MILESTONE SCIENTIFIC INC.
Form 10-K
April 02, 2018

**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, 2017**

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

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**Milestone Scientific Inc.**

**(Exact name of registrant as specified in its charter)**

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| **Delaware** | **13-3545623** |
|---|---|
| **State or other jurisdiction of Incorporation or organization** | **(I.R.S. Employer Identification No.)** |

**220 South Orange Avenue, Livingston, NJ 07039**

**(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:**

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common Stock, par value $.001 per share | NYSE American |

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

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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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment of this Form 10-K.

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

| | | |
|---|---|---|
| Large accelerated filer | | Accelerated filer |
| Non-accelerated filer | (Do not check if a smaller reporting company) | Smaller reporting company |

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, 2017, 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 $27,488,612. This amount is based on the closing price of $1.50 per share of the registrant's common stock as of such date, as reported on the NYSE American.

As of April 2, 2018, the registrant has a total of 33,183,238 shares of Common Stock, $0.001 par value outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

**MILESTONE SCIENTIFIC INC.**

**Form 10-K Annual Report**

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**FORWARD-LOOKING STATEMENTS**

*Certain statements made in this Annual Report on Form 10-K are "forward-looking statements" (within the meaning of the Private Securities Litigation Reform Act of 1995) regarding the plans and objectives of management for future operations. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Milestone Scientific Inc. ("Milestone Scientific") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. 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 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, particularly in view of Milestone Scientific's early stage operations, 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. Milestone Scientific undertakes no obligation to revise or update publicly any forward-looking statements for any reason.*

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 ®; Safety Wand®; STA Single Tooth Anesthesia System®; and The Wand ®.*

**PART I**

All references in this report to "Milestone Scientific, Inc.," "us," "our," "we," the "Company "or "Milestone" refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Inc. and Milestone Medical Inc. and affiliate, Milestone Education LLC, 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*®; *Safety Wand*®; *STA Single Tooth Anesthesia System*®; and *The Wand*®.

**Item 1. Business**

**Overview**

Milestone Scientific is a biomedical technology research and development company that patents, designs, develops and commercializes innovative diagnostic and therapeutic injection technologies and devices for medical, dental, cosmetic and veterinary applications. 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 systems make injections precise, efficient and virtually painless. Milestone's proprietary *DPS* Dynamic Pressure Sensing technology® is our technology platform that advances the development of next-generation devices, regulating flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, with specific applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections.

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.

In 1997, Milestone Scientific released its first commercial product, the first computer-controlled local anesthesia delivery (C-CLAD) system, into the North American marketplace. This product was our proprietary, computer-controlled anesthetic delivery device, initially marketed as *The Wand*®, a computer-controlled local anesthesia delivery (C-CLAD) device with a single-use disposable handpiece for the dental market, regulating and controlling the flow rate of anesthetics. This device was later rebranded commercially as the *CompuDent*® System with the addition of several new features.

In 2001, Milestone Scientific was issued the initial United States Patent for *CompuFlo*® technology, entitled "Pressure/Force Computer Controlled Drug Delivery Instrument with Exit Pressure," allowing the device to continuously monitor and control the exit pressure of medication and/or fluid during an injection. We call this innovation *DPS* Dynamic Pressure Sensing technology. This same technology also enables doctors to accurately identify different tissue types based on detecting exit pressure during an injection. Later in 2004, the United States Patent Office issued a "Notice of Allowance" for patent protection on two additional critical elements of our *CompuFlo* technology: "Drug Delivery Instrument with Profiles" and "Pressure/Force Computer Controlled Drug Delivery with Automated Charging".

Given our experience and established brand awareness within the dental industry, we elected to focus our initial product development efforts on the integration of *CompuFlo's DPS* Dynamic Pressure Sensing technology into our legacy dental injection system. In 2006, the FDA cleared the first system utilizing *CompuFlo's* DPS Dynamic Pressure Sensing technology— the STA (Single Tooth Anesthesia) System and handpiece for use in the dental market, providing continuous real-time visual and audible pressure feedback from the tip of the needle while also precisely regulating the flow rate. Because of combining the ability to regulate the flow rate and monitor pressure at the tip of the needle, Milestone Scientific developed the industry's first solution for painlessly administering an intra-ligamnetary injection, i.e., "*single-tooth anesthesia*" which could be used as the only injection necessary for achieving dental anesthesia, foregoing the need to administer traditional injections such as a nerve branch block. In addition to *single-tooth anesthesia* the STA System can effectively perform all the traditional injections that dentist's routine gives but can provide them virtually pain free and with a numerous clinical advantage. This device, which also utilizes a disposable handpiece, is currently marketed by Milestone Scientific as the *Wand STA*® System.

Milestone Scientific believes our dental devices have set a new standard of care for dental injections. Our dental devices have been used to administer tens of millions of injections worldwide. Each of our devices has a related single use disposable handpiece, leading to a continuing revenue stream following 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 *Wand STA* System.

Building on the success of our proprietary, core technology platform for dental injections, and desiring to pursue other growth opportunities, we have recently 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. In June 2017, we received FDA regulatory clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for certain medical applications. 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 widely 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.

Milestone Scientific remains focused on advancing efforts to achieve the following five 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 in June 2017, Milestone Scientific is transitioning from a research and development organization to a commercially focused medical device company;

Commercializing our *CompuFlo* Epidural System, a transformative device for epidural anesthesia procedures;

Expanding the global footprint of our *CompuFlo* Epidural System by partnering with distribution companies worldwide; and

Continuing the commercial launch of our proprietary cosmetic injection device for delivery of botulinum toxin (such as *Botox*® and *Dysport*®).

Our dental devices are sold in the United States, Canada and in 53 other countries with FDA, CE and other clearances Since receiving FDA clearance in 2017 our epidural devices have had minimal sales in the United States and Europe.

**_DPS_ Dynamic Pressure Sensing Technology®; Our Proprietary Core Technology Platform**

Our first commercial product, our proprietary, computer-controlled anesthetic delivery device, initially marketed as *The Wand* later rebranded commercially as the *CompuDent*® System, for the dental market, uses patented technology,

including a single-use disposable handpiece, to control the flow rate of the anesthesia during the injection, allowing virtually painless injections for all dental procedures with optimal effectiveness. Over the years, the *CompuDent* System has been widely heralded as a revolutionary device, considered one of the major advances in dentistry in the 20th Century, and has been favorably evaluated in more than 50 peers reviewed or independent clinical research reports.

Our next significant intellectual property advancement was a quantum 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 to 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. These algorithms contain the critical components of specific drugs, parameters of needles, tubing and syringes and all other pertinent components for the safe and efficacious delivery of medications for all procedures. *CompuFlo*® technology also enables devices to provide a digital record of the time and volume of anesthetic or medicament injected.

Each CompuFlo® 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 electromechanical (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 a 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 150-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 have can control the flow rate, we believe our patented *DPS* Dynamic Pressure Sensing technology and *CompuFlo* Systems provide the ability to accurately and precisely control the pressure of the injection as well.

We believe our DPS Dynamic Pressure Sensing technology and *CompuFlo* Systems provides the following benefits:

minimizes the pain associated with injections, resulting in a more comfortable injection experience for the patient;

provides visual and audible in-tissue pressure feedback, identifying the desired target location to the healthcare provider, extending 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;

allows the healthcare provider to know when the target location is present and permits the healthcare provider to inject medicaments precisely at the desired location;

provides a digital record of the time and volume of anesthetic or medicament injected;

minimizes tissue damage because the flow rate and pressure of the injection are controlled;

provides an integrated injection database of algorithms that have been defined which allow for the measurement of the exit pressure, containing the critical components of specific drugs, parameters of needles, tubing and syringes and all other pertinent components for the safe and efficacious delivery of medications;

the pencil grip used with the handpieces allows significant tactile sense and accurate control;

new injections made possible with the technology eliminate collateral numbness;

bi-directional rotation of the handpieces eliminates needle deflection resulting in greater success and more rapid onset of anesthesia in injections;

the use of a single patient use, disposable handpieces minimize the risk of cross contamination; and

Our first system utilizing a DPS Dynamic Pressure Sensing technology platform was our STA System and related handpiece for the dental market, currently marketed as the *Wand STA System*. Another platform extension of our DPS Dynamic Pressure Sensing technology® platform is the *CompuFlo* Epidural System. In addition, we have developed platform extensions of our DPS Dynamic Pressure Sensing technology platform for intra-articular (for administering corticosteroids, hyaluronic acid and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions), cosmetic and veterinary applications. We intend to continue to develop and commercialize new applications of our DPS Dynamic Pressure Sensing Technology Platform as commercial line extensions.

***CompuFlo*** **Epidural Computer Controlled Anesthesia System**

In June 2017, we received FDA regulatory clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for certain medical applications. The *CompuFlo* Epidural Computer Controlled Anesthesia System obtained CE mark approval in September 2014, allowing it to be marketed and sold in most European countries and many other countries accepting CE approved devices. Because of receiving such FDA clearance, we are transitioning from a research and development organization to a commercially focused medical device company and beginning to commercialize our DPS Dynamic Pressure Sensing technology platform and related devices for medical applications.

The *CompuFlo* Epidural Computer Controlled Anesthesia 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 Computer Controlled Anesthesia 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* Computer Controlled Anesthesia 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 Computer Controlled Anesthesia 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.

An abstract presented at the 45th Chilean Congress of Anesthesiology on November 11, 2017, entitled: Utilization of Dynamic Pressure Sensing™ in Epidural Procedures for Child Birth and representing the first formal presentation of our *CompuFlo* Epidural Computer Controlled Anesthesia System device in South America, summarized the results of a recent independent, investigator-led clinical study evaluating the use of Milestone's *CompuFlo* Epidural device in 50 labor and delivery patients, concluding that the epidural space was correctly identified in 100% of the patients. In addition, the epidural space was located on the first attempt with all the patients. There were no cases of accidental puncture of the dura, a common risk factor for traditional epidural procedures using the loss of resistance technique. We believe that this represents a significant benefit for the payors, physicians, and most importantly, the patients.

In July 2017, Milestone Scientific acquired certain patent rights and other intellectual property rights related to the computer-controlled injection device of APAD Octrooi B.V. and APAD B.V. This patent portfolio solidifies our patent rights for computer-controlled local anesthetic delivery (C-CLAD) technology and expands our proprietary rights and provides low cost and simple instrument to deliver epidural injections.

***CompuFlo*** **Intra-Articular Computer Controlled Injection System**

Another platform extension utilizing our DPS Dynamic Pressure Sensing technology platform and *CompuFlo* System are our devices for administering corticosteroids and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions. As features of our DPS Dynamic Pressure Sensing technology, this device also precisely controls in-tissue pressure, increasing patient safety by reducing the risk of tissue damage and post-treatment pain related to excessive pressure that may occur during certain injections. Identification of the tissue, in which the needle tip is imbedded, is believed to be highly important in intra-articular injections and numerous organ, subcutaneous and intramuscular injections.

We believe our intra-articular injection device is particularly efficacious for arthritis patients who are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious because the doctor using a syringe fails to locate the intra-articular space or does not inject the appropriate volume of corticosteroids or other medicament into that space. Our *CompuFlo* System has been shown successful in an independent animal study in administering medicaments into a certain intra-articular space using its computer-controlled pressure sensing capabilities.

The intra-articular device has obtained CE mark clearance and may be marketed and sold in most European countries and many other countries accepting CE approved devices. In December 2016, we received notification from the FDA that our 510(k) applications for marketing approval of the intra-articular device did not demonstrate that the device was as safe and effective as legally marketed devices. We intend to submit a new 510(k) application that we believe will demonstrate substantial equivalency; however, we can provide no assurances of when, if ever, we will receive FDA clearance for our intra-articular device.

