annual Blackout. In relation to the annual financial results, Insiders will not be pre-cleared to trade in Company securities during the period beginning on February 15th and ending.

two full business days after the issuance of the annual earnings release or the filing of the Company's 10-K, whichever occurs first. Thus, if annual earnings are released or the 10-K is filed on March 31st, Insiders will not be permitted to trade between February 15th and April 2nd. Quarterly Blackout. In relation to the quarterly financial results, Insiders will not be pre-cleared to trade in Company securities during the period beginning at the end of the Company's fiscal quarter and ending two full business days after the issuance of the quarterly earnings release or the filing of the Company's 10-Q, whichever occurs first. Thus, if the fiscal quarter in question ends on September 30th and earnings are released or the 10-Q is filed on November 8th, Insiders will not be permitted to trade between September 30th and November 10th. The Company may also on occasion issue interim earnings guidance or other potentially material information by means of a press release, SEC filing on Form 8-K or other means designed to achieve widespread dissemination of the information. Trades by Insiders are also unlikely to be pre-cleared while the Company is in the process of assembling the information to be released and until the information has been released and fully absorbed by the market. Event-Specific Blackout. From time to time, an event may occur that is material to the Company and is known by only a few Insiders. So long as such an event remains material and non-public, no Insiders will be permitted to trade in Company securities. The existence of an event-specific blackout will not be announced, other than to those who are aware of the event giving rise to the blackout. If, however, a person whose trades are subject to pre-clearance request permission to trade in Company securities during an event-specific blackout, the Chief Financial Officer will inform the requester of the existence of a blackout period without disclosing the reason for the blackout. No person made aware of the existence of an event-specific blackout should disclose the existence of the blackout to any other person. The failure of the Chief Financial Officer to designate a person as being subject to an event-specific blackout will not in any event relieve that person of the obligation not to trade while aware of material non-public information.

Reports of Beneficial Ownership

The Company's directors, executive officers, and beneficial owners of ten percent or more of a class of equity securities of the Company are required to file initial reports of their beneficial ownership of any class of the Company's securities with the SEC on Form 3. Thereafter, each reporting person must file Forms 4 and 5 reporting all reportable changes in beneficial ownership. A report on Form 4 is due for each then-reportable change in beneficial ownership by the second business day after the transaction. A report on Form 5 is due from each reporting person within 45 days after the end of the Company's fiscal year. All reports on Forms 3, 4 and 5 must be electronically filed. The Company's Chief Financial Officer will assist in the preparation of these reports, but the ultimate responsibility for making sure that all changes in ownership are accurately and promptly reported rests with the individual.

Post-Termination Transactions

If upon termination of an Insiders' employment with or service to the Company the Insider is in possession of material non-public information, such person may not trade in Company securities until that information has become public or is no longer material. In all other respects, the procedures set forth in this Policy will cease to apply to transactions in Company securities by an Insider upon the expiration of any blackout period that is applicable to Insider transactions at the time of termination of service.

Certifications

From time to time on request from the Chief Financial Officer, each employee, officer, and director will be required to certify his or her understanding of and intent to comply with this Policy. In addition, directors and officers will be expected to make this certification no less frequently than annually.

Subsidiaries

Subsidiary

Wand Dental , Inc.
Milestone Innovations Inc.

Jurisdiction of Incorporation

Delaware
Delaware

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Milestone Scientific, Inc. on Form S-3 (No. 333-275088), and Form S-8 (No. 333-134245, No. 333-252100, and No. 333-257895) of our report dated March 29, 2024, with respect to our audits of the consolidated financial statements of Milestone Scientific, Inc. as of and for the years ended December 31, 2023 and 2022, which report is included in this Annual Report on Form 10-K of Milestone Scientific, Inc. for the year ended December 31, 2023.

