MILESTONE SCIENTIFIC INC.
Form 10-K
April 01, 2019

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, 2018

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3545623**

State or other jurisdiction of Incorporation or organization (I.R.S. Employer Identification No.)

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

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

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

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

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging Growth Company	

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

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

As of June 29, 2018, 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 $15,368,647. This amount is based on the closing price of $.79 per share of the registrant's common stock as of such date, as reported on the NYSE American. As of March 29, 2019, the registrant has a total of 40,855,720 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 its business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific. Although Milestone Scientific believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. Considering the significant uncertainties inherent in the forward-looking statements included herein, 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.

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. 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.

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, used in various dental injections, with specific applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections.

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 re-branded 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-ligamentary 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 dentists routinely give but can provide them virtually pain free and with numerous clinical advantages. 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, US territories, Canada and in 60 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 *CompuDent*® Wand/STA system later re-branded commercially as the *Wand /STA* 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 CompuDent® and Wand/STA System also includes a disposable injection handpiece that is extremely comfortable, light and easy to use, providing for precise tactile control during the injection, an electro-mechanical (computer-controlled) fluid delivery instrument and the ability to record data from the injection event. The pencil grip used with the handpieces provides the practitioner with enhanced tactile sense and accurate control and allows bi-directional rotation, eliminating needle deflection, resulting in 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; and

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

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.

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

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

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 System in South America, summarized the results of a recent independent, investigator-led clinical study evaluating the use of Milestone's *CompuFlo* Epidural System 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.

In November 2018, a new clinical study published in the International Journal of Obstetric Anesthesia that finds the *CompuFlo* Epidural System to be successful in objectively identifying the epidural space—even in difficult patients. Accurate epidural space identification can build physician and resident confidence while reducing the number of attempts, poor catheter placement and accidental dural punctures that can be costly to the hospital and painful for the patient.

In January 2019, the Company announced the results of a four hundred patient clinical trial by researchers from the University of Miami, University of Texas and Northwestern University, and two prominent California-based pain clinics. Published-Ahead-of-Print in Anesthesia & Analgesia (the official Journal of the International Anesthesia Research Society), the randomized, controlled study compared the effectiveness of the *CompuFlo* Epidural System in labor and delivery and chronic pain management, where loss of resistance and fluoroscopy are the current standards of care. The *CompuFlo* Epidural System was found to be ninety-nine percent successful in objectively identifying the epidural space even in challenging patients with a higher body mass index.

In February 2019, the company announced a new 120-patient clinical study published in Anesthesiology Research & Practice that verifies the *CompuFlo* Epidural System consistently differentiates false loss of resistance from true loss of resistance during epidural placement. In all cases where the *CompuFlo* Epidural System's pressure measurements were used to objectively identify the epidural space, the block was performed successfully with no complications.

In February 2019, the Company announced Ospedale "Pugliese Ciaccio" di Catanzaro is the first hospital in Italy to use the *CompuFlo* Epidural System for all epidurals in labor and delivery. For a local hospital performing a limited number of epidurals, the *CompuFlo* Epidural System offers a real-time, objective tool for accurate epidural space identification to help reduce failure rates and accidental dural punctures that can require further treatment and interventions.

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

Another platform extension utilizing our DPS Dynamic Pressure Sensing technology platform and *CompuFlo Epidural* 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 organs, 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* Epidural 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 a legally marketed devices. The original 510K filed with FDA expired in January 2019. We intend to submit a new 510(k) application in 2019 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 owned 40% by Milestone Scientific. 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 not 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 regulatory process and, if approved 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

Epidural 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, US territories, Canada and in 60 other 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 were 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, 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. In April 2018, Milestone Scientific entered into a Release, Assignment and Termination Agreement (the "Termination Agreement") with the issuer of the promissory note, pursuant to which, Milestone Scientific repaid the $250,000 payment made by the issuer and the issuer returned the Milestone China Shares to Milestone Scientific and cancelled the promissory note. Because of the Termination Agreement and related repayment made by Milestone Scientific, the Company derecognized the outstanding note receivable balance of $1,150,000 and the related deferred gain from financing transaction of $1,400,000. No gain or loss was recognized on the transaction.

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 were 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

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the *CompuFlo* Epidural System. In June 2017, the FDA approved the *CompuFlo* Epidural System for epidural injections. Milestone Scientific is in the process of meeting with medical device distributors within the United States and foreign markets. Milestone Scientific's immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA Office of Device Evaluation, we filed a new 510(k) application for the device in June 2018. In August 2018, the FDA provided Milestone Scientific with a list of questions on the intra-articular 510(k) application filed in June 2018. Due to the delay in responding to FDA questions Milestone Scientific will be required file a new 510(K) application in 2019.

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. In October 2018, Milestone Medical signed a Distributor Agreement in the U.S. This agreement provides that this Distributor will purchase and hold an inventory of the *CompuFlo* Epidural System and disposables for sale. At this time there have been no minimum purchase established with the Distributor. The Distributor identified above purchased five *CompuFlo* Epidural Systems and disposables after executing the Agreement.

We have entered into a limited number of distributor arrangements in Europe and the Middle East for our *CompuFlo* Epidural System. Our distribution strategy is initially aimed at having KOLs use and accept the device and initiates 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, related party, 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

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

Milestone Scientific's devices compete based on their performance characteristics and the benefits provided to the 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, Dentapen from Septodant, the Calajet from Aseptico, 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 1990's, 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 Calajet 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, we believe that without a substantial distribution network this instrument will have a difficult time to be successful in the USA.

The Dentapen from Septodent is the newest competitor in the market. This device is manufactured in Europe and began marketing in the USA in 2018. This device is priced similar to Wand/STA, but at this time, to our knowledge, it is slow to attract viable distribution 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 maintain an effective distribution network with a strong marketing plan. Any new products must comply with applicable regulatory authorities before they may be marketed. Milestone Scientific cannot assure that it can compete successfully, that competitors will not develop technologies or products that render our products less marketable or obsolete, or, that Milestone Scientific will succeed in improving its existing products, effectively develop new products, or obtain required regulatory approval 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

System 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 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 the 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, we believe that 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 System, allowing such product to be marketed in most European countries and many other countries accepting CE approved devices. In April 2017, Milestone Scientific obtained regulatory approval to sell the *CompuFlo* Epidural System and its handpieces in Australia. As of May 2014, the *Wand/STA* System was approved for sale in China. In March 2018 Milestone Scientific obtained regulatory approval to market the *CompuFlo* Epidural System in Canada.