**Cosmetic Botulinum Injection Device**

The American Society of Plastic Surgeons (ASPS) reported that among the 14.2 million cosmetic minimally-invasive procedures performed in 2015, the top performed procedure, at 6.7 million procedures, was Botulinum Toxin Type A (commonly known as Botox) injection. Leveraging our experience in minimizing the pain of dental anesthetic injections, we established a joint venture in 2014 to develop and commercialize a device for the pain free injection of botulinum toxin. The joint venture entity, Milestone Advanced Cosmetic Systems, Inc., is owned 50% by us and 50% by Milestone China Company Limited ("Milestone China"), a company organized under the laws of Hong Kong and then owned 40% by Milestone Scientific, but as to which Milestone Scientific now only has an option to purchase up to 40% of Milestone China (as more particularly described below under Distribution and Marketing Arrangements). Milestone China contributed $900,000 of cash to the joint venture and we have provided a royalty-free license to utilize our technology to the joint venture to develop a botulinum toxin injection device.

In November 2017, we announced plans for the commercial launch of our proprietary cosmetic injection device using our DPS Dynamic Pressure Sensing technology platform and our *CompuFlo* Cosmetic System for delivery of botulinum toxin. Our proprietary cosmetic injection device features improved needle placement with a comfortable stylus grip, precise dosing, the same technology platform that has made dental and epidural injections painless, and an intuitive touch-screen interface. Based on the positive outcomes of a series of multi-state human factor studies with targeted customers, we are moving towards the commercial launch of our cosmetic device and applying for marketing clearance in Europe (CE clearance), and United States (FDA clearance). Although the Company's instrument has progressed beyond the development stage, additional equity financing is necessary to fund the commercialization of the instrument. To this end, the Company is currently in the process of pursuing additional financing. However, the Company and Milestone China can provide no assurance that additional financing will be consummated on acceptable terms, or at all

We believe that the touch screen and other platform improvements embodied by our cosmetic device will form the basis for our next generation of devices.

**Veterinary Nerve Block Anesthesia Device**

The effectiveness of our veterinary nerve block anesthesia device (existing medical device) for such use was confirmed by a pilot study and final report completed by Cornell University, College of Veterinary Medicine. Additional studies with other universities are in process with respect to horses and small animals. We are exploring commercialization opportunities.

**The Wand STA System**

In 2006, we received FDA clearance for our *Wand STA* System and disposable handpiece, the first system utilizing *CompuFlo*'s *DPS* Dynamic Pressure Sensing technology, for use in the dental market. The *Wand STA* System and handpiece continue to provide all of the benefits of the *CompuDent* System, allowing dentists to provide virtually painless injections for all dental procedures, including routine fillings, as well as more sophisticated implants, root canals and crowns, while better facilitating single tooth anesthesia (now generally performed with a high pressure spring loaded gun-like device), but also incorporates the "pressure feedback" elements of Milestone Scientific's patented *CompuFlo* System, thereby allowing dentists to administer injections accurately and painlessly into the periodontal ligament space, effectively anesthetizing a single tooth. Injections made by the *Wand STA* System eliminate collateral numbness of the tongue, lips and facial muscles and often hasten the onset of anesthesia by eliminating the need for mandibular blocks. The *Wand STA* also identifies intrafilamentary tissue, so dentists can find the precise location for *single tooth anesthesia*. This injection is of significant value in that it allows the dentist to profoundly anesthetize the tooth within one minute per root, versus up to 15-18 minutes for a block injection to take effect. The *Wand STA* System can perform all the injections that can be done with a conventional dental syringe, and in addition, we provide the ability to perform the following: the palatal-anterior superior alveolar, anterior middle superior alveolar and inferior alveolar nerve block. The *Wand STA* System achieves these injections predictably and reliably. To date, substantially all our revenue has been generated by the *Wand STA* System for dental applications.

Since its market introduction in the spring of 2007, the *Wand STA* System has received favorable reviews and awards from the dental industry. In July 2007, noted industry publication Dentistry Today featured the *Wand STA* System as one of the "Top 100 Products in 2007," helping to promote much broader recognition of the instrument and validating the *Wand STA* System's value proposition for dentists and patients, alike. In early 2008, Medical Device & Diagnostic Industry magazine distinguished the *Wand STA* System as a 2008 Medical Design Excellence Award winner in the "Dental Instruments, Equipment and Supplies" product category. Of the 33 products to receive this coveted award, the *Wand STA* System was one of only two winning products that serve dental practitioners. In December 2008, Milestone Scientific continued to win broad acclaim for the *Wand STA* System by winning a "Townie Choice Award". The "Townie Choice" awards were originally started by Dr. Howard Darran and Farran Media, publisher of Dentaltown Magazine, to assist dentists in making product purchasing decisions, and are considered the "people's choice" of the products and services available to the dental industry today. That same month, the *Wand STA* System was also named as a Dental Products Report "Top 100 2008 Product of Distinction." Additionally, the *Wand STA* System was named one of Dentistry Today's "Top 100 Products" for the third consecutive year in 2010.

**Other Devices**

At earlier stages of development are our products using *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 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.

**Distribution and Marketing Arrangements**

Our dental devices are sold in the United States, Canada, and in over 53 countries abroad. In June 2017, we received FDA regulatory clearance to sell our first medical device, the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States. Since receiving FDA clearance in 2017 our epidural devices have had minimal sales in the United States and Europe.

**Dental Market**

In the spring of 2009, Milestone Scientific signed a distribution and marketing agreement with China National Medicines Corporation, dba Sinopharm. In early October 2012, the State Food and Drug Administration ("CFDA") of

the People's Republic of China approved the *Wand STA* System. However, the CFDA's approval of the *Wand STA* handpieces was not received until May 2014 and the distribution of these handpieces in China began in the fourth quarter of 2014. The distribution and marketing agreement with Sinopharm was terminated in September 2014. Proximate to that time, we entered into a new agreement with Milestone China to be our distributor for the *Wand STA* System and handpieces in China. Milestone Scientific then owned, but now has an option to purchase, forty (40%) percent of Milestone China (the "Milestone China Shares"). In June 2017, Milestone Scientific sold its Milestone China Shares to an unaffiliated United States domiciled purchaser for a promissory note secured by a pledge of the Milestone China Shares, and received a 10-year option to repurchase the Milestone China Shares at the same price as the purchase price paid for the Milestone China Shares within the first two years and at fair market value (as defined in such agreement) for the remainder of the 10-year term.

As of March 2, 2018, the promissory note was in default. If Milestone Scientific exercises its rights as a secured party it may be obligated to return to the purchaser up to the $250,000 received for the Milestone China Shares as surplus. At this time Milestone Scientific has not received a response from the purchaser of the Milestone China Shares, Milestone Scientific has not recorded any financial benefit from the sale of Milestone China Shares to date.

In November 2012, Milestone Scientific signed an exclusive distributor and marketing agreement with a well-known U.S. domestic manufacturer and distributor, for the sale and distribution of the *Wand STA* System and handpieces in the United States and Canada. The marketing initiative included participation in United States and Canadian dental shows, as well as pediatric dental shows; an active advertising initiative targeting major dental publications; and direct mailing campaigns to over 150,000 dentists across the United States and Canada. This exclusive distributor and marketing agreement was converted to a non-exclusive agreement as of December 31, 2016.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016, that agreement was replaced by a new agreement with Henry Schein providing for an exclusive distribution arrangement for our dental products in the United States and Canada by a newly formed marketing and sales group at Henry Schein. Under this arrangement, we have a semi-dedicated independent sales force visiting dentists. Henry Schein's exclusive products sales specialist team, which is comprised of 25 sales representatives and supported by over 1,000 field service representatives, will exclusively market and distribute the *Wand STA* System and handpieces, together with a select group of other devices in the United States and Canada. Our agreement with Henry Schein has minimum purchase orders to maintain exclusivity in the third through tenth years. We believe that this exclusive arrangement will be more effective than previous arrangements relying on Wand Dental's appearances at dental shows and catalog sales.

**Medical Market**

Having received FDA clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in June 2017, we are in discussions with a small number of regional and national distributors. Our immediate focus is on marketing our epidural device throughout Europe.

In February and March 2018 Milestone Scientific hired an Executive VP of Global Sales and Marketing and a Vice President of US Sales to fill a significant gap in our commercialization efforts of the CompuFlo Epidural System.

We have entered into a limited number of distributor arrangements in Europe and the Middle East for our *CompuFlo* Epidural Computer Controlled Anesthesia System. Our distribution strategy is initially aimed at having KOLs use and accept the device and initiate their own studies.

**Veterinary Market**

We are exploring various commercialization opportunities.

**Patents and Intellectual Property**

Milestone Scientific and its subsidiaries currently hold approximately 214 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 29 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 products, 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, upon 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 the manufacturer of the *Wand STA* System, epidural and intra-articular devices and with one of the principal manufacturers of the handpieces for those items, respectively. Pursuant to these informal arrangements, our third-party manufacturers manufacture 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 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 handpieces since 2003. The manufacturer of our handpieces is in the People's Republic of China and the manufacturer of the device is in the United States. Changes to pricing of the *Wand STA* System 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 handpieces exist, Milestone Scientific would need to recover its existing tools or have new tools produced to establish relationships with new suppliers. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of the supply, whether as a result or termination of the relationship, would have a material adverse effect on our financial condition, business and results of operations.

**Competition**

Now, 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 practitioner, patient and the 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, and the Comfort Control Syringe by Dentsply.

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.

Another computer-controlled injection instrument is called the Comfort Control Syringe or CCS. In the early 1990s, Dr. Mark Smith, a dentist from Ontario, Canada, invented a device that he incorporated into his practice as the local anesthetic delivery method. After perfecting the system, he released the rights of this device to Dentsply. In this system, many of the functions of the computer can be controlled directly from the syringe during the injection process. The base unit allows the dentist to program one of five different injections by pressing a single button. The five

buttons marked on the base unit are block, infiltration, PDL, intraosseous and palatal. Each of these injections has a specific corresponding rate of local anesthetic delivery associated with it. The CCS enables a wide range of injection speeds controlled by the operator and the ability to control the computer directly from the syringe, but, since the CCS computer can be controlled by hand, the syringe must contain a certain amount of electronic equipment and this adds bulk to its circumference. The circumference of the CCS syringe is 112mm compared to 36mm for a traditional syringe, and 17mm for the *Wand STA* System. In addition, because of the electronics in the syringe, the operator will feel a slight amount of vibration in the syringe while the injection occurs. This will not affect the anesthesia, but it certainly is a feeling that is different from the traditional syringe or the *Wand STA* System, which both have no such vibration. The vibration in the Quicksleeper is minimal. This instrument is no longer being marketed.

The newest competition is the Calajet instrument. This instrument is manufactured in Europe and has been very slow to grow market acceptances. It recently began marketing in the USA with similar result. The instrument is a higher price than the Wand STA and does not provide the DPS software. Although a competitor, without a substantial distribution network this instrument will have a difficult time to be successful in the USA.

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.

Rapid technological change and research may affect 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 must devote 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 establish an effective distribution network with a strong marketing plan. Any new products must be first approved by 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 for those products.

**Government Regulation**

The manufacture and sale of medical devices and other medical products are subject to extensive regulation by the FDA pursuant to the U.S. Food, Drug and Cosmetic Act ("FDC Act"), and by other federal, state and foreign authorities. Under the FDC 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 the 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 Instrument Regulation ("QSR"), also referred to as "Good Manufacturing Practices" ("GMP") regulations. Some Class I devices are further exempted 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.

Pre-market Notification, 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 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 Computer Controlled Anesthesia System in June 2017. For us to commercialize other products in United States, Milestone Scientific would have to submit additional 510(k) applications to the FDA.

In 2017, the FDA reduced barrier to marketing clearance for certain dental devices. As such the entry into the dental market for other manufactures of injection devices may increase. However, any new device will be very limited in sales volume without a significant distributor in the dental market.

Though certain dental 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 will be 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 FDC 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.

The Medical Device Reporting (“MDR”) regulation obligates us to provide information to the FDA on product malfunctions or injuries alleged to have been associated with the use of the product or in connection with certain product failures that could cause serious injury. If, because of FDA inspections, MDR reports or other information, the FDA believes that Milestone Scientific is not in compliance with the law, the FDA can institute proceedings to detain or seize products, enjoin future violations, or assess civil and/or criminal penalties against us, our officers or employees. Any action by the FDA could result in disruption of operations for an undetermined amount of time.