/s/ Marcum LLP

Marcum LLP
East Hanover, New Jersey
March 29, 2024

Rule 13a-14(a)/15d-14(a) Certification

I, Arjan Haverhals, certify that:

1. I have reviewed this annual report on Form 10-K of Milestone Scientific Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether material or not, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2024

/S/ Arjan Haverhals
Arjan Haverhals
Chief Executive Officer
Chief Accounting Officer
(Principal Executive Officer)

CERTIFICATION
PURSUANT TO 18
U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Milestone Scientific Inc. ("Milestone") on Form 10-K for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Arjan Haverhals, Chief Executive Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone

Date March 29, 2024

/S/ Arjan Haverhals
Arjan Haverhals
Chief Executive Officer
Chief Accounting Officer
(Principal Executive Officer)

This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference. A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.

MILESTONE SCIENTIFIC INC.

POLICY FOR THE RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

A. OVERVIEW

In accordance with the applicable rules of The New York Stock Exchange (the "NYSE Rules"), and Section 10D and Rule 10D-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") ("Rule 10D-1"), the Board of Directors (the "Board") of Milestone Scientific Inc. (the "Company") has adopted this Policy (the "Policy") to provide for the recovery of erroneously awarded Incentive-based Compensation from Executive Officers. All capitalized terms used and not otherwise defined herein shall have the meanings set forth in Section H below.

B. RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

- (1) In the event of an Accounting Restatement, the Company will reasonably promptly recover the Erroneously Awarded Compensation Received in accordance with the NYSE Rules and Rule 10D-1 as follows:
 - (i) After an Accounting Restatement, the Compensation Committee (if composed entirely of independent directors, or in the absence of such a committee, a majority of independent directors serving on the Board) (the "Committee") shall determine the amount of any Erroneously Awarded Compensation Received by each Executive Officer and shall promptly notify each Executive Officer with a written notice containing the amount of any Erroneously Awarded Compensation and a demand for repayment or return of such compensation, as applicable.
 - (a) For Incentive-based Compensation based on (or derived from) the Company's stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement:
 - i. The amount to be repaid or returned shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the Company's stock price or total shareholder return upon which the Incentive-based Compensation was Received; and
 - ii. The Company shall maintain documentation of the determination of the reasonable estimate and provide the relevant documentation as required by the rules of the NYSE .
 - (ii) The Committee shall have discretion to determine the appropriate means of recovering Erroneously Awarded Compensation based on the particular facts and circumstances. Notwithstanding the foregoing, except as set forth in Section B(2) below, in no event may the Company accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of an Executive Officer's obligations hereunder.
 - (iii) To the extent that the Executive Officer has already reimbursed the Company for any Erroneously Awarded Compensation Received under any duplicative recovery obligations established by the Company or applicable law, it shall be appropriate for any such reimbursed amount to be credited to the amount of Erroneously Awarded Compensation that is subject to recovery under this Policy.
 - (iv) To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company when due, the Company shall take all actions reasonable and appropriate to recover Erroneously Awarded Compensation from the applicable Executive Officer. The applicable Executive Officer shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(2) Notwithstanding anything herein to the contrary, the Company shall not be required to take the actions contemplated by Section B(1) above if the Committee (which, as specified above, is composed entirely of independent directors or in the absence of such a committee, a majority of the independent directors serving on the Board) determines that recovery would be impracticable and any of the following two conditions are met:

- (i) The Committee has determined that the direct expenses paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before making this determination, the Company must make a reasonable attempt to recover the Erroneously Awarded Compensation, documented such attempt(s) and provided such documentation to the NYSE; or
- (ii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

C. DISCLOSURE REQUIREMENTS

The Company shall file all disclosures with respect to this Policy required by applicable U.S. Securities and Exchange Commission (" **SEC**") filings and rules.

D. PROHIBITION OF INDEMNIFICATION

The Company shall not be permitted to insure or indemnify any Executive Officer against (i) the loss of any Erroneously Awarded Compensation that is repaid, returned, or recovered pursuant to the terms of this Policy, or (ii) any claims relating to the Company's enforcement of its rights under this Policy. Further, the Company shall not enter into any agreement that exempts any Incentive-based Compensation that is granted, paid or awarded to an Executive Officer from the application of this Policy or that waives the Company's right to recovery of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date of this Policy).