Employees

As of December 31, 2018, the Company had a total 16 full-time employees including 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 filing. 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 evaluated 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 $8.0 million and $5.2 million for the years ended December 31, 2018 and 2017, respectively. Overall, at December 31, 2018, we had an accumulated deficit of approximately $86 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 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

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

The report of our independent auditors on our consolidated financial statements for the period ended December 31, 2018 included an emphasis of matter paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our auditors' doubts are based on our recurring losses from operations and working capital deficit. Our ability to continue as a going concern will be determined by our ability to generate sufficient revenues from the sale of our products to sustain our operations and/or raise additional capital in the form of debt or equity financing. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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, 2018 and 2017, net cash flow used in operations was approximately $1.6 million and approximately $1.2 million, respectively. We expect to continue to spend substantial amounts on commercialization activities, including the commercialization of our 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 products and disruptions at the manufacturing facility of our manufacturers 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 manufacturers of our products. We have one manufacturer of the handpieces for our devices which is under a long-term contract. We have a single manufacturer manufacturing our devices. Our current arrangement with our manufacturers is on a purchase order by purchase order basis. As a result, we do not have price protection or a supply commitment for our devices or handpieces. If either manufacturer insists on a material change in terms or determines to discontinue manufacture of our products, it could have an adverse effect on our financial condition and results of operation

An operational disruption in the facility of the manufacturer of our handpieces or 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 products.

If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements.

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 Wand Dental has informal arrangements with the manufacturer of the Wand/STA Instrument, *CompuDent*, *CompuMed*, *CompuFlo* Epidural System, 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 been supplied by the manufacturer of the Wand/STA Instrument, *CompuDent*, *CompuMed*, *CompuFlo* Epidural System 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 of termination of the relationship or otherwise, 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, preliminary or permanently prohibit us, our licensees, if any, and our customers from making, using, selling, offering to sell or importing one or more of our products or using our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

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

In 2018, export sales outside of the United States made up approximately 50% of our total sales, and we sell our products to customers in approximately 62 countries and US territories . We have exposure to risks of operating in many foreign countries, including:

- fluctuations in foreign currency exchange rates, could increase the end user cost for instruments;
- restrictions on, or difficulties and costs associated with, the currency exchange from foreign countries to obtain 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; and
- 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 34.73% of the issued and outstanding shares of common stock. As a result, they can exercise substantial control over our affairs and corporate actions requiring stockholder approval, including electing directors, selling all or substantially all our assets, merging with another entity or amending our certificate of incorporation. This control could delay, deter or prevent a change in control and could adversely affect the price that investors might be willing to pay in the future for Milestone Scientific's securities. In addition, because of the concentration of ownership of our shares of common stock, our stockholders may from time to time, observe instances where there may be less liquidity in the public markets for our securities.

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, 2018. 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 2018 and 2017, 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 in 2018 and 2017, respectively, and the cost is expected to continue in 2019.

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 33,859,034 outstanding shares of common stock at December 31, 2018, 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. As of December 31, 2018, we have sold $3,435,775 (2,452,900 shares) of common stock under that registration statement. Subsequent to December 31, 2018, in February 2019 we issued 6,282,400 shares and 1,570,600 warrants to purchase common shares under our S-3

registration statement. Additionally, in a private placement we issued 714,286 restricted common shares and 178,571 warrants to purchase common stock. 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 de-listed. If our stock were no longer listed on NYSE American, the liquidity of our securities likely would be impaired.

Our common stock currently trades on the NYSE American under the symbol “MLSS”. If we fail to adhere to NYSE American's strict listing criteria, including with respect to stock price, our market capitalization and stockholders’ equity, our stock may be de-listed. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. Any failure at any time to meet the continuing NYSE American listing requirements could have an adverse impact on the value of and trading activity in our common stock.

Currently we are not in compliance with NYSE America Exchange, Stockholder Equity listing requirements. We filed a plan to regain compliance in December 2018, which the NYSE American Exchange has accepted. Under the plan, we will review our progress to regain compliance with the staff of the Exchange on a periodic timetable during the period covered by the plan. Failure to adhere to the plan or regain compliance status with NYSE America Exchange requirements will result in the Company's shares being delisted from NYSE American Exchange.

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. 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”. The following table sets forth the high and low sales prices of Milestone’s common stock for the periods presented

	High	Low	2017	High	Low
2018					
First Quarter	$1.19	$0.72	First Quarter	$1.65	$1.00
Second Quarter	$0.94	$0.65	Second Quarter	$1.80	$1.20
Third Quarter	$0.89	$0.71	Third Quarter	$1.55	$1.08
Fourth Quarter	$0.75	$0.28	Fourth Quarter	$1.60	$0.91

Holders

As of March 29, 2019, we had approximately 91 stockholders of record of our common stock. We believe that we have approximately 2,085 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, 2018, Milestone Scientific issued a total of 422,504 shares of its common stock as follows:

25,000 shares to the Chairman of the Board with a total value of $29,500;
47,402 shares to an employee for compensation with a total value of $45,000; and
an aggregate of 350,102 shares to consultants for services rendered with a total value of $289,750

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 common stock and in April 2018 issued an additional 244,959 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 there-under. 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.

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, US territories, Canada, and in over 58 other countries abroad. 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 Europe. There have been five medical instruments sold in the United States in 2018 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 November 20, 2018, Milestone Scientific Inc. received a letter from NYSE American LLC (the "Exchange") stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the "Company Guide").On December 20, 2018, the Company submitted a plan of compliance (the "Plan") to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020.

On January 24, 2019, the Company received a letter from the Exchange stating that the Company's Plan has been accepted by the Exchange. The Company is still not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide and its listing on the Exchange is being continued pursuant to an extension granted by the Exchange. If the Company is not in compliance with the continued listing standards by May 20, 2020, or if the Company does not make progress consistent with the Plan, the Exchange will initiate delisting procedures as appropriate. The Company may appeal a staff delisting determination in accordance with Section 10 and Part 12 of the Company Guide.

In 2018, we remained focused on advancing efforts to achieve our three primary objectives; in our Medical sector; those being:

Identify distributors in the United States for the Epidural instruments, now that FDA clearance has been received;
Worldwide distribution of the *CompuFlo* Epidural Computer Controlled Anesthesia System; and
Complete the Cosmetic device and obtain European Regulatory Approve (CE market clearance).

Wand STA Dental 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

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.

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 sale's specialists. Specifically, up to 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 are currently in the field selling the instrument.

Henry Schein also plans to increase the number of exclusive product specialist in 2019 and 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.

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 FM Produkty Dla Stomatologii in Poland 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 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 China became the Company exclusive distributor of dental products in China. As of December 31, 2018 and 2017, Milestone Scientific's investment in Milestone China was $0. As of December 31, 2018 and 2017, Milestone Scientific's share of cumulative suspended losses of Milestone China were $3,380,388 and $3,147,470, respectively.