In September 2014 we received CE mark approval for the marketing of the *CompuFlo* Epidural Computer Controlled Anesthesia System, in each case allowing such product to be marketed in most European countries and many other countries accepting CE approved devices. In July 2003, Milestone Scientific obtained regulatory approval to sell the *CompuDent* System and its handpieces in Australia and New Zealand. As of May 2014, the *Wand STA* System was approved for sale in China.

**Employees**

As of December 31, 2017, the Company had a total 14 full-time employees consisting of two executive officers of Milestone Scientific. Milestone Scientific also has a consultant who serves as a Director of Clinical Affairs and a business development consultant.

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 220 South Orange Avenue, Livingston, New Jersey 07039 and our telephone number is (973) 535-2717. Our web address is www.milestonescientific.com. Information contained on or accessed through our website is not part of this prospectus supplement. Our common stock is listed on the NYSE American under the ticker symbol “MLSS”.

**Item 1A. Risk Factors**

The following factors may affect the growth and profitability of Milestone Scientific and should be considered by any prospective purchaser or current holder of our securities. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks.

**We have a history of operating losses that 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, medical device company with a history of limited revenue and significant operating losses and our prospects must be considered considering the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. With only one exception (*i.e.,* 2013), we have generated net losses in all periods since the commencement of our operations, including operating losses of approximately $5.2 million and $6.5 million for the years ended December 31, 2017 and 2016, respectively. Overall, at December 31, 2017, we had an accumulated deficit of approximately $78.6 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we undertake to commercialize our *CompuFlo*® Epidural Computer Controlled Anesthesia System. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, 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

**We require additional funding and 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.**

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2017 and 2016, net cash flow used in operations was approximately $ 1.2 million and approximately $5.4 million, respectively. We expect to continue to spend substantial amounts on product development and commercialization activities, including the commercialization of our recently FDA-approved *CompuFlo*® Epidural Computer Controlled Anesthesia System. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. In addition, we may seek other alternatives to maximize the value of our intellectual property for dental applications, to focus more on, and finance, our medical applications. If we are unable to raise additional capital, we will have to delay, curtail or eliminate the commercialization of our *CompuFlo*® Epidural Computer Controlled Anesthesia System, our efforts to obtain FDA approval of our intra-articular device and/or our product development and other commercialization efforts.

**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.**

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.

**Relying exclusively on third parties to manufacture our products, changes in our informal manufacturing arrangements made by the manufacturer of our devices and disruptions at the manufacturing facility of our manufacturer 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. At present, we have an informal arrangement with the manufacturer of our products. While we have more than one manufacturer of the hand pieces for our devices, we only have a single manufacturer manufacturing our devices. Our current arrangement with such sole source of supply 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. If the manufacturer insists on a material change in terms or determines to discontinue manufacture of our devices, it could have an adverse effect on our financial condition and results of operation.

An operational disruption in the facility of the manufacturer of our devices could negatively impact production and our financial results. The occurrence of a natural disaster, such as a hurricane, tropical storm, earthquake, tornado, severe weather, flood, fire or other unanticipated problems such as labor difficulties, equipment failure or unscheduled maintenance 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 might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs.

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 product.

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

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.

**We depend on two principal manufacturers. If we cannot maintain our existing relationships or develop new ones, we may have to cease operations.**

Milestone Scientific and its subsidiary has informal arrangements with the manufacturer of the Wand STA Instrument, CompuDent®, CompuMed® CompuFlo Epidural, and CompuFlo Intra-Articular and with one of the principal manufacturers of the handpieces, for those items, respectively. Pursuant to the informal arrangements, they manufacture these devices and handpieces under specific purchase orders without minimum purchase commitments. Milestone Scientific has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum purchase commitments. Milestone Scientific has been supplied by the manufacturer of the Wand STA Instrument, CompuDent®, CompuMed® CompuFlo Epidural and CompuFlo Intra-Articular devices since the commencement of production in 1998, and the manufacturer of its handpieces since 2003.

However, termination of the manufacturing relationship with any of these manufacturers could significantly and adversely affect our ability to produce and sell these products. Though other alternate sources of supply for handpieces exist, Milestone Scientific would need to recover its existing tools or have new tools produced to establish relationships with new suppliers. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of the supply, whether as a result or termination of the relationship, would have a material adverse effect on our financial condition, business and results of operations.

**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.

**We may be subject to product liability claims that are not fully covered by insurance and that could put Milestone Scientific under financial strain.**

Milestone Scientific could be subject to claims for personal injury from the alleged malfunction or misuse of the dental and medical products. While Milestone Scientific carries liability insurance that is believed to be adequate, there is no assurance that the insurance coverage will be sufficient to pay such claims should they be successful. A partially or completely uninsured claim, if successful and of significant magnitude, could have a material adverse effect on our business, financial condition and results of operations.

**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.**

Although the FDA has cleared our application to begin marketing the *CompuFlo*® Epidural Computer Controlled Anesthesia 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 Computer Controlled Anesthesia 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, if any.

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.

**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 dress, are important to our business. We will endeavor to protect our intellectual property rights in key jurisdictions in which our products are produced or used and in jurisdictions into which our products are imported. Our success will depend to a significant degree upon our ability to protect and preserve our intellectual property rights. However, we may be unable to obtain or maintain protection for our intellectual property in key jurisdictions. Although we own and have applied for patents and trademarks throughout the world, we may have to rely on judicial enforcement of our patents and other proprietary rights. Our patents and other intellectual property rights may be challenged, invalidated, circumvented and rendered unenforceable or otherwise compromised. A failure to protect, defend or enforce our intellectual property could have an adverse effect on our financial condition and results of operations. Similarly, third parties may assert claims against us and our customers and distributors alleging our products infringe upon third party intellectual property rights.

We believe that the intellectual property underlying our products is a competitive advantage. We rely on a combination of patent rights, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patents, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the U.S. Patent and Trademark Office. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies resulting from such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

If we must take legal action to protect, defend or enforce our intellectual property rights, any suits or proceedings could result in significant costs and diversion of our resources and our management’s attention, and we may not prevail in any such suits or proceedings. A failure to protect, defend or enforce our intellectual property rights could have an adverse effect on our results of operations.

**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, the majority of an innovative product's commercial value is realized during the early stages of commercialization, before competing products are developed. Our market advantage is based, in part, on patent rights and the need for new competing products and systems to obtain regulatory approval before they can be commercialized. The scope of our patent rights may be limited and may also depend on the availability of meaningful legal remedies.

Our failure to adequately protect our intellectual property rights, through patents or otherwise, or limitations on the use or loss of such rights, could have a material adverse effect on our ability to prevent the commercialization of competing anesthetic delivery systems. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable, and the validity and enforceability of patents cannot be predicted with certainty.

**Third parties could obtain patents that may require us to negotiate licenses to commercialize our technologies, and we cannot assure you that the required licenses would be available on reasonable terms or at all.**

Third parties may claim that one or more aspects of our technologies or products may infringe on their intellectual property rights.

Our computer-controlled anesthesia systems are complex systems and numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of drug delivery systems. In addition, many companies have employed intellectual property litigation as a strategy to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the U.S. and in foreign jurisdictions. If any of our computer-controlled anesthesia systems are found to infringe third party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign the system to avoid infringement. Even if we can redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or costlier product. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily 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.

**We are exposed to the risks inherent in international sales and operations.**

In 2017, export sales outside of the United States made up approximately 57% of our total sales, and we sell our products to customers in approximately 53 countries. 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 US 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;

difficulties in obtaining approval for significant transactions;

**Continued instability in the credit and financial markets may negatively impact our ability to commercialize our products.**

Financial markets in the United States, Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be reduced. As a small medical device company, we rely on third parties for several important aspects of our business, including contract manufacturing of products, distribution of our products and sales and marketing. These third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued volatility in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of any adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

**Our 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 product. If government and other healthcare payers do not provide adequate coverage and reimbursement for any of our products, market acceptance of such product 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 are subject to substantial domestic and international government regulation, including regulatory quality standards applicable to our manufacturing and quality processes. Failure by us to comply with these standards could have an adverse effect on our business, financial condition or results of operations.**

The FDA regulates the approval, manufacturing and sales and marketing of many of our products in the United States. Significant government regulation also exists 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, which require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report to the Centers for Medicare and Medicaid Services for subsequent public disclosure. 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.

**Excessive returns under our Exclusive Distribution and Supply Agreement with Henry Schein, Inc. could have a material adverse effect on our business, financial condition and results of operations.**

In June 2016, we entered into a new exclusive distribution and supply agreement with Henry Schein pursuant to which they were appointed as the exclusive distributor for our dental products in the United States and Canada. Under that agreement, Henry Schein has a right to return our products for full credit against the purchase price paid by them under limited circumstances in accordance with such agreement, including but not limited to, returns due to shipment error by us or factory defect. Excessive returns during any calendar year could have a material adverse effect on our business, financial condition and results of operations.

**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.

**We rely on the continuing services of our Interim Chief Executive Officer and Director of Clinical Affairs.**

We depend on the personal efforts and abilities of our Interim Chief Executive Officer and Director of Clinical Affairs. Milestone Scientific maintains a key man life insurance policy in the amount of $1,000,000 on the life of its Interim Chief Executive Officer. However, the loss of his services or the services of our Director of Clinical Affairs, on whom we maintain no insurance, could have a materially adverse effect on our business results of operations and prospects.

**Milestone Scientific is effectively controlled by a limited number of stockholders.**

Milestone Scientific's principal stockholders, Leonard Osser, Gian Domenico Trombetta and K. Tucker Andersen beneficially own approximately 39.68% 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 de facto 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.

**Adherence to Sarbanes-Oxley Act and SEC rules concerning internal controls may be costly and compliance could have an adverse effect on Milestone Scientific.**

The management of Milestone Scientific has assessed the effectiveness of internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Milestone Scientific complied with Sarbanes-Oxley requirements to include in the annual report a management report on the effectiveness of the internal control over financial reporting. In 2017 and 2016, Milestone Scientific utilized an outside consultant on a quarterly basis to review compliance with the internal controls over financial reporting. This expense amounted to approximately $15,000 and $20,000 in 2017 and 2016, respectively and the cost is expected to continue in 2018.

**The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.**

Our stock price may experience substantial volatility because of many factors, including:

sales or potential sales of substantial amounts of our common stock;

delay or failure in initiating our strategy to commercialize our CompuFlo® Epidural Computer Controlled Anesthesia System;

the success of our strategy to commercialize our CompuFlo® Epidural Computer Controlled Anesthesia 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 Computer Controlled Anesthesia 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 to products and services for the healthcare industry;

conditions in the medical device industries;

governmental regulation and legislation;

variations in our anticipated or actual operating results; and

change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for small, medical device companies 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.

**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 33,191,571 outstanding shares of common stock, 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. In addition, we have an effective S-3 registration statement on file with the SEC covering the sale by us of up to $30 million of securities, including common stock, preferred stock, debt, convertible debt and warrants. To date, we have sold $3,435,775 (2,452,900 shares) of common stock under that registration statement. 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

**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; and 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 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 delisted. 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 delisted. 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. Although we currently satisfy the listing criteria for NYSE American, if our stock price declines, we could be at risk of falling below NYSE American continuing listing criteria.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Description of Property**

The headquarters for Milestone Scientific is located at 220 South Orange Ave, Livingston, New Jersey. Milestone Scientific leases approximately 7,625 square feet of office space. The lease term expires January 31, 2020 at a monthly cost of $12,522. Additionally, Milestone Scientific has other smaller insignificant leases ending through 2017. 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**

On June 1, 2015, our common stock was listed on the NYSE American under the symbol “MLSS”. Prior to its listing on the NYSE American, Milestone’s common stock traded on the OTC Market on the OTCQB market tier under the same symbol. The following table sets forth the high and low sales prices of Milestone’s common stock for the periods presented.

| **2017** | HIGH | LOW | **2016** | HIGH | LOW |
|---|---|---|---|---|---|
| First Quarter | $1.65 | $1.10 | First Quarter | $2.54 | $ 1.27 |
| Second Quarter | $1.80 | $1.20 | Second Quarter | $3.10 | $ 1.70 |
| Third Quarter | $1.55 | $1.08 | Third Quarter | $2.96 | $ 1.94 |
| Fourth Quarter | $1.60 | $0.91 | Fourth Quarter | $2.19 | $ 1.29 |

**Holders**

As of April 2, 2018, we had approximately 130 stockholders of record of our common stock. We believe that we have approximately 2,185 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. For information regarding securities authorized under the equity compensation plan, see Item 12.