E. ADMINISTRATION AND INTERPRETATION

This Policy shall be administered by the Committee, and any determinations made by the Committee shall be final and binding on all affected individuals.

The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy and for the Company's compliance with the NYSE Rules and Section 10D, Rule 10D-1 and any other applicable law, regulation, rule or interpretation of the SEC or the NYSE promulgated or issued in connection therewith.

F. AMENDMENT; TERMINATION

The Committee may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary. Notwithstanding anything in this Section F to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the NYSE rule.

G. OTHER RECOVERY RIGHTS

This Policy shall be binding and enforceable against all Executive Officers and, to the extent required by applicable law or guidance from the SEC or the NYSE, their beneficiaries, heirs, executors, administrators or other legal representatives. The Committee intends that this Policy will be applied to the fullest extent required by applicable law. Any employment agreement, equity award agreement, compensatory plan or any other agreement or arrangement with an Executive Officer shall be deemed to include, as a condition to the grant of any benefit thereunder, an agreement by the Executive Officer to abide by the terms of this Policy. Any right of recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to the Company under applicable law, regulation or rule or pursuant to the terms of any policy of the Company or any provision in any employment agreement, equity award agreement, compensatory plan, agreement or other arrangement.

H. DEFINITIONS

For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

(1) ***“Accounting Restatement”*** means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

(2) ***“Clawback Eligible Incentive Compensation”*** means all Incentive-based Compensation Received by an Executive Officer (i) on or after the effective date of the applicable NYSE Rules, (ii) after beginning service as an Executive Officer, (iii) who served as an Executive Officer at any time during the applicable performance period relating to any Incentive-based Compensation (whether or not such Executive Officer is serving at the time the Erroneously Awarded Compensation is required to be repaid to the Company), (iv) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (v) during the applicable Clawback Period (as defined below).

(3) ***“Clawback Period”*** means, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date (as defined below), and if the Company changes its fiscal year, any transition period of less than nine months within or immediately following those three completed fiscal years.

(4) ***“Erroneously Awarded Compensation”*** means, with respect to each Executive Officer in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid.

(5) ***“Executive Officer”*** means each individual who is currently or was previously designated as an “officer” of the Company as defined in Rule 16a-1(f) under the Exchange Act. For the avoidance of doubt, the identification of an executive officer for purposes of this Policy shall include each executive officer who is or was identified pursuant to Item 401(b) of Regulation S-K, as well as the principal financial officer and principal accounting officer (or, if there is no principal accounting officer, the controller).

(6) ***“Financial Reporting Measures”*** means measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and all other measures that are derived wholly or in part from such measures. Stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return) shall, for purposes of this Policy, be considered Financial Reporting Measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented in the Company’s financial statements or included in a filing with the SEC.

(7) ***“Incentive-based Compensation”*** means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

(8) ***“NYSE”*** means The New York Stock Exchange.

(9) “**Received**” means, with respect to any Incentive-based Compensation, actual or deemed receipt, and Incentive-based Compensation shall be deemed received in the Company’s fiscal period during which the Financial Reporting Measure specified in the Incentive-based Compensation award is attained, even if the payment or grant of the Incentive-based Compensation to the Executive Officer occurs after the end of that period.

(10) “**Restatement Date**” means the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

Effective as of October 18, 2023

Exhibit A

**ATTESTATION AND ACKNOWLEDGEMENT OF POLICY FOR THE RECOVERY OF ERRONEOUSLY
AWARDED COMPENSATION**

By my signature below, I acknowledge and agree that:

- I have received and read the attached Policy for the Recovery of Erroneously Awarded Compensation (this “*Policy*”).
- I hereby agree to abide by all of the terms of this Policy both during and after my employment with the Company, including, without limitation, by promptly repaying or returning any Erroneously Awarded Compensation to the Company as determined in accordance with this Policy.

Signature: _____

Printed Name: _____

Date: _____