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.

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

	2018		
	Dental	Medical	Total
Domestic US / Canada:			
Device	$491,375	$32,500	$523,875
Handpieces	4,211,243	-	4,211,243
Other	96,088	-	96,088
Total Domestic US / Canada	$4,798,706	$32,500	$4,831,206
International Rest of the World:			
Device	$1,292,844	$81,000	$1,373,844
Handpieces	2,444,639	6,100	2,450,739
Other	66,087	200	66,287
Total International Rest of the World	$3,803,570	$87,300	$3,890,870
International China:			
Device	$109,374	$-	$109,374
Handpieces	790,626	-	790,626
Other	-	-	-
Total International China	$900,000	$-	$900,000
Total Product Sales	$9,502,276	$119,800	$9,622,076

	2017 Dental	Medical	Total
Domestic US / Canada:			
Device	$914,495	$ -	$914,495
Handpieces	4,346,664	-	4,346,664
Other	78,550	-	78,550
Total Domestic US / Canada	$5,339,709	$ -	$5,339,709
International Rest of the World:			
Device	$1,427,016	$ -	$1,427,016
Handpieces	2,325,622	2,000	2,327,622
Other	116,539	-	116,539
Total International Rest of the World	$3,869,177	$ 2,000	$3,871,177
International China:			
Device	$643,600	$ -	$643,600
Handpieces	1,425,600	-	1,425,600
Other	1,800	-	1,800
Total International China	$2,071,000	$ -	$2,071,000
Total Product Sales	$11,279,886	$ 2,000	$11,281,886

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 was a variable interest entity of which Milestone Scientific was the primary beneficiary and is consolidated into Milestone Scientific's financial statements. Milestone Scientific purchased the remaining 50% of Milestone Education in September 2018 for $1.00 increasing its ownership of Milestone Education to 100%. All significant, intra-entity transactions and balances are eliminated in the consolidation.

Current Product Platform

See Item 1. Description of Business.

Summary of Critical Accounting Policies and Significant Judgments and Estimates

Principles of Consolidation

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 was a variable interest entity of which Milestone Scientific was the primary beneficiary and is consolidated into Milestone Scientific's financial statements. Milestone Scientific purchased the remaining 50% of Milestone Education in September 2018 for $1.00 increasing its ownership of Milestone Education to 100%. All significant, intra-entity transactions and balances are eliminated in the consolidation. 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 has a variable interest in Milestone China, it considered the guidance in ASC 810, “Consolidation” as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

Power Criterion: The power to direct the activities that most significantly impact the entity’s economic performance; and

Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE

Milestone Scientific does not have the ability to control the activities that most significantly impact Milestone China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of Milestone China to the CEO and a group of significant shareholders, including the Milestone China CEO, of Milestone China which have the power to direct the activities that most significantly impact the economic performance of Milestone China. Management has concluded that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and continues to be accounted for under the equity method. See Note H.

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 judgment and estimates are most critical in understanding and evaluating the reported financial results.

Assessment of our Ability to Continue as a Going Concern

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

Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses. The Company’s continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability. Milestone Scientific raised capital in February 2019 in a public and private offering in the aggregate gross proceeds of approximately $2.45 million. Management is actively pursuing financing or other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all.

The consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recover ability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern.

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.

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 Company’s impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

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

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs. At December 31, 2018, Milestone Scientific identified certain patents purchased in 2017 that will not be further developed and commercialized before the estimated useful life expires and, as such, an impairment charge was recorded.

Revenue Recognition

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps:

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

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

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Results of Operations

The following table sets forth the consolidated results of operations for the year ended December 31, 2018 compared to 2017 . The trends suggested by this table may not be indicative of future operating results:

	2018	2017
Operating results:		
Product sales, net	$9,622,076	$11,281,886
Cost of products sold	5,190,775	4,312,507
Gross profit	4,431,301	6,969,379
Operating expenses:		
Selling, general and administrative expenses	10,645,206	11,930,951
Research and development expenses	245,636	272,746
Impairment to long lived assets	1,539,794	-
Loss from operations	(7,999,335)	(5,234,318)
Other income, net	307,564	(135,235)
Net loss	(7,691,771)	(5,369,553)
Net loss attributable to noncontrolling interests	(260,126)	182,760
Net loss attributable to Milestone Scientific Inc.	$(7,431,645)	$(5,186,793)

Cash flow:	December 31, 2018	December 31, 2017
Net cash used in operating activities	$(1,628,106)	$(1,229,434)
Net cash used in investing activities	(15,421)	(199,175)
Net cash (used in) provided by financing activities	(250,000)	463,336

Year ended December 31, 2018 compared to year ended December 31, 2017

Net sales for 2018 and 2017 were as follows:

	2018	2017	Increase Decrease	%
Dental	$9,502,276	$11,279,886	$(1,777,610)	-15.76 %
Medical	119,800	2,000	117,800	5890.00%
Total sales, net	$9,622,076	$11,281,886	$(1,659,810)	-14.71 %

Consolidated revenue for the twelve months ended December 31, 2018 and 2017 were approximately $9.6 million and $11.3 million, respectively. Dental revenue for the twelve months ended December 31, 2018 and 2017 were approximately $9.5 million and $11.3 million, respectively. Dental revenues decreased by approximately $1.8 million, which was principally related to decreased devices and handpiece sales in the United States and Canada by approximately $541,000 in 2018 and a decrease in international sales in 2018 by approximately $1.2 million due to a reduction in shipments to Milestone China. The reduction in shipments to Milestone China is due to Milestone China working through inventory purchases from 2017 and the modification to their business strategy to better serve the China dental market. Domestic inventory purchases by Henry Schein have been reduce due to lower target inventory model within Henry Schein. However, in the domestic market, our exclusive distribution agreement with Henry Schein has begun to pay off as the sell through has been consistent. Medical revenue for the twelve months ended December 31, 2018 and 2017, were approximately $120,000 and $2,000, respectively. In June 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 and the United States.

Gross Profit for 2018 and 2017 were as follows:

	2018	2017	Increase Decrease	%
Dental	$4,580,753	$7,187,562	$(2,606,809)	-36.27%

Medical	(149,452)	(218,183)	68,731	-31.50%
Total gross profit	$4,431,301	$6,969,379	$(2,538,078)	-36.42%

Consolidated gross profit for the twelve months ended December 31, 2018 and 2017, were approximately 46% and 62%, respectively. Dental gross profit for the twelve months ended December 31, 2018 and 2017, were approximately $4.6 million (48%) and $7.2 million (64%), respectively. Dental gross margin for the twelve months ended December 31, 2018 decreased due to a reserve of approximately $309,000 for slow moving and damaged hand pieces, a reserve of approximately $1.2 million for the underlying inventory associated with deferred cost due to Milestone China's market under performance and liquidity constraints. Milestone Scientific also incurred approximately $165,000 of costs to correct discoloration issues with instruments and damaged handpieces. The Medical gross profit was impacted by a reserve of $234,350 for slow moving Intra-articular medical instruments due to the continued delay of the Intra-articular regulatory approval. .