**Sales of Unregistered Securities**

See NOTE K – STOCKHOLDERS' EQUITY, to the audited consolidated financial statements that accompany this Report for information regarding the issuance of unregistered securities. These issuances were exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act") and a legend restricting the sale, transfer, or other disposition of these shares other than in compliance with the Act was imprinted on stock certificates evidencing the shares.

As of December 31, 2017, Milestone Scientific issued a total of 352,015 shares of its common stock as follows:

120,000 shares to the Board of Directors with a total value of $159,480;

10,913 shares to an employee for compensation with a total value of $15,000; and

an aggregate of 410,729 shares to consultants for services rendered with a total value of $548,511.

In addition, as of July 13, 2017, pursuant to the Asset Purchase Agreement with APAD Octrooi B.V. and APAD B.V. (collectively, the "Sellers"), Milestone Scientific issued an aggregate of 1,646,358 shares of its common stock to the Sellers in consideration for certain patent rights and other intellectual property rights related to the Sellers' computer-controlled injection instrument.

The foregoing shares were issued in reliance upon the exemptions from the registration requirements of the Securities Act of 1933, as amended (the "Act"), pursuant to Sections 4(a)(2), Section 4(a)(5) and/or Regulation D promulgated thereunder. A legend restricting resale, transfer, or other disposition of these shares other than in compliance with the Act was imprinted on the stock certificates evidencing such shares.

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**ITEM 6. Selected Financial Data**

Milestone Scientific is a “smaller reporting company” as defined by Regulations 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, that 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**

Our common stock was listed on the NYSE American on June 1, 2015 and trades under the symbol “MLSS”. We have developed a proprietary, computer-controlled anesthetic delivery instrument, using *The Wand*®, a single use disposable handpiece. The instrument 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 several other disciplines. The dental instruments are sold in the United States, Canada, and in over 53 other countries abroad. There have been no medical instruments sold in the United States and limited amounts sold internationally as of the reporting date. Certain of our medical instruments have obtained European CE mark approval and can be marketed and sold in most European countries. In June 2017, the FDA approved our 510(k) applications for marketing clearance in the United States of our *CompuFlo*® Epidural Computer Controlled Anesthesia System. We are in the process of introductory meetings with medical device distributors within the United States and foreign markets.

In 2017, we remained focused on advancing efforts to achieve our three primary objectives; those being:

Worldwide distribution of the C*ompuFlo*® Epidural Computer Controlled Anesthesia System.

Identify distributors in the United States for the Epidural instruments, now that FDA clearance has been received;

Complete the Cosmetic device and obtain European Regulatory Approve (CE market clearance)

**Wand STA Instrument Growth**

Since its market introduction in early 2007, the Wand STA Instrument and prior C-CLAD products have been used to deliver over 66 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.

**Global Distribution Network**

**United States and Canadian Market**

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, Inc. (“Henry Schein”). In June 2016, that agreement was replaced with an exclusive distribution arrangement for our dental products for the United States and Canada with Henry Schein. Under this arrangement we have a semi-dedicated independent sales force visiting dentists. We believe that this arrangement will be more effective than previous arrangements which primarily relied upon appearances at dental shows and catalog sales.

To date, Henry Schein has endeavored to accomplish the goals set forth in the exclusive distribution agreement for *The Wand*® STA instrument and handpieces, including training of its exclusive products sales specialists. Specifically, 25 exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand*® STA instrument and handpieces and all 25 are currently in the field selling the instrument.

Henry Schein also plans to train an additional customer service representative to support dentists across North America through its exclusive product sales customer call center, as business volume increases.

**International Market**

On the global front, we have granted exclusive marketing and distribution rights for the Wand STA Instrument to select dental suppliers in various international regions in Asia, Africa, South America and Europe. They include Istrodent (Pty) Ltd. in South Africa and Unident AB in the Scandinavian countries of Denmark, Sweden, Norway and Iceland.

In October 2012, the State Food and Drug Administration (CFDA) of the People's Republic of China approved our Wand STA *Single Tooth Anesthesia System*® (STA System). In May 2014, the CFDA also approved the Wand STA handpieces for sale in China.

In September 2014, Milestone Medical received CE clearance to distribute their epidural and intra-articular instruments in the European Community (EU). Milestone Medical signed a distribution agreement in March 2015 with a medical distributor in Poland for the distribution of the epidural instrument. This distribution agreement was terminated in late 2016 due to the distributor's inadequate performance under the distribution agreement. Milestone Medical is continuing to pursue distributors for the instrument in the EU community.

In June 2014, Milestone Scientific invested $1 million in Milestone China Ltd. ("Milestone China") by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting. Milestone Scientific recorded a loss on its investment in Milestone China of $0 and $164,837 as of December 31, 2017 and 2016, respectively exclusive of deferral of gross profit. Milestone Scientific's investment in Milestone China was $0 as of December 31, 2017 and December 31, 2016, respectively. Milestone Scientific incurred cumulative losses beyond its investment in Milestone China of $3,147,470 and $1,124,350 as of December 31, 2017 and December 31, 2016, respectively, which have been suspended.

In June 2017, Milestone Scientific entered into an agreement for the sale of its interest in Milestone China (a forty (40%) percent interest) (the "Milestone China Shares") to an unaffiliated United States domiciled purchaser and a 10-year option agreement to repurchase the Milestone China Shares. The purchase price for the Milestone China Shares was $1,400,000 of which $125,000 was paid in cash and $1,275,000 was paid by delivery of a non-interest bearing secured promissory note. The note is payable in quarterly installments of $125,000 until paid in full and is secured by the Milestone China Shares until full repayment. In addition, pursuant to such note, the purchaser is precluded from selling all or substantially all its assets prior to repayment of the note. The 10-year option agreement provides Milestone Scientific an option to repurchase the Milestone China Shares at $1,400,000 within the first two years and at fair market value (as defined in such agreement) for the remainder of the 10-year term. The transaction has been accounted for as a secured financing and Milestone Scientific will continue to account for its relationship with Milestone China under the equity method of accounting. A note receivable is presented on the Company's balance sheet, along with a deferral from financing transaction ($1,400,000). The carrying value of the forty (40%) percent investment at the transaction date was zero.

The sale of the Milestone China Shares allows Milestone Scientific to continue to expand in the China market by supplying Milestone China with the STA Single Tooth Anesthesia System® and related hand pieces, while eliminating the burden on Milestone Scientific's management as a 40% minority owner. Milestone Scientific believes that the sale will provide Milestone China with a new partner that may accelerate its penetration of the China market.

As of March 2, 2018, the promissory note was in default. If Milestone Scientific exercises its rights as a secured party it may be obligated to return to the purchaser up to the $250,000 received for the Milestone China Shares as surplus. At this time Milestone Scientific has not received a response from the purchaser of the Milestone China Shares, Milestone Scientific has not recorded any financial benefit from the sale of Milestone China Shares to date.

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

| | 2017 | | | 2016 | | |
|---|---|---|---|---|---|---|
| | Dental | Medical | Total | Dental | Medical | Total |
| **Domestic US/Canada** | | | | | | |
| Instruments | $914,495 | $ - | $914,495 | $930,873 | $ - | $930,873 |
| Handpieces | 4,346,664 | - | 4,346,664 | 2,356,209 | - | 2,356,209 |
| Other | 78,550 | - | 78,550 | 65,479 | - | 65,479 |
| | $5,339,709 | $ - | $5,339,709 | $3,352,561 | $ - | $3,352,561 |
| **International Rest of the World** | | | | | | |
| Instruments | $1,427,016 | $ - | $1,427,016 | $1,185,908 | $ - | $1,185,908 |
| Handpieces | 2,325,622 | 2,000 | 2,327,622 | 2,363,143 | 21,253 | 2,384,396 |
| Other | 116,539 | - | 116,539 | 133,540 | - | 133,540 |
| | $3,869,177 | $ 2,000 | $3,871,177 | $3,682,591 | $21,253 | $3,703,844 |
| **International China** | | | | | | |
| Instruments | $643,600 | $ - | $643,600 | $2,000,000 | $ - | $2,000,000 |
| Handpieces | 1,425,600 | - | 1,425,600 | 1,425,600 | - | 1,425,600 |
| Other | 1,800 | - | 1,800 | - | - | - |
| | $2,071,000 | $ - | $2,071,000 | $3,425,600 | $ - | $3,425,600 |
| **Total Product Sales** | | | | | | |
| Domestic | $5,339,709 | $ - | $5,339,709 | $3,352,561 | $ - | $3,352,561 |
| International -Rest of World | 3,869,177 | 2,000 | 3,871,177 | 3,682,591 | 21,253 | 3,703,844 |
| International -China | 2,071,000 | - | 2,071,000 | 3,425,600 | - | 3,425,600 |
| | $11,279,886 | $ 2,000 | $11,281,886 | $10,460,752 | $21,253 | $10,482,005 |

Milestone Scientific plans to support increased sales and marketing activity through our current distributors and through newly appointed distributors of the Wand STA instruments and handpieces in the international market. In the United States and Canada, Milestone Scientific will continue the utilization of independent hygienists for training individual practitioners and group practices domestically, refined and directed advertising to dental professionals, continue to develop Key Opinion Leaders (KOL) and support and broaden our global distribution network. Additionally, with the recent FDA marketing clearance for the epidural instrument, Milestone Scientific is initiating marketing and sales efforts in the US to establish medical sector distributors for the sale of this instrument

In February and March 2018 Milestone Scientific hired an Executive VP of Global Sales and Marketing and a Vice President of US Sales to fill a significant gap in our commercialization efforts of the CompuFlo Epidural System.

**Current Product Platform**

See Item 1. Description of Business.

**Summary of Critical Accounting Policies and Significant Judgments and Estimates**

Milestone Scientific's discussion and analysis of the financial condition and results of operations is based upon its consolidated financial statements that have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of its wholly-owned and majority-owned subsidiaries including, Wand Dental, Milestone Advanced Cosmetic and Milestone Medical. Milestone Education is a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

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 to accounts receivable, inventories, stock-based compensation and contingencies. 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.

While significant accounting policies are more fully described in Note C to the consolidated financial statements included elsewhere in this report, Milestone Scientific believes that the following accounting policies and significant judgments and estimates are most critical in understanding and evaluating the reported financial results.

**Assessment of our Ability to Continue as a Going Concern**

Our management has made various estimates in assessing our ability to continue as a going concern as of the report date of our independent auditor's report included in this Form 10-K. These estimates include, an increase in the revenues generated by Wand Dental because of the new distribution agreement with Henry Schein, an increase in international revenue, (non-China) a reduction in our profit margins due to the nature of the distribution relationships with both Henry Schein and Milestone China, and reduction our selling, general and administrative costs for one-time expenses incurred during 2017. Based on this assessment, management believes that our cash on hand, accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-K.

**Accounts Receivable**

Milestone Scientific sells a significant amount of its products on credit terms to its major distributors. Milestone Scientific estimates losses from the inability of its customers to make payments on amounts billed. Most of credit sales are due within ninety days from invoicing. Milestone Scientific has not incurred any significant credit losses.

**Inventories**

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market. 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.

**Impairment of Long-Lived Assets**

Milestone Scientific reviews long-lived assets for impairment whenever events or circumstances (i.e. a triggering event) indicate that the carrying amounts may not be recoverable. The carrying value of the assets is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets. Milestone Scientific adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. There have been no impairment indicators or triggering events and therefore there was no impairment as of December 31, 2017.