Selling, general and administrative expenses for 2018 and 2017 were as follows:

	2018	2017	Increase Decrease	%
Dental	$3,207,575	$3,968,747	$(761,172)	-19.18%
Medical	2,369,290	2,046,141	323,149	15.79 %
Corporate	5,068,341	5,916,063	(847,722)	-14.33%
Total selling, general and administrative expenses	$10,645,206	$11,930,951	$(1,285,745)	-10.78%

Consolidated selling, general and administrative expenses for the twelve months ended December 31, 2018 and 2017, were approximately $10.6 million and $11.9 million, respectively. The decrease of approximately $1.3 million is predominantly due to the decrease in Corporate expenses relating to consulting fees. Milestone Scientific continues the process of managing expenses while building on the business platform in the medical segment.

Research and Development for 2018 and 2017 were as follows:

	2018	2017	Increase Decrease	%
Dental	$-	$10,251	$(10,251)	-100.00%
Medical	92,489	124,820	(32,331)	-25.90 %
Corporate	153,147	137,675	15,472	11.24 %
Total research and development	$245,636	$272,746	$(27,110)	-9.94 %

Consolidated research and development expenses for the twelve months ended December 31, 2018 and 2017, were approximately $246,000 and $273,000, respectively. The decrease is due to a reduction in development costs associated with the Epidural and Intra Articular devices as the Epidural was approved during 2017 and the Intra Articular previously filed its original 510K with FDA in late 2016 which subsequently expired in January 2019. The Company intends to submit a new 510(k) application in 2019 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.

Profit (Loss) from Operations for 2018 and 2017 were as follows:

	2018	2017	Increase Decrease	%
Dental	$1,373,178	$3,127,570	$(1,754,392)	-56.09%
Medical	(2,611,231)	(2,389,145)	(222,086)	9.30 %
Corporate	(6,761,282)	(5,972,743)	(788,539)	13.20 %
Total loss from operations	$(7,999,335)	$(5,234,318)	$(2,765,017)	52.82 %

In addition to the impact on loss from operations of the items previously noted above Milestone Scientific took a charge of approximately $1.5 million for an impairment of long-lived assets (APAD patents). The patents were purchased in 2017 for approximately $2,639,000 with a three-year estimated useful life. During 2018, Milestone Scientific identified that the APAD Patents will not be developed into marketable instruments in the near term.

The dental segment of the business continues to control expenses for a stable market. Costs in the medical segment are beginning to increase (on a managed basis) as personnel are expanded in the U.S. to focus on our domestic Epidural

device business.

Liquidity and Capital Resources

At December 31, 2018, Milestone Scientific had cash and cash equivalents of approximately $743,000 and working capital of approximately $1.1 million versus working capital of $5.3 million in 2017. For the twelve months ended December 31, 2018 and 2017, we had negative cash flows from operating activities of approximately $1.6 million and $1.2 million, respectively. Based on current and expected cash to be used in operating activities substantial doubt exists about the Company's ability to continue as a going concern for at least the next twelve months from the financial reporting date.

Management believes that the current cash flow and support from the dental business will not be able to mitigate the uncertainty around the realization of Milestone China Accounts Receivables together with the expected selling expenditures for its Epidural medical device, as well as other operating expenditures and new product development programs, over the next twelve months from the financial reporting date. Without additional funding a delay, scale back or elimination of some or all of the Company's development programs could be required, all of which could have a material adverse impact on the Company.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in January 2017 and in February 2019 (a capital raise in a public and private offering in the aggregate of approximately $2.45 million) provides Milestone Scientific with working capital to continue to develop its medical devices , as well as to 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.

Now that the *CompuFlo* Epidural System has obtained FDA clearance in the United States (June 2017), the development costs will be reduced in 2019 but the selling costs are expected to increase significantly. The FDA clearance has provided the Company with the opportunity to establish distribution in the USA. At the same time, the Company is looking to establish additional financing to support the Epidural device commercialization process. The intra-articular device will restart the 510K application process later this year. Most of the cost associated with this application will be internal personnel cost with some third-party expense which estimated at $15,000 to be paid in 2019.

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.

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, 2018, 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	$228,496	$159,138	$40,656	$28,702
Purchase obligations (1)	$959,173	$751,332	$207,841	$-

Total	$1,187,669	$910,470	$248,497	$28,702

(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, 2018 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, 2018. 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, 2018. 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, 2018 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 discretion of the Board of Directors The current executive officers and directors of Milestone Scientific and their respective ages as of April 1, 2019 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leslie Bernhard (1) (2) (3)	74	Chairman of the Board	2003
Leonard Osser	71	Interim Chief Executive Officer and Director	1991
Joseph D'Agostino	67	Chief Financial Officer and Chief Operating Officer	2008
Leonard Schiller (1) (2) (3)	78	Director	1997
Michael McGeehan (1)	53	Director	2017
Gian Domenico Trombetta	58	Director	2014
Edward J. Zelnick, M.D. (1) (2) (3)	73	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 1, 2019.

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	74	Director of International Professional Relations
Mark Hochman, D.D.S.	59	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 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 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 an 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., a public media company, since February 2016 and Point Capital, Inc., 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 that 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.

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, 2018.

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 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, 2018 and 2017 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 2018 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 (4)	Other Compensation	Total
Leonard A. Osser (1)						
Interim Chief Executive Officer	2018	$304,167	$-	$-	$ 236,317	$540,484
Managing Director of Asian Operations	2017	$205,000	$350,000	$336,970	$ 227,311	$1,119,281
Leslie Bernhard						
Interim Chief Executive Officer	2017	$50,000	$29,500	$-	$ -	$79,500
Daniel Goldberger (5)						
Former Chief Executive Officer	2017	$68,750	$-	$-	$ 178,600	$247,350
Gian Domenico Trombetta (2)						
Chief Executive Officer - Wand Dental Inc	2018	$280,000	$-	$-	$ -	$280,000
	2017	$280,000	$180,000	$-	$ -	$460,000
Joseph D'Agostino (3)						
Chief Financial Officer and Chief Operating Officer	2018	$200,000	$-	$-	$ 25,298	$225,298
	2017	$178,700	$90,000	$86,650	$ 27,027	$382,377
Sharon Smith (6)						
Executive Vice President Global Marketing	2018	$167,535	$116,500	$-	$ -	$284,035
Eric Gilbert (7)						
Vice President US Sales and Marketing	2018	$155,242	$70,000	$-	$ -	$225,242

1. Leonard Osser, deferred a portion of his yearly compensation of approximately $184,000 in 2018. Other compensation represents payments made for health insurance coverage of approximately $19,000 and car allowance of approximately $14,400. In 2018, Mr. Osser, deferred his pension of approximately $203,111 which is included in other payments. Mr. Osser did not receive a performance bonus in 2018 however, he did receive $350,000, in a performance bonus for the year ended December 31, 2017, of which $175,000 was 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. Other compensation represents payments made for health insurance coverage $4,900 and car allowance $7,200, pension payment $203,111. While Mr. Osser served as Managing Director of Asian Operations, he received $55,000 in compensation and $12,100 in other compensation which is included in this schedule.

2. Gian Domenico Trombetta deferred a portion of his yearly compensation of approximately $180,000 in 2018. Mr. Trombetta did not receive a performance bonus in 2018 however, he received $180,000, in a performance bonus for the year ended December 31, 2017, of which $90,000 will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. Approximately $45,000 was deferred from 2017. 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.

3. Joseph D'Agostino deferred a portion of his yearly compensation of approximately $28,000 in 2018. Other compensation represents payments made for health insurance coverage of approximately $16,000 and car allowance of approximately $9,000. Mr. D'Agostino did not receive a performance bonus in 2018 however, he received $90,000, in a performance bonus for the year ended December 31, 2017, of which $45,000 was 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.

4. 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, 2018 and 2017, which is located on pages F-8 through F-13 of this Report. Compensation cost is generally recognized over the vesting period of the award. See the table on page 40 entitled Outstanding Equity Awards at December 31, 2018.

5. The settlement to Mr. Goldberger was finalized and paid in 2018 in the amount of $175,000. 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.

6. Sharon Smith received $116,500, in a performance bonus for the year ended December 31, 2018, and will be paid in common stock upon the termination of her employment with the Company.

7. Eric Gilbert received $70,000, in a performance bonus for the year ended December 31, 2018, and will be paid in common stock upon the termination of his employment with the Company.

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 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 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). In February 2018, Milestone Scientific and Mr. Goldberger signed a Settlement and Release Agreement with respect to Mr. Goldberger's leaving the Company. The gross settlement was $175,000, which was paid during 2018.

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 December 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 advise on executive and/or director compensation matters.

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

Annual CEO Compensation consists of a base salary component 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, 2018

	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	1,055,135	$1,205,707
	185,186	-	$ 2.23	11/20/2019		
	57,306	-	$ 3.89	6/23/2020		
	64,454	18,534	$ 1.72	2/4/2021		
	133,134	38,286	$ 2.09	11/10/2021		
	48,240	13,872	$ 1.74	2/4/2021		
	186,457	150,513	$ 1.14	1/18/2022		
Total	**748,110**	**221,205**			**1,055,135**	**$1,205,707**
Gian Domenico Trombetta	103,125	29,654	$ 1.72	2/4/2021	202,617	$329,863
	77,184	22,194	$ 1.61	12/21/2019		
Total	**180,309**	**51,848**			**202,617**	**$329,863**
Joseph D'Agostino	150,000	-	$ 2.09	11/11/2019		
	49,261	-	$ 2.03	11/20/2019	234,315	$406,145
	103,404	29,736	$ 1.72	2/4/2021		
	38,592	11,097	$ 1.61	1/8/2022		
	47,946	38,704	$ 1.04	1/8/2022		
Total	**389,203**	**79,537**			**234,315**	**$406,145**

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, 2018.

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

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

3. Based on the closing price per share the dated granted as reported on the NYSE American.

Director Compensation

NAME	Fees Earned or Paid in Cash ($)
Leslie Bernhard	$66,000
Leonard Schiller	$36,000
Edward J. Zelnick, M.D.	$36,000
Michael McGeehan	$36,000

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 March 29, 2019 , 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	4,461,641	(3)	10.29	%
Joseph D'Agostino	1,543,658	(4)	3.56	%
Leslie Bernhard	75,000	(5)	*	
Leonard Schiller	235,158	(6)	*	
Edward J. Zelnick, M.D.	47,500	(7)	*	
Michael McGeehan	108,250	(8)	*	
Gian Domenico Trombetta	7,197,489	(9)	16.60	%
All directors & executive officers as group (7 persons)	13,668,696		31.52	%
K. Tucker Andersen	3,400,975		7.84	%
Tom Cheng	2,015,629		4.65	%
* Less than 1%	1,695,000		3.91	%

1. The addresses of the persons named in this table are as follows: Leonard Osser, Joseph D'Agostino, Gian Domenico Trombetta, Leslie Bernhard, Edward Zelnick, M.D and Michael McGeehan 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, and Tom Cheng, c/o United Systems 18725 E. Gale Ave Suite 221, City of Industry, CA 91748.

2. A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 29, 2019, as applicable, upon the exercise of options and warrants or conversion of convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants and convertible securities that are held by such person (but not held by any other person) and that are exercisable or convertible within 60 days from March 29, 2019 have been exercised or converted. Except as otherwise indicated, and subject to applicable community property and similar laws, each of the persons named has sole voting and investment power with respect to the shares shown as beneficially owned. The percentages for each beneficial owner are determined based on dividing the number of shares of common stock beneficially owned by the sum of the outstanding shares of common stock on March 29, 2019 and the number of shares underlying options exercisable and convertible securities convertible within 60 days from March 29, 2019 held by the beneficial owner

3. Includes 2,568,706 shares held by Mr. Osser or his family, 1,055,135 shares to be issued at the termination of his employment agreement, and 766,550 shares subject to common stock options and 71,250 shares subject to warrants to purchase common stock of the company.

4. Includes 931,137 shares held by Mr. D'Agostino, 234,315 shares to be issued at the termination of his employment, and 378,206 shares subject to common stock options.

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 to purchase common stock of the company.

7. Includes 40,000 shares held by Dr. Zelnick and 7,500 shares subject to common stock warrants to purchase common stock of the company.

8. Includes 87,000 shares held by Mr. McGeehan and 21,250 shares subject to common stock warrants

9. Includes 202,617 shares to be issued at the termination of his employment, 148,439 shares subject to common stock options, 178,571 shares subject to warrants to purchase common stock of the company in the name of Bp4 Sr.l, and 6,667,872 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.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes, as of December 31, 2018, 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 be issued upon exercise of outstanding options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities 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)	1,630,220	$ 1.64	1,007,587
Total	1,703,553	$ 1.71	1,007,587

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 2018 or 2017.

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 years ended December 31, 2018 and 2017, zero and 83,333 shares were exercised, respectively.