**Revenue Recognition**

Revenue from product sales is recognized, net of discounts and allowances to domestic distributors, on the date of shipment for substantially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific recognizes revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. In all cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone Scientific has no obligation on these sales for any post 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. Devices and hand pieces are not bundled but rather sold separately and, as such, there are no multiple element determinations in connection with the revenue recognition

**Results of Operations**

The following table sets forth for the consolidated results of operations for the year ended December 31, 2017 compared to 2016 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

| Operating results: | Years Ended December 31, 2017 | December 31, 2016 |
|---|---|---|
| Net Sales | $11,281,886 | $10,482,005 |
| Cost of Sales | 4,312,507 | 4,175,533 |
| Gross Profit | 6,969,379 | 6,306,472 |
| Operating expenses: | | |
| Selling, general, and administrative | 11,930,951 | 11,549,961 |
| Research & development | 272,746 | 1,270,471 |
| Operating Loss | $(5,234,318) | $(6,513,960) |
| Other Expenses, net | (135,235) | (780,529) |
| Net Loss | (5,369,553) | (7,294,489) |
| Net loss attributable to noncontrolling interest | 182,760 | 1,347,982 |
| Net loss attributable to Milestone Scientific Inc. | $(5,186,793) | $(5,946,507) |

| | Years Ended December 31, 2017 | December 31, 2016 |
|---|---|---|
| Cash flow: | | |
| Net cash used in operating activities | $(1,229,434) | $(5,398,581) |
| Net cash (used in) provided by investing activities | (199,175) | 8,206 |
| Net cash provided by financing activities | 463,336 | 4,798,220 |

**Year ended December 31, 2017 compared to year ended December 31, 2016**

**Net sales for 2017 and 2016 were as follows:**

| | **2017** | **% of Revenue** | **2016** | **%** | **Increase (Decrease) $** | **% of Change** |
|---|---|---|---|---|---|---|
| Dental | $11,279,886 | 99.98 % | $10,460,752 | 99.80 % | $ 819,134 | 7.83 % |
| Medical | 2,000 | 0.02 % | 21,253 | 0.20 % | (19,253) | -90.59 % |
| Total Sales | $11,281,886 | 100.00 % | $10,482,005 | 100.00 % | $ 799,881 | 7.63 % |

Consolidated revenue for the twelve months ended December 31, 2017 and 2016 were approximately $11.3 million and $10.5 million, respectively. Dental revenue for the twelve months ended December 31, 2017 and 2016 were approximately $11.3 million and $10.5 million, respectively. Dental revenues increased by approximately $819,000 which was principally related to increased handpiece sales in the United States and Canada sales by approximately $2 million in 2017 to 2016. International sales in 2017 decreased by approximately $1.2 million over the same period in 2016 due to a reduction in shipments to Milestone China. The reductions in shipments to Milestone China is due to Milestone China working through inventory purchases from late 2016 and the modification to their business strategy to better serve the China dental market. However, in the domestic market our exclusive distribution agreement with Henry Schein increased domestic sales in 2017 as the product and sales force training has been substantially completed as of December 31, 2017. Medical revenue for the twelve months ended December31, 2017 and 2016 were approximately $2,000 and $21,000, respectively. On June 12, 2017 the company announced that the CompuFlo® Epidural Computer Controlled Anesthesia System received 510(k) marketing clearances from the U.S. Food and Drug Administration (FDA). Milestone is in the process of attending medical device trade shows and attending introductory meetings with medical device distributors within the United States and European markets. The Company’s focus is on marketing its Epidural devices throughout Europe.

**Gross Profit for 2017 and 2016 were as follows:**

| | 2017 | % of Revenue | 2016 | % of Revenue | Increase (Decrease) $ | % of Change |
|---|---|---|---|---|---|---|
| Dental | $7,187,562 | 103.13 % | $6,297,402 | 99.86 % | $ 890,162 | 14.14 % |
| Medical | (218,183 ) | -3.13 % | 9,070 | 0.14 % | (227,253 ) | -2505.55 % |
| Total Sales | $6,969,379 | 100.00 % | $6,306,472 | 100.00 % | $ 662,909 | 10.51 % |

Consolidated gross profit for the twelve months ended December 31, 2017 and 2016 were approximately 62% and 60%, respectively. Dental gross profit for the twelve months ended December 31, 2017 and 2016 were approximately $7.2 million and $6.3 million, respectively. Dental gross margin for the twelve months ended December 31, 2017 was 64%, which increased from 60% for the twelve months ended December 31, 2016. The increase in gross profit relates to the increase in US sales which was offset by special pricing in China to facilitate an increase in market share.

**Selling, general and administrative expenses for 2017 and 2016 were as follows:**

| | 2017 | % | 2016 | % | Increase (Decrease) $ | % of Change |
|---|---|---|---|---|---|---|
| Dental | $3,968,747 | 33.26 % | $4,080,627 | 35.33 % | $(111,880 ) | -2.74 % |
| Medical | 2,046,141 | 17.15 % | 2,716,970 | 23.52 % | (670,829 ) | -24.691 % |
| Corporate | 5,916,063 | 49.59 | 4,752,364 | 41.15 % | 1,163,699 | 24.49 % |
| Total | $11,930,951 | 100.00 % | $11,549,961 | 100.00 % | $380,984 | 3.30 % |

Consolidated selling, general and administrative expenses for the twelve months ended December 31, 2017 and 2016 were approximately $12 million versus $11.5 million, respectively. The increase of approximately $536,000 is predominantly due to the increase in Corporate expenses, as Milestone Scientific began the process of increasing the business platform in the medical segment growth.

**Research and Development for 2017 and 2016 were as follows:**

| | 2017 | % | 2016 | % | Increase (Decrease) $ | % of Change |
|---|---|---|---|---|---|---|
| Dental | $10,251 | 3.76 % | $35,310 | 2.78 % | $ (25,059 ) | -70.97 % |
| Medical | 124,820 | 45.76 % | 509,797 | 40.13 % | (384,977 ) | -75.52 % |
| Corporate | 137,675 | 50.48 % | 725,364 | 57.09 % | (587,689 ) | -81.02 % |
| Total | $272,746 | 100.00 % | $1,270,471 | 100.00 % | $ (997,725 ) | -78.53 % |

Consolidated research and development expenses for the twelve months ended December 31, 2017 and 2016 were approximately $273,000 and $1,270,000, respectively. The decrease is due to reduction in development costs associated with the epidural and intra articular devices.

**Profit (Loss) from Operations for 2017 and 2016 were as follows:**

| | 2017 | % | 2016 | % | Increase (Decrease) $ | % of Change |
|---|---|---|---|---|---|---|
| Dental | $3,127,570 | -59.75 % | $2,096,727 | -32.19 % | $1,030,843 | 49.16 % |
| Medical | (2,389,145) | 45.64 % | (3,217,697) | 49.40 % | 828,552 | -25.75 |
| Corporate | (5,972,743) | 114.11% | (5,392,990) | 82.79 % | (579,753) | 10.75 % |
| Total | $(5,234,318) | 100.00% | $(6,513,960) | 100.00% | $1,279,648 | -19.64 % |

The loss from operations for the twelve months ended December 31, 2017 and 2016 was approximately $5.2 million and $6.5 million, respectively, a decrease of approximately $1.3 million. This decrease is primarily attributable to the increase in Corporate expenses relating to our epidural and intra articular devices in 2017 offset by an increase in gross profit.

**Liquidity and Capital Resources**

At December 31, 2017, Milestone Scientific had cash and cash equivalents of approximately $2.6 million, total current assets of approximately $12 million and working capital of approximately $5.3 million. We believe that our cash on hand, accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-K.

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. For the twelve months ended December 31, 2017 and 2016, we had negative cash flows from operating activities of approximately $1.2 million and $5.4 million, respectively.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in December 2016 and January 2017 provided Milestone Scientific with working capital to continue to develop its medical devices and obtain regulatory approval for one of its medical devices (the June 2017 FDA approval of the epidural device), as well as to aggressively market its dental devices. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, and a reduction in operating expenses. Management believes that the Company will have sufficient cash and liquidity to meet its anticipated obligations over the next twelve-month period following the date of this report.

Now that the *CompuFlo* Epidural System has obtained FDA clearance in the United States (June 2017), the development costs will be reduced in 2018. The FDA clearance will provide the Company with the opportunity to establish distribution in the USA. At the same time, the Company and its parent are looking to establish additional financing opportunity for the Epidural device sales. The intra-articular device will begin the 510K application process later this year. Most of the cost associated with this application will be internal personnel cost and some low level third party review expense.

Milestone Scientific believes that the FDA clearance of its 510(k) application with respect to the *CompuFlo*® Epidural Computer Controlled Anesthesia will provide Milestone Scientific with the opportunity to enter the US medical device market and generate revenues in the future. Milestone Scientific believes that it has sufficient inventory of the epidural devices to satisfy the near-term marketing opportunities.

In February and March 2018 Milestone Scientific hired an Executive VP of Global sales and Marketing and a Vice President of US Sales to fill a significant gap in our commercialization efforts of the *CompuFlo* Epidural System.

Milestone Scientific believes that the June 2016 exclusive distribution agreement with Henry Schein will continue to improve its domestic revenues in 2018. The dental agreement has provided a substantial increase in US and Canada 2017 dental revenue (approximately $2 million). To further reduce Milestone Scientific's expenditures, Milestone Medical is carefully managing expenses related to obtaining FDA clearance for the intra-articular devices. The *CompuFlo* Epidural System received FDA 510K approval in June 2017. By limiting the FDA related expenses and increasing the dental device revenue through the dental distribution agreement, our estimated cash flow projection of the consolidated company and its subsidiaries, management believes that Milestone Scientific will have resources to fund its operations over the next 12 months from the filing date of this Form 10-K.

Our Consolidated Balance Sheets included in this Report reflects a decrease of approximately $1.3 million in current assets from December 31, 2016 to December 31, 2017. This decrease in current assets was primarily due to a reduction in cash ($1 million), accounts receivable from related parties, other receivables and inventory of approximately $2.2 million. This was offset by an increase in accounts receivable, deferred cost, note receivable and prepaid expenses and other current assets of an aggregate of approximately $1.9 million.

In this Report our consolidated balance sheets included reflects increase in current liabilities by approximately $1.1 million from approximately $5.6 million to approximately $6.7 million. The increase is primarily due to a decrease in accounts payable of approximately $364,000, accounts payable related party of approximately $249,000, an increase deferred revenue of approximately $844,000 and an increase in accrued expenses of approximately $850,000.

**Off-Balance Sheet Arrangements**

Milestone Scientific does not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to the financial position or results of operations.

**Contractual Obligations**

The impact of the consolidated contractual obligations at December 31, 2017, expected on the liquidity and cash flows in future periods, is as follows:

| | Total | Less than 1 Year | 1-3 Years | 3-5 Years |
|---|---|---|---|---|
| Operating lease obligations | $313,050 | $150,264 | $162,786 | $ - |
| Purchase obligations (1) | $1,961,718 | $1,546,036 | $415,682 | - |
| Total | $2,274,768 | $1,696,300 | $578,468 | $ - |

(1) Purchase obligations include agreements for the purchase of dental devices.

**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**

Milestone Scientific's Interim Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of Milestone Scientific's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based upon that evaluation, Milestone Scientific's Interim Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of December 31, 2017 are effective to ensure that information required to be disclosed in the reports Milestone Scientific 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 and that such information is accumulated and communicated to Milestone Scientific's management, including the Interim Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

**Management's Annual Report on Internal Control over Financial Reporting**

Milestone Scientific management is responsible for establishing and maintaining internal controls over financial reporting. The internal controls over financial reporting includes those policies and procedures that:

Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles in the United States, and that the receipts and expenditures are being made only in accordance with authorizations of the management and directors; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control instruments, no matter how well designed, have inherent limitations. Therefore, even those instruments determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Milestone Scientific management assessed the effectiveness of its internal control over financial reporting as of December 31, 2017. In making this assessment, management used the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") adopted in 2013. Based on the assessment and the criteria set forth by COSO, management believes that Milestone Scientific maintained effective internal control over financial reporting as of December 31, 2017.

There have been no changes in Milestone Scientific's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone Scientific's last fiscal quarter ended December 31, 2017 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

**Item 9B. Other Information**

None.

**PART III**

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

Milestone Scientific's directors are elected annually by the stockholders and serve for one-year terms until his/her successor is elected and qualified or until such director's earlier death, resignation or removal. The executive officers and key personnel are appointed by and serve at the pleasure of the Board of Directors The current executive officers and directors of Milestone Scientific and their respective ages as of April 2, 2018 are as follows:

| NAME | AGE | POSITION | DIRECTOR SINCE |
|---|---|---|---|
| Leslie Bernhard (1) (2) (3) | 73 | Chairman of the Board and Director | 2003 |
| Leonard Osser | 70 | Interim Chief Executive Office, and Director | 1991 |
| Joseph D'Agostino | 66 | Chief Financial Officer and Chief Operating Officer | |
| Leonard Schiller (1) (2) (3) | 77 | Director | 1997 |
| Michael McGeehan (1) | 52 | Director | 2017 |
| Gian Domenico Trombetta | 57 | Director | 2014 |
| Edward J. Zelnick, M.D. (1) (2) (3) | 72 | Director | 2015 |

1. Member of the Audit Committee

2. Member of the Compensation Committee

3. Member of the Nominating and Corporate Governance Committee

The following are the names of individuals who are not executive officers of Milestone Scientific but are deemed key personnel of Milestone Scientific, their respective ages and positions as of April 2, 2018

| NAME | AGE | POSITION |
|---|---|---|
| Eugene Casagrande, D.D.S. | 73 | Director of Professional Relations |
| Mark Hochman, D.D.S. | 58 | Director of Clinical Affairs |

**Leonard Osser, Interim Chief Executive Officer and Director**

Leonard Osser has been Interim Chief Executive Officer since December 2017. 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 of 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 a 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 was primarily engaged as the principal owner and Chief Executive Officer of U.S. Asian Consulting Group, Inc., a New Jersey-based provider of consulting services specializing in distressed or turnaround situations in both the public and private markets. 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.

**Joseph D'Agostino, Chief Financial Officer and Chief Operating Officer**

Joseph D'Agostino has been Milestone Scientific's Chief Financial Officer since October 2008 and Chief Operating Officer since September 2011. Mr. D'Agostino joined Milestone Scientific in January 2008 as Acting CFO and has over 25 years of finance and accounting experience serving both publicly and privately held companies. A results-oriented and decisive leader, he has specific proven expertise in treasury and cash management, strategic planning, information technology, internal controls, Sarbanes-Oxley compliance, operations and financial and tax accounting. Mr. D'Agostino served as Senior Vice President and Treasurer of Summit Global Logistics, a publicly traded, full service international freight forwarder and customs broker with operations in the United States and China. Previous executive posts also included Executive Vice President and CFO of Haynes Security, Inc., a leading electronic and manned security solutions company serving government agencies and commercial enterprises; Executive Vice President of Finance and Administration for Casio, Inc., the U.S. subsidiary of Casio Computer Co., Ltd., a leading manufacturer of consumer electronics with subsidiaries throughout the world; and Manager of Accounting and Auditing for Main Hurdman's National Office in New York City (merged into KPMG). Mr. D'Agostino is a Certified Public Accountant and holds memberships in the American Institute of CPA's, New Jersey Society of CPA's, Financial Executive Institute, He is a graduate of William Paterson University where he earned a Bachelor of Arts degree in Science.

**Leslie Bernhard, Chairman of the Board**

Leslie Bernhard has served as Milestone Scientific's Chairman of the Board since October 2009 and served as Interim Chief Executive Officer from October 2017 to December 19, 2017. In addition, Ms. Bernhard has also had been serving as an Independent Director (as defined below) of Milestone Scientific since May 2003. Since 2007, Ms. Bernhard has also been serving as an independent director of Universal Power Group, Inc., a global supplier of power solutions. In 1986 she co-founded AdStar, Inc., an electronic ad intake service to the newspaper industry, and served

as its president, chief executive officer and executive director until 2012. Ms. Bernhard holds a BS Degree in Education from St. John's University. Ms. Bernhard's professional experience and background with AdStar and with us, as one of our directors since 2003, have given her the expertise needed to serve as Chairman of the Board, and Chairman of the Audit Committee.

**Gian Domenico Trombetta, Director**

Gian Domenico Trombetta has been a director of Milestone Scientific in May 2014 and the President and Chief Executive Officer of Milestone Scientific's Dental Division (Wand Dental Inc.) since October 2014. He founded Innovest S.p.A 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 a MBA degree from INSEAD-Fontainbleau-France. Mr. Trombetta business background and experience has given him the expertise needed to serve as one of our directors.

**Leonard M. Schiller, Director**

Leonard Schiller has been a director of Milestone Scientific since April 1997. Mr. Schiller has been a partner in the Chicago law firm of Schiller Strauss & Lavin PC since 1977 and since 2002, its President. Mr. Schiller also serves as a director on the boards of Jerrick Media Holdings, Inc. (OTCQB: JMDA), a public media company, since February 2016 and Point Capital, Inc. (OTCQB: PTCI), a business development company, since July 2014. Mr. Schiller's professional experience and background have given him the expertise needed to serve as Chairman of the Compensation Committee and as one of our directors.

**Edward J. Zelnick, M.D., Director**

Edward J. Zelnick, M.D. has been a director of Milestone Scientific since February 2015. Dr. Zelnick has been a medical doctor for over 45 years and has a background in clinical research. Since June 2002 he has been the chief executive officer of Horizon Institute for Clinical Research, a company that recruits test subjects and clinicians for clinical research trials. Dr. Zelnick received a Bachelor of Science degree in chemistry from the University of Pittsburgh in 1966 and his M.D. degree from New York Medical College in 1970. Dr. Zelnick's professional experience and background as a medical doctor and in clinical research, have given him the expertise needed to serve as one of our directors.

**Michael McGeehan**

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 Inc., (subsidiary of Milestone Scientific) a maker of a painless, anesthetic injection system for dentists. 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 background has given him the experience needed to serve as one of our directors.

**Mark Hochman, D.D.S., Director of Clinical Affairs**

Mark Hochman, D.D.S. has served as Milestone Scientific's Director of Clinical Affairs and Director of Research and Development since 1999. He has a Doctor of Dental Surgery with advanced training in the specialties of

Periodontics and Orthodontics from New York University of Dentistry and has been practicing dentistry since 1984. He is a former clinical associate professor at NYU School of Dental Surgery. Recognized as a world authority on Advanced Drug Delivery Instruments, Dr. Hochman has published numerous articles in this area, and shares in the responsibility for inventing much of the technology currently available from Milestone Scientific.

**Dr. Eugene Casagrande, Director of International & Professional Relations**

Since 1998, Eugene Casagrande, D.D.S. has served as Director of International and Professional Relations, charged with pursuing a broad range of clinical and industry-related strategic business opportunities for Milestone Scientific. Dr. Eugene R. Casagrande has practiced Cosmetic and Restorative Dentistry for over 30 years in Los Angeles. He is past president of the California State Board of Dentistry and the Los Angeles Dental Society and is a Fellow of the American and International Colleges of Dentists. Dr. Casagrande was a member of the faculty of the University of Southern California, School of Dentistry. He was also the Executive Director of the Los Angeles Oral Health Foundation and the Program Director of the Los Angeles Pediatric Oral Health Access Program. As the Director of International & Professional Relations for Milestone Scientific for over 19 years, he has published multiple articles and has lectured both nationally and internationally at over 100 dental schools and in over 50 countries on Computer-Controlled Local Anesthesia.

**Director Independence and Committees of the Board**

The Board has determined as of December 19, 2017, Leslie Bernhard, Leonard M. Schiller, Dr. Edward J. Zelnick, and Michael McGeehan (the “Independent Directors”) are independent as that term is defined in the listing standards of the NYSE American. As disclosed above, Leslie Bernhard, Leonard M. Schiller, Dr. Edward J. Zelnick, and Michael McGeehan are members of the Audit Committee and are independent for such purposes. Leslie Bernhard, Leonard M. Schiller, and Dr. Edward J. Zelnick, are members of the Compensation Committee and are independent for such purposes.

In determining director independence, the Board considered the stock awards to the Independent Directors for the year ended December 31, 2017, disclosed in "Item 11 – Executive Compensation – Director Compensation" above, 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.

Milestone Scientific's Board of Directors has established a compensation, audit nominating and corporate governance committees (respectively, "Compensation Committee," "Audit Committee," and "Nominating Committee".) The Compensation Committee reviews and recommends to the Board of Directors the compensation and benefits of all the officers of Milestone Scientific, reviews general policy matters relating to compensation and benefits of employees of Milestone Scientific and administers the issuance of stock options to Milestone Scientific's officers, employees, directors and consultants. All compensation arrangements between Milestone Scientific and its directors, officers and affiliates are reviewed by the Compensation Committee. The Audit Committee meets with management and Milestone Scientific's independent auditors to determine the adequacy of internal controls and other financial reporting matters; all the members are independent directors. The Board of Directors has determined that, Leslie Bernhard qualifies as an Audit Committee Financial Expert pursuant to Item 407(d)(5) of Regulation S-K, Leslie Bernhard is independent, as that term is defined in the listing standards of the NYSE American.

The Nominating Committee has dual responsibilities. The Nominating Committee will assist the board by identifying and recommending individuals qualified to become member of the board. Additionally, the committee will evaluate the size and composition of the board and its members, reviewing governance issues and making recommendations to the board regarding possible changes and reviewing and monitoring compliance with the code of ethics and insider trading policy.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors, and persons 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. Executive 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 furnished 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, 2017.

**Code of Ethics**

Milestone Scientific has adopted a code of ethics that applies to its directors, principal executive officer, principal financial officer and other persons performing similar functions. This code of ethics is filed herewith as an exhibit to this annual report and 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 Chief Financial Officer, Joseph D'Agostino at the principal executive office, located at 220 South Orange Avenue, Livingston, NJ 07039.

**Item 11. Executive Compensation.**

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2017 and 2016 by Milestone Scientific's (i) CEO and (ii) two most highly compensated executive officers other than the CEO who were serving as executive officers at the end of the 2017 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").

**SUMMARY COMPENSATION TABLE**

| Name and Principal Position | Year | Salary | Bonuses | Option Awards (2) | Other Compensation | Total |
|---|---|---|---|---|---|---|
| Leslie Bernhard | | | | | | |
| Interim Chief Executive Officer-Former | 2017 | $50,000 | $29,500 | $- | $ - | $79,500 |
| Daniel Goldberger (3) | | | | | | |
| Chief Executive Officer-Former | 2017 | $68,750 | $- | $- | $ 178,600 | $247,350 |
| Leonard A. Osser (1) (2) | | | | | | |
| Interim Chief Executive Officer and Managing Director of Asian Operations | 2017 | $205,000 | $350,000 | $336,970 | $ 227,311 | $1,119,281 |
| | 2016 | $300,000 | $400,000 | $422,019 | $ 238,030 | $1,360,049 |
| Gian Domenico Trombetta (1) (2) | | | | | | |
| Chief Executive Officer - Wand Dental Inc | 2017 | $280,000 | $180,000 | $- | $ - | $460,000 |
| | 2016 | $279,999 | $160,000 | $221,743 | $ - | $661,742 |
| Joseph D'Agostino (1) (2) | | | | | | |
| Chief Financial Officer | 2017 | $178,700 | $90,000 | $86,650 | $ 27,027 | $382,377 |
| | 2016 | $171,600 | $80,000 | $222,344 | $ 35,144 | $509,088 |

1. Leonard Osser received $350,000, and $400,000 in a performance bonus for the years ended December 31, 2017 and 2016, respectively, of which $175,000 in 2017 and $200,000 in 2016, were deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. In accordance with Mr. Osser's employment agreement, one half of his annual bonus is paid in cash and one half in common stock. On July 10, 2017, Mr. Osser resigned from his positions of Chief Executive Officer. Other compensation represents payments made for health insurance coverage $4,900 and car allowance $7,200, pension payment $203,111. Upon his resignation, Mr., Osser served as Managing Director of Asian Operations, Mr. Osser received $55,000 in compensation and $12,100 in other compensation which is included in this schedule.