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 is $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 Scientific), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were $1.2 million and $2.1 million for the years ended December 31, 2018 and 2017, respectively. As December 31, 2018 and 2017, Milestone Scientific owed this manufacturer $1.3 million and $1.0 million, respectively, which is included in accounts payable, related party on the consolidated balance sheets. In February 2019, Milestone Scientific board of directors granted United Systems (controlling shareholder, Tom Cheng) 285,714 shares of stock at $.35 or $100,000 for consulting services. These shares were included in shares to be issued at December 31, 2018.

During 2018 Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of December 31, 2018, Wand Dental has deferred royalty income of $342,540 that will be recognized at the earlier of when payment of the royalties is received from United Systems or when collectability is deemed to be assured and is included in accounts receivable, related party and deferred revenue, related party on the consolidated balance sheets. This receivable is included in the reserved receivables in Note H.

Also, during the year ended December 31, 2018, a Distribution Agreement between Wand Dental and United Systems was formed. Under the Distribution agreement United Systems purchased 1,000 STA instruments in June 2018, for delivery to Milestone China. Due to the related party nature and collectability concerns Wand Dental has deferred the sale. Milestone Scientific has deferred approximately $750,000 of related party sales of devices to Milestone China under the agreement with United Systems as of December 31, 2018. As of December 31, 2018, Milestone Scientific recorded accounts receivable, related party and deferred revenue, related party of $750,000 and deferred cost, related of $686,365, respectively. The deferred revenue, accounts receivable and deferred cost from this transaction are included in accounts receivable, deferred revenue and deferred cost related, party related to Milestone China disclosed on the consolidated balance sheets. This receivable, deferred revenue and deferred cost is included in the reserved receivables in Note H.

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. See note H for a description of related party transactions with Milestone China.

In *August 2016,* K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a *three*-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were $100,000 for years ended December 31, *2018* and *2017,* respectively.

In *January 2017,* Milestone Scientific entered into a *twelve*-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific, to provide consulting services. This agreement will renew for successive *twelve*-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were $80,000 for years ended December 31, *2018* and *2017,* respectively.

The Director of Clinical Affairs’ royalty fee was approximately $465,000 and $554,000 for the years ended December 31, 2018 and 2017, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $186,000 and $275,000 for the years ended December 31, 2018, and 2017, respectively. As of December 31, 2018 and 2017 Milestone Scientific owed the Director Clinical Affairs for royalties of approximately

$364,000 and $162,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

Item 14. Principal Accounting Fees and Services

Audit Fees and Audit Related

Milestone Scientific incurred audit and financial statement review fees of approximately $246,500 and $235,500, respectively from Friedman LLP, its principal accountant for 2018 and 2017. These fees include fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Q's or services that are normally provided in connection with statutory and regulatory filings.

Tax Fees

Milestone Scientific incurred tax fees of approximately $42,500 and $30,500 respectively from Friedman LLP, its principal accountant for 2018 and 2017.

All Other Fees

Milestone Scientific incurred other accounting fees of approximately $50,000 and $26,000 respectively from Friedman LLP, its principal accountant for 2018 and 2017.

Audit Committee Administration of the Engagement

The engagement with Friedman LLP, the principal accountants, was approved in advance by the Board of Directors and the Audit Committee. No non-audit or non-audit related services were approved by the Audit Committee in 2018.

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 *
4.1	Specimen stock certificate (2)
4.3	Form of Common Stock Purchase Warrant issued in the 2016 Public Offering (16)
4.4	Form of Common Stock Purchase Warrant issued in the Feb. 2019 Public Offering (21)
4.5	Form of Common Stock Purchase Warrant issued in the Feb. 2019 Private Placement (22)
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)
10.3	2011 Equity Compensation Plan (7)
10.4	Master Supply and Distribution Agreement, dated July 3, 2013, between Milestone Scientific Inc and Tri-anim Health Services, Inc (9)
10.5	Agreement with Mark Hochman, dated July 2015 (13)
10.6	Investment Agreement, dated April 15, 2014, between Milestone Scientific Inc. and BP4 S.p.A. (12)
10.7	Exclusive Distribution and Supply Agreement, dated as of June 20, 2016, among Milestone Scientific Inc., Wand Dental, Inc. and Henry Schein, Inc. (14)
10.8	Amended and Restated Employment Agreement, dated December 1, 2016, between Wand Dental Inc. and Gian Domenico Trombetta (15)
10.9	Final Form of Asset Purchase Agreement, dated June 2, 2017, among APAD Octrooi B.V., APAD B.V., and Milestone Scientific Inc. (17)
10.10	Final form of the Memorandum of Agreement, dated June 6, 2017, between Solee Science & Technology U.S.A. Ltd. and Milestone Scientific Inc. (18)
10.11	

	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)
10.12	Final form of the Stock Option Agreement, dated June 6, 2017, Solee Science & Technology U.S.A. Ltd. and Milestone Scientific Inc. (18)
10.13	New Employment Agreement between Milestone Scientific Inc. and Leonard Osser dated as of July 11, 2017. (19)
10.14	Employment Agreement between Milestone Scientific Inc. and Daniel Goldberger dated as of July 11, 2017. (19)
10.15	Covenant Agreement between Milestone Scientific Inc. and Daniel Goldberger dated and effective as of July 11, 2017. (19)
10.16	Consultant Agreement between Milestone Medical Inc. and U.S. Asian Consulting Group, LLC dated as of July 10, 2017. (20)
10.17	Underwriting Agreement, dated as of February 1, 2019 between Milestone Scientific Inc. and Maxim Group LLC, as underwriter (21)
10.18	Stock Purchase Agreement, dated as of February 8, 2019 between Milestone Scientific Inc. and BP4 S.p.A. (22)
21.1	List of Subsidiaries*
23.1	Consent of Friedman, 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*

* Filed herewith.

** Indicates management contract or compensatory plan or arrangement.

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

2) Incorporated by reference to Amendment No. 1 to Milestone Scientific's Registration Statement on Form 10-KSB for the year ended May 15, 1995
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.
7) Filed as Appendix A to Milestone Scientific's Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.
9) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on July 9, 2013.
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.
21) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on February 1, 2019.
22) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on February 14, 2019.

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 1, 2019

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

Signature	Date	Title
/s/ Leonard Osser Leonard Osser	April 1, 2019	Interim Chief Executive Officer (Principal Executive Officer)
/s/ Joseph D'Agostino Joseph D'Agostino	April 1, 2019	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)
/s/ Leslie Bernhard Leslie Bernhard	April 1, 2019	Chairman and Director Director

/s/ Gian Domenico Trombetta
Gian Domenico Trombetta

April 1, 2019

/s/ Edward J. Zelnick, M.D. Director

Edward J. Zelnick, M.D.