Gian Domenico Trombetta received $180,000, and $160,000 in a performance bonus for the years ended December 31, 2017 and 2016, respectively, of which $90,000 in 2017 and $80,000 in 2016, were deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. In accordance with Mr. Trombetta employment agreement, one half of his annual bonus is paid in cash and one half in common stock. Mr. Trombetta elected not to receive the stock option coverage for his 2017 bonus award.

Joseph D’Agostino received $90,000, and $80,000 in a performance bonus for the years ended December 31, 2017 and 2016, respectively, of which $45,000 in 2017 and $40,000 in 2016, were deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. In accordance with Mr. D’Agostino's employment agreement, one half of his annual bonus is paid in cash and one half in common stock. Other compensation represents payments made for health insurance coverage $18,027 and car allowance $9,000.

2. 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 years ended December 31, 2017 and 2016, which is located on pages F-9 through F-14 of this Report. Compensation cost is generally recognized over the vesting period of the award. See the table on page 39 entitled Outstanding Equity Awards at December 31, 2017.

3. On October 2, 2017, Milestone Scientific accepted the resignation of the then CEO, Daniel Goldberger. Included in other compensation is $175,000 for severance per the agreement with Mr. Goldberger dated February 2018 and $3,600 related to health insurance and car allowance.

**Employment Contracts**

In July 2017, Milestone Scientific entered into a three-year employment agreement with Daniel Goldberger to serve as President and Chief Executive Officer of Milestone Scientific. Under the agreement, Mr. Goldberger would receive base compensation of $300,000 per annum and may additionally earn annual bonuses of up to an aggregate of $400,000, payable one half in cash and one half in Milestone Scientific common stock ("Bonus Shares") contingent upon achieving performance benchmarks periodically set for each year by the compensation committee of the Board. In addition to any such shares of common stock, Mr. Goldberger was entitled to receive stock options ("Bonus Options") to acquire twice the number of any Bonus Shares earned, pursuant to a non-qualified stock option grant agreement under Milestone Scientific's then existing equity compensation plan. The Bonus Options had a five-year term and were to vest in equal annual installments on each of the first, second and third anniversary of the grant date, subject to continued employment on such vesting date and accelerated vesting upon the occurrence of certain events. The exercise price of the Bonus Options was based on the fair market value of per share of common stock on the date of grant.

In July 2017, Milestone Scientific entered into a ten-year new employment agreement with Leonard Osser, who previously served as the Company's President and Chief Executive Officer, to serve as Managing Director – China Operations. This new agreement provides for annual compensation of $300,000 consisting of $100,000 in cash and $200,000 in the Company's common stock valued at the average closing price of the Company's common stock on the NYSE or such other market or exchange on which its shares are then traded during the first fifteen (15) trading days of the last full calendar month of each year during the term of this agreement. This agreement supersedes all prior employment agreements between Mr. Osser and Milestone Scientific. 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 July 2017, Mr. Osser also resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive $100,000 per year for Mr. Osser's services.

In July 2017, Milestone Scientific granted to Mr. Goldberger non-qualified stock options to purchase 921,942 shares of common stock at an exercise price of $2.00 per share. Those options had a five-year term and were to vest in equal annual installments on each of the first, second and third anniversaries of the grant date, subject to his continued employment on the vesting date and accelerated vesting upon the occurrence of certain events.

On October 5, 2017, Milestone Scientific Inc. announced that Daniel Goldberger had resigned as President and Chief Executive Officer effective October 2, 2017, upon which the previously described stock options granted to him in July 2017 terminated prior to vesting (see Note M).

On October 5, 2017, Milestone Scientific also announced the appointment of Leslie Bernhard, the Company's current Chairman of the Board, as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer. In connection with her appointment to serve as the Company's Interim Chief Executive Officer, Ms. Bernhard was paid an annual salary of $200,000 received a one-time bonus of 100,000 shares of the Company's Common Stock. In addition, at the completion of her service as Interim Chief Executive Officer, Ms. Bernhard shall be entitled to receive a cash bonus in an amount to be determined by the Board of Directors at that time. On December 19 ,2017 the Board of Directors appointed Leonard Osser Interim Chief Executive Officer, replacing Leslie Bernhard. Ms. Bernhard negotiated a one-time bonus of 25,000 shares of Milestone Scientific stock for her services as Interim Chief Executive Officer in-lieu of 100,000 shares.

On December 19 ,2017 the Board of Directors appointed Leonard Osser Interim Chief Executive Officer, replacing Leslie Bernhard. Mr. Osser will enter into a similar employment contract that he received during 2017 before he resigned his position as CEO of the company. Mr. Osser placed on hold his position as Managing Director-China Operations and his consulting agreement with Milestone Medical to rejoined Milestone Scientific Inc. as Interim Chief Executive Officer.

**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 of Directors, 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, the 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 advice 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 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. In addition, Milestone Scientific reviews the compensation practices of 28 other companies. 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 at December 31, 2017**

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 at December 31, 2017.

| | Options Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|
| **Name** | **Number of Securities Underlying Unexercised Options (#) Exercisable (1)** | **Number of Securities Underlying Unexercised Options (#) Unexercisable (1)** | **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)** |
| Leonard Osser | 73,333 | - | $ 1.49 | 11/20/2019 | 886,866 | $1,031,762 |
| | 248,448 | - | $ 1.65 | 12/31/2018 | | |
| | 185,186 | - | $ 2.23 | 11/20/2019 | | |
| | 44,699 | 12,607 | $ 3.89 | 6/23/2020 | | |
| | 46,105 | 36,883 | $ 1.72 | 2/4/2021 | | |
| | 95,238 | 76,191 | $ 2.09 | 11/10/2021 | | |
| | 20,497 | 41,615 | $ 1.72 | 2/4/2021 | | |
| | 112,323 | 224,647 | $ 1.14 | 1/18/2022 | | |
| **Total** | **825,829** | **391,943** | | | **886,866** | **1,031,762** |
| Gian Domenico Trombetta | 73,767 | 59,013 | $ 1.72 | 2/4/2021 | 116,079 | $240,066 |
| | 32,798 | 66,580 | $ 1.61 | 1/8/2022 | | |
| **Total** | **106,565** | **125,593** | | | **116,079** | **240,066** |
| Joseph D'Agostino | 66,666 | - | $ 1.50 | 12/31/2018 | | |
| | 150,000 | - | $ 2.09 | 11/11/2019 | 191,046 | $361,378 |
| | 49,261 | - | $ 2.03 | 11/20/2019 | | |
| | 73,967 | 59,173 | $ 1.72 | 2/4/2021 | | |
| | 16,397 | 33,292 | $ 1.61 | 1/8/2022 | | |
| | 28,883 | 57,767 | $ 1.04 | 1/18/2022 | | |
| **Total** | **385,174** | **150,232** | | | **191,046** | **$361,378** |

1. Represents stock option grants at fair market value on the date of grant.

2. Issuance of the shares of common stock has been deferred until the termination of his employment with Milestone Scientific in accordance with the terms of his respective employment arrangement.

3. Based on the closing price per share of $1.18 as reported on the NYSE American on December 31, 2017.

**Director Compensation**

| NAME | Fees Earned or Paid in Cash ($) | Bonus Paid in Stock | Total ($) |
|---|---|---|---|
| Leslie Bernhard (1) | $38,500 | $96,000 | $134,500 |
| Leonard Schiller | $36,000 | $66,500 | $102,500 |
| Edward J. Zelnick, M.D. | $36,000 | $26,600 | $62,600 |
| Michael McGeehan | $9,000 | $- | $9,000 |

1. Includes $8,500 July thru December 2017 compensation for serving as Chairman of the Audit Committee.

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

The following table, together with the accompanying footnotes, sets forth information, as of April 2, 2018 , 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 officers of Milestone Scientific as a group:

| Names of Beneficial Owner (1) | Shares of Common Stock Beneficially Owned (2) | | Percentage of Ownership |
|---|---|---|---|
| Executive Officers and Directors | | | |
| Leonard Osser | 4,183,921 | (3) | 12.08% |
| Joseph D'Agostino | 1,550,679 | (4) | 4.48% |
| Leslie Bernhard | 75,000 | (5) | - |
| Leonard Schiller | 235,158 | (6) | - |
| Edward J. Zelnick, M.D. | 28,750 | (7) | - |
| Michael McGeehan | 1,000 | (8) | - |
| Gian Domenico Trombetta | 6,262,768 | (9) | 18.09% |
| All directors & executive officers as group (6 persons) | 12,361,276 | | 35.70% |
| K. Tucker Andersen | 3,292,003 | (10) | 9.51% |
| Tom Cheng | 1,712,599 | | 4.95% |
| Debra Ginsberg | 1,695,000 | (11) | 4.90% |
| * Less than 1% | | | |

1. The addresses of the persons named in this table are as follows: Leonard Osser, Joseph D'Agostino, Gian Domenico Trombetta, Leslie Bernhard and Edward Zelnick, M.D. are at 220 South Orange Avenue in, New Jersey 07039; Leonard M. Schiller, c/o Schiller, Klein & McElroy, P.C., 33 North Dearborn Street, Suite 1030, Chicago, Illinois 60602; K. Tucker Andersen, c/o Above All Advisors, 61 Above All Road, Warren, CT 06754, Tom Cheng, c/o United Systems 18725 E. Gale Ave Suite 221, City of Industry, CA 91748 and Debra Ginsberg, 5 Bay Ridge Road Key Largo, FL 33037.

2. A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from April 2, 2018, 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 April 2, 2018 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 April 2, 2018 and the number of shares underlying options exercisable and convertible securities convertible

within 60 days from April 2, 2018 held by the beneficial owner

3. Includes 2,283,706 shares held by Mr. Osser or his family, 1,055,350 shares to be issued at the termination of his employment agreement, and 844,865 shares subject to common stock options.

4. Includes 931,137 shares held by Mr. D'Agostino, 234,371 shares to be issued at the termination of his employment, and 385,171 shares subject to common stock options. w.

5. Includes 75,000 shares held by Ms. Bernhard.

6. Includes 229,533 shares held by Mr. Schiller and 5,625 shares subject to common stock warrants.

7. Includes 25,000 shares held by Dr. Zelnick and 3,750 shares subject to common stock warrants.

8. Includes 1,000 shares held by Mr. McGeehan

9. Includes 202,617 shares to be issued at the termination of his employment, 106,565 shares subject to common stock options and 5,953,586 shares held directly by BP4 S.r.l. ("BP4") of which 2,953,586 shares are issuable upon the conversion of $7 million of preferred stock at $2.37 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.

10. Includes an aggregate of 1,279,301 shares of common stock underlying outstanding options, 1,193,990 shares of common stock issuable upon termination of employment and 2,953,586 shares of common stock issuable upon the conversion of $7 million of preferred stock at $2.37 per share.

11. The information with respect to their 5% shareholder has been derived from form 13G submitted by the owner of shares to the SEC on March 20, 2018, reporting beneficial ownership as of December 31, 2017.

**Securities Authorized for Issuance under Equity Compensation Plans**

**Equity Compensation Plan Information**

The following table summarizes, as of December 31, 2017, the (i) options granted under the Milestone Scientific 2004 Stock Option Plan (the “2004 Plan”) and (ii) options granted under the Milestone Scientific 2011 Equity Compensation Plan (f/k/a Milestone Scientific 2011 Stock Option Plan) (the “2011 Plan”). The shares covered by outstanding options and warrants are subject to adjustment for changes in capitalization, stock splits, stock dividends and similar events. No other equity compensation has been issued.

| Equity compensation plan approved by stockholders | Number of Securities to | Weighted-average exercise price of | Number of securities |
|---|---|---|---|

| | be issued upon exercise of outstanding options and warrants | outstanding options and warrants | remaining available for future issuance under equity compensation plan |
|---|---|---|---|
| Grants under our 2004 Stock Option Plan (1) | 73,333 | $ 1.49 | - |
| Grants under our 2011 Stock Option Plan (2) | 1,912,002 | $ 1.73 | 1,001,889 |
| **Total** | **1,985,335** | | **1,001,889** |

1. The 2004 Plan, as amended, provided for awards of options up to a maximum 750,000 shares of Milestone Scientific's common stock and expired in July 2014. Options were granted to employees, officers, directors and consultants of Milestone Scientific for the purchase of common stock of Milestone Scientific at a price not less than the fair market value of the common stock on the date of the grant. In general, options awarded under the 2004 Plan became exercisable over a three-year period from the grant date and expire five years after the date of grant. No options were exercised in 2017 or 2016.