April 1, 2019

/s/ Leonard Schiller Director

Leonard Schiller

April 1, 2019

/s/ Michael McGeehan Director

Michael McGeehan

REPORT INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

For the Years Ended December 31, 2018 and 2017

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, 2018 and 2017, and the related consolidated statements of operations, statements of changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B to the consolidated financial statements, the Company has recurring losses and negative cash flows from operations. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 consolidated 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 1, 2019

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

ASSETS	December 31, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	$743,429	$2,636,956
Accounts receivable, net	1,978,456	1,535,513
Accounts receivable, related party, net	100,000	1,725,450
Note receivable from financing transaction, current	-	500,000
Prepaid expenses and other current assets	414,541	436,410
Deferred cost, related party	50,000	1,109,671
Inventories, net	1,921,051	3,379,209
Advances on contracts	648,783	697,192
Total current assets	5,856,260	12,020,401
Furniture, fixtures and equipment, net	82,557	141,760
Patents, net	435,273	2,789,748
Note receivable from financing transaction, noncurrent	-	650,000
Other assets	26,878	26,878
Total assets	$6,400,968	$15,628,787
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,205,396	$977,623
Accounts payable, related party	1,663,849	985,678
Accrued expenses and other payables	1,481,715	2,179,268
Accrued expenses, related party	-	108,640
Deferred profit, related party	421,800	751,500
Deferred revenue, related party	100,000	1,725,450
Total current liabilities	4,872,760	6,728,159
Deferred gain from financing transaction	-	1,400,000
Total liabilities	$4,872,760	$8,128,159
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 (liquidation preference of $7,000,000 as of December 31, 2018 and 2017)	7	7
Common stock, par value $.001; authorized 50,000,000 shares; 33,859,034 shares issued,2,470,565 shares to be issued and 33,825,701 shares outstanding as of December 31, 2018; 33,191,571 shares issued, 1,401,247 shares to be issued and 33,158,238 shares outstanding as of December 31, 2017;	36,330	34,593

Additional Paid in Capital	88,414,718	86,689,084
Accumulated deficit	(85,999,929)	(78,568,284)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	1,539,610	7,243,884
Noncontrolling interest	(11,402)	256,744
Total stockholders’ equity	1,528,208	7,500,628
Total liabilities and stockholders’ equity	$6,400,968	$15,628,787

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2018 AND 2017

	2018	2017
Product sales, net	$*9,622,076*	$*11,281,886*
Cost of products sold	*5,190,775*	*4,312,507*
Gross profit	*4,431,301*	*6,969,379*
Selling, general and administrative expenses	*10,645,206*	*11,930,951*
Research and development expenses	*245,636*	*272,746*
Impairment of long lived assets	*1,539,794*	-
Total operating expenses	*12,430,636*	*12,203,697*
Loss from operations	*(7,999,335)*	*(5,234,318)*
Other expenses	*(7,232)*	*(4,930)*
Interest income	*7,447*	*9,298*
Loss before provision for income taxes and equity in net losses of equity investments	*(7,999,120)*	*(5,229,950)*
Provision for income taxes	*(23,986)*	*(19,093)*
Loss before equity in net earnings (losses) of equity investments	*(8,023,106)*	*(5,249,043)*
Earnings from Milestone Education	*1,635*	-
Earnings (loss) from China Joint Venture	*329,700*	*(120,510)*
Net loss	*(7,691,771)*	*(5,369,553)*
Net loss attributable to noncontrolling interests	*(260,126)*	*(182,760)*
Net loss attributable to Milestone Scientific Inc.	$*(7,431,645)*	$*(5,186,793)*
Net loss per share applicable to common stockholders—		
Basic	$*(0.21)*	$*(0.16)*
Diluted	$*(0.21)*	$*(0.16)*
Weighted average shares outstanding and to be issued—		
Basic	*35,299,034*	*32,703,897*
Diluted	*35,299,034*	*32,703,897*

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2018 AND 2017

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, January 1, 2017	7,000	$7	31,727,705	$31,720	$82,761,503	$(73,381,491)	$36,106	$(911,516)	$8,536,329
Stock based compensation		-			651,413	-	-	-	651,413
Common stock to be issued to employee for compensation		-	10,913	11	14,989	-	-	-	15,000
Common stock issued to employee for exercise of stock options		-	83,333	83	62,417	-	-	-	62,500
Common stock issued for payment of consulting services		-	410,729	419	548,092	-	-	-	548,511
Common stock issued to employee for bonuses		-	158,082	158	259,834	-	-	-	259,992
Common stock issued for Asset acquisition		-	1,646,358	1,646	2,484,354	-	-	-	2,486,000
Common Stock exchanged for MMD		-	311,998	312	(403,710)	-	403,398	-	-
Common stock issued to		-	120,000	120	159,480	-	-	-	159,600

directors for bonuses									
Sale of Common Stock - Public Offering		-	123,700	124	150,712	-	-	-	150,836
Net loss		-			-	(5,186,793)	(182,760)	-	(5,369,553)
Balance, December 31, 2017	7,000	$7	34,592,818	$34,593	$86,689,084	$(78,568,284)	$256,744	$(911,516)	$7,500,628
Stock based compensation		-			409,021	-	-	-	409,021
Common stock issued to employee for bonuses		-	25,000	25	29,475				29,500
Common stock issued for payment of consulting services		-	350,102	350	289,400	-	-	-	289,750
Common stock issued to employee for compensation		-	47,402	47	44,953	-	-	-	45,000
Common stock issued for Asset Acquisition		-	244,959	245	286,357	-	-	-	286,602
Common stock to be issued to employee for bonuses		-	511,155	511	449,488	-	-	-	449,999
Common stock to be issued for payment of consulting services		-	535,437	536	209,463	-	-	-	209,999
Common stock to be issued to employee for compensation		-	22,727	23	7,477	-	-	-	7,500
Acquired controlling interest in Milestone Education		-	-	-	-	-	(8,020)	-	(8,020)
Net loss		-	-	-	-	(7,431,645)	(260,126)	-	(7,691,771)

Balance as December 31, 2018	7,000	$7	36,329,600	$36,330	$88,414,718	$(85,999,929)	$(11,402)	$(911,516)	$1,528,208