2. The 2011 Plan, as amended, provides for awards of restricted common stock and options to purchase up to a maximum 4,000,000 shares of common stock and expires in June 2021. 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. For the year ended December 31, 2017, 83,333 shares were exercised.

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

In 2016, Milestone Scientific entered a three-year consulting agreement with K. Tucker Anderson to provide business and strategic services to Milestone Scientific. The fee for these services are $100,000 per year which is paid in shares of common stock on a quarterly basis, valued at the closing price per share of common stock on the last trading day of each quarter.

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Milestone Scientific purchased $2,146,108 and $3,025,249 for the twelve months ended December 31, 2017 and 2016, respectively. Milestone Scientific owed $985,678 and $1,235,052 to this manufacturer as of December 31, 2017 and 2016, respectively

Milestone Scientific had $2,071,000 of related party sales of handpieces and devices to Milestone China and Milestone China's agent for the twelve months ended December 31, 2017. Milestone Scientific had $3,425,000 of related party sales of handpieces and devices to Milestone China for the twelve months ended December 31, 2016. As of December 31, 2017, and 2016, Milestone Scientific recorded deferred revenues of $1,725,450 and $1,001,800, respectively, and deferred costs of $1,109,611 and $620,041, respectively, associated with sales to Milestone China. As of December 31, 2017, and 2016, Milestone China's agent owed $1,725,450 and $2,714,600, respectively, to Milestone Scientific which is included in related party accounts receivable on the condensed consolidated balance sheets.

In August 2016, a stockholder of Milestone Scientific entered a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were $100,000 for each of the twelve months ended December 31, 2017 and 2016.

In January 2017, Milestone Scientific entered into a 12-month agreement with Innovest S.p.A. to provide consulting services. This agreement will renew for successive 12-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were $80,000 for the twelve months ended December 31, 2017. This agreement is expected to continue into 2018.

**Item 14. Principal Accounting Fees and Services**

Effective July 18, 2016, our Audit Committee engaged Friedman LLP ("Friedman") to replace Baker Tilly Virchow Krause, LLP ("Baker Tilly") as our principal accounting firm. The aggregate fees billed by our principal

accounting firms for the years ended December 31, 2017 and 2016 are as follows:

| Audit fees* | 2017 | 2016 |
|---|---|---|
| Audit Fees and Audit Related fees | $244,300 | $291,500 (1) |
| Tax Fees | 13,854 | 30,000 |
| Total Fees | $258,154 | $321,500 |

* Includes 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-Qs or services that are reasonably related to the performance of the audit or normally provided in connection with statutory and regulatory filings.

(1) The audit fees in 2016 includes $180,000 of fees billed by Friedman and $111,500 of fees billed by Baker Tilly.

**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 designees 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**

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

Schedules are omitted because the information required is not applicable or the required information is shown in the consolidated financial statements or notes thereto.

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.

| Exhibit No | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of Milestone filed on September 6, 2013 (11) |
| 3.2 | Form of Certificate of Designation filed on April 18, 2014 (12) |
| 3.3 | Certificate of Correction to the Certificate of Designation filed on May 12, 2014 (13) |
| 3.4 | By-laws of Milestone (1) |
| 4.1 | Specimen stock certificate (2) |
| 4.2 | Form of warrant agreement, including form of warrant (4) |
| 4.3 | Form of Common Stock Purchase Warrant issued in the 2016 Public Offering (16) |
| 10.1 | Lease dated November 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (3) |
| 10.2 | Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (4) |
| 10.4 | Employment Agreement with Leonard Osser, dated September 1, 2009** (6) |
| 10.5 | 2011 Equity Compensation Plan (7) |
| 10.6 | Amendment to the Employment Agreement with Leonard Osser, dated March 6, 2013** (11) |
| 10.7 | Master Supply and Distribution Agreement, dated July 3, 2013, between Milestone Scientific Inc and Tri-anim Health Services, Inc (9) |
| 10.8 | Amendment to the Employment Agreement with Leonard Osser, effective March 17, 2014** (10) |
| 10.9 | Agreement with Mark Hochman, dated July 2015 (13) |
| 10.1 | Investment Agreement, dated April 15, 2014, between Milestone Scientific Inc. and BP4 S.p.A. (12) |
| 10.11 | Exclusive Distribution and Supply Agreement, dated as of June 20, 2016, among Milestone Scientific Inc., Wand Dental, Inc. and Henry Schein, Inc. (14) |

| | |
|---|---|
| 10.12 | Amended and Restated Employment Agreement, dated December 1, 2016, between Wand Dental Inc. and Gian Domenico Trombetta (15) |
| 10.13 | Final Form of Asset Purchase Agreement, dated June 2, 2017, among APAD Octrooi B.V., APAD B.V., and Milestone Scientific Inc. (17) |
| 10.14 | Final form of the Memorandum of Agreement, dated June 6, 2017, between Solee Science & Technology U.S.A. Ltd. and Milestone Scientific Inc. (18) |
| 10.15 | Final form of the Promissory Note, dated June 6, 2017, in the principal amount of $1,275,000 made by Solee Science & Technology U.S.A. Ltd. to Milestone Scientific Ltd. (18) |
| 10.16 | Final form of the Stock Option Agreement, dated June 6, 2017, Solee Science & Technology U.S.A. Ltd. and Milestone Scientific Inc. (18) |
| 10.17 | New Employment Agreement between Milestone Scientific Inc. and Leonard Osser dated as of July 10, 2017. (19) |
| 10.18 | Employment Agreement between Milestone Scientific Inc. and Daniel Goldberger dated as of July 10, 2017. (19) |
| 10.19 | Covenant Agreement between Milestone Scientific Inc. and Daniel Goldberger dated and effective as of July 10, 2017. (19) |
| 10.20 | Consultant Agreement between Milestone Medical Inc. and U.S. Asian Consulting Group, LLC dated as of July 10, 2017. (20) |

| | |
|---|---|
| 21.1 | List of Subsidiaries (12) |
| 23.1 | Consent of Friedman, LLP* |
| 23.2 | Consent of Baker Tilly Virchow Krause, LLP* |
| 31.1 | Rule 13a-14(a) Certification-Chief Executive Officer* |
| 31.2 | Rule 13a-14(a) Certification-Chief Financial Officer* |
| 32.1 | Section 1350 Certifications-Chief Executive Officer*** |
| 32.2 | Section 1350 Certifications-Chief Financial Officer*** |
| 101.INS | XBRL Instance Document* |
| 101.SCH | XBRL Taxonomy Extension Schema Document* |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document* |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document* |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document* |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document* |

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* 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 Registration Statement on Form SB-2 No. 333-92324.
2) Incorporated by reference to Amendment No. 1 to Milestone Scientific's Registration Statement on Form SB-2 No. 333-92324.
3) Incorporated by reference to Milestone Scientific's Form 10-KSB for the year ended December 31, 1996.
4) Incorporated by reference to Milestone Scientific's Form 10-KSB for the year ended December 31, 2004.
5) Incorporated by reference to Milestone Scientific's Registration Statement on Form S-2 No. 333-110367, Amendment No. 5.
6) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2009.
7) Filed as Appendix A to Milestone Scientific's Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.
8) Incorporated by reference to Milestone Scientific's 10-K for the year ended December 31, 2014.
9) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on July 9, 2014.
10) Incorporated by reference to Milestone Scientific's Form 10-Q filed with the SEC on May 13, 2014.
11) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2013.
12) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on April 18, 2014.
13) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2015.
14) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on June 30, 2016.
15) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on December 2, 2016.
16) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on December 16, 2016.
17) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on June 2, 2017.
18) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on June 7, 2017.
19) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on July 10, 2017.
20) Incorporated by reference to Milestone Scientific's Form 10-Q filed with the SEC on August 14, 2017.

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**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/ Leonard Osser
Interim Chief Executive Officer
(Principal Executive Officer)

Date: April 2, 2018

In accordance with the Exchange Act, 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 |
|---|---|---|
| /s/ Leonard Osser<br>Leonard Osser | April 2, 2018 | Interim Chief Executive Officer<br>(Principal Executive Officer) |
| /s/ Joseph D'Agostino<br>Joseph D'Agostino | April 2, 2018 | Chief Financial Officer and Chief Operating Officer<br>(Principal Financial Officer) |
| /s/ Leslie Bernhard<br>Leslie Bernhard | April 2, 2018 | Chairman and Director |
| /s/ Gian Domenico Trombetta<br>Gian Domenico Trombetta | April 2, 2018 | Director |
| /s/ Edward J. Zelnick, M.D.<br>Edward J. Zelnick, M.D. | April 2, 2018 | Director |
| /s/ Leonard Schiller<br>Leonard Schiller | April 2, 2018 | Director |
| /s/ Michael McGeehan | April 2, 2018 | Director |

Michael
McGeehan

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**REPORT INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the Years ended December 31, 2017 and 2016**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and

Stockholders of Milestone Scientific, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Milestone Scientific, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, statement of changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Friedman LLP

We have served as the Company's auditor since 2016

East Hanover, New Jersey

April 2, 2018

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | $2,636,956 | $3,602,229 |
| Accounts receivable, net | 1,535,513 | 802,384 |
| Accounts receivable from related party | 1,725,450 | 2,714,600 |
| Other receivable | - | 10,000 |
| Notes receivable from financing transaction, short term | 500,000 | - |
| Prepaid expenses and other current assets | 436,410 | 291,929 |
| Deferred cost related party | 1,109,671 | 620,041 |
| Inventories net | 3,379,209 | 4,602,719 |
| Advances on contracts | 697,192 | 700,900 |
| Total current assets | 12,020,401 | 13,344,802 |
| Furniture, fixtures & equipment net | 141,760 | 159,026 |
| Patents, net | 2,789,748 | 660,454 |
| Notes receivable from financing transaction long term | 650,000 | - |
| Other assets | 26,878 | 17,355 |
| Total assets | $15,628,787 | $14,181,640 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | $977,623 | $1,341,207 |
| Accounts payable related party | 985,678 | 1,235,052 |
| Accrued expenses and other payables | 2,287,908 | 1,436,262 |
| Deferred profit, related party | 751,500 | 630,990 |
| Deferred revenue, related party | 1,725,450 | 1,001,800 |
| Total current liabilities | 6,728,159 | 5,645,311 |
| Deferred gain from financing transaction | 1,400,000 | - |
| Total liabilities | 8,128,159 | 5,645,311 |
| Commitments and Contingencies | | |
| Stockholders' Equity | | |
| Series A convertible preferred stock, par value $.001, authorized 5,000,000 shares, and 7,000 shares issued and outstanding as December 31, 2017 and 2016. | 7 | 7 |
| Common stock, par value $.001; authorized 50,000,000 shares; 33,191,571 shares issued, 1,401,247 shares to be issued and 33,158,238 shares outstanding as of December 31, 2017; 30,457,224 shares issued, 1,270,481 shares to be issued and 30,423,891 shares outstanding as of December 31, 2016 | 34,593 | 31,720 |
| Additional paid-in capital | 86,689,084 | 82,761,503 |
| Accumulated deficit | (78,568,284) | (73,381,491) |
| Treasury stock, at cost, 33,333 shares | (911,516) | (911,516) |
| Total Milestone Scientific Inc. stockholders' equity | 7,243,884 | 8,500,223 |

| | | |
|---|---|---|
| Noncontrolling interest | *256,744* | *36,106* |
| Total equity | *7,500,628* | *8,536,329* |
| Total liabilities and stockholders' equity | $*15,628,787* | $*14,181,640* |