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2018 AND 2017

	2018	2017
Cash flows from operating activities:		
Net loss	$(7,691,771)	$(5,369,553)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	66,604	62,474
Amortization of patents	814,681	510,676
Impairment to long lived assets	1,539,794	-
Stock compensation	409,021	651,413
(Income) loss on China joint venture	(329,700)	120,510
Increase inventory allowance	543,545	219,834
Increase in deferred cost reserve	1,250,928	-
Changes in operating assets and liabilities:		
Increase in accounts receivable	(442,943)	(733,129)
Decrease (increase) in accounts receivable, related party	(192,540)	989,150
Decrease in other receivables	-	10,000
Decrease in inventories	914,613	1,003,676
Decrease in advances on contracts	48,409	3,708
Decrease (increase) in prepaid expenses and other current assets	21,869	(144,481)
Decrease in other assets	-	(9,523)
Increase (decrease) in accounts payable	227,773	(363,584)
Increase (decrease) in accounts payable, related party	678,171	(249,374)
Increase in deferred cost, related party	(191,257)	(489,630)
Increase in accrued expenses	620,797	1,834,749
Decrease in accrued expenses, related party	(108,640)	-
Increase in deferred revenue, related party	192,540	723,650
Net cash used in operating activities	(1,628,106)	(1,229,434)
Cash flows from investing activities:		
Purchase of intangible assets	-	(39,520)
Purchase of property and equipment	(7,401)	(6,008)
Acquisition of Milestone Education	(8,020)	-
Purchase of intangibles assets-Apad	-	(153,647)
Net cash used in investing activities	(15,421)	(199,175)
Cash flows from financing activities:		
(Payments) proceeds financing transaction	(250,000)	250,000
Proceeds from exercise of stock options	-	62,500
Net proceeds on Public Placement Offering	-	150,836
Net cash (used in) provided by financing activities	(250,000)	463,336
Net decrease in cash and cash equivalents	(1,893,527)	(965,273)
Cash and cash equivalents at beginning of period	2,636,956	3,602,229
Cash and cash equivalents at end of period	$743,429	$2,636,956

Supplemental disclosure of cash flow information:		
Shares issued to employees for compensation	$45,000	$194,885
Shares issued to consultants in lieu of cash payments	289,750	350,249
Deferred revenue and accounts receivable, related party adjustment	1,817,990	10,000
Shares issued for assets acquired	-	2,486,000
(Reversal) sale of Milestone China share, financing transaction	(1,400,000)	1,150,000

See notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE A — ORGANIZATION AND BUSINESS

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

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery device, using *The Wand*®, a single use disposable handpiece. The device is marketed in dentistry under the trademark *CompuDent®,* and *STA Single Tooth Anesthesia System*® and in medicine under the trademark *CompuMed®. CompuDent*® is suitable for all dental procedures that require local anesthetic. *CompuMed*® is suitable for many medical procedures regularly performed in Plastic Surgery, Hair Restoration Surgery, Podiatry, Colorectal Surgery, Dermatology, Orthopedics and many other disciplines. The dental devices are sold in the United States, Canada and in 60 other countries. To date there have been five (5) medical devices sold in the United States and limited amounts sold internationally, although certain medical devices have obtained CE mark approval and can be marketed and sold in most European countries. In June 2017, Milestone Scientific received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the *CompuFlo*® Epidural Computer Controlled Anesthesia System ("Epidural").

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the FDA for both intra-articular and epidural injections with the CompuFlo® Computer Controlled Anesthesia System. In June 2017, the FDA approved the *CompuFlo*® Epidural Computer Controlled Anesthesia System for epidural injections. Milestone Scientific is in the process of introductory meetings with medical device distributors within the United States and foreign markets. Milestone Scientific's immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA Office of Device Evaluation, we intend to file a new 510(k) application for the device in 2019.

In November 20, 2018, Milestone Scientific Inc. received a letter from NYSE American LLC (the "Exchange") stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the "Company Guide").On December 20, 2018, the Company submitted a plan of compliance (the "Plan") to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020.

On January 24, 2019, the Company received a letter from the Exchange stating that the Company's Plan has been accepted by the Exchange. The Company is still not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide and its listing on the Exchange is being continued pursuant to an extension granted by the Exchange.

NOTE B- GOING CONCERN AND LIQUIDITY

In accordance with Accounting Standard Codification ("ASC") 205-40, "Presentation of Financial Statements – Going Concern", the Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception. At December 31, 2018, the Company's cash on hand and net current assets decreased to $.7 million and $1.0 million from $2.6 million and $5.3 million in 2017, respectively. Based on the expected cash needed for operating activities, the Company's current cash and liquidity including the February 2019 financing is not sufficient to finance the operating requirements for at least the next 12 months from the filing date. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses. However, the Company's continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability, if ever. Management is actively pursuing financing or other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all.

In February 2019, Milestone Scientific consummated a public and private offering of Common Stock. The public offering generated gross proceeds of approximately $2.0 million through the issuance of 5,715,000 shares of common stock and warrants of 1,428,000 to purchase common shares. Subsequent to the public offering, the underwriter exercised its overallotment option and paid approximately $198,000 for 567,400 additional shares. See Note T.

Also, in February 2019, the Company generated gross proceeds from a private offering of approximately $250,000 through the issuance of 714,286 shares of common stock and warrants of 178,594 to purchase common shares to Bp4 S.p.A., a principal stockholder of Milestone Scientific, that exercised its right to participate on a prorated basis in the recent public offering. Bp4's CEO is a director of Milestone Scientific and also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific. See Note T.

These consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do *not* include any adjustments to reflect the possible future effects on the recover ability and classification of assets or the amounts and classification of liabilities that *may* result from the inability of the Company to continue as a going concern.

NOTE C — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1. **Principles of Consolidation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of Milestone Scientific and its wholly owned and majority owned subsidiaries, including, Wand Dental (wholly owned), Milestone Advanced Cosmetic (majority owned) and Milestone Medical (majority owned). Milestone Education was a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. During 2018, Milestone Scientific purchased the remaining 50% of Milestone Education in September 2018, increasing its ownership of Milestone Education to 100%. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

2. **Reclassifications**

Certain reclassifications have been made to the *2017* financial statements to conform to the consolidated *2018* financial statement presentation. These reclassifications had *no* effect on net loss or cash flows as previously reported.

3. Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the allowance for doubtful accounts, inventory valuation, and cash flow assumptions regarding evaluations for impairment of long-lived assets and going concern considerations, and valuation allowances on deferred tax assets. Actual results could differ from those estimates**.**

4. Revenue Recognition

Under ASC *606,* the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements within the scope of ASC *606,* the Company performs the following *five* steps:

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

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

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has *no* obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Sales Returns

We do not take returns from customer who do not have the right of return. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Company’s warranty policy. Returns *not* within the warranty policy are evaluated and the customer is charged for repair.

Financing and Payment

Our payment terms differ by geography and customer, but payment is generally required within *90* days from the date of shipment or delivery.

Disaggregation of Revenue

We operate in *two* operating segments: dental and medical. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. See Note O for revenues by geographical market, based on the customer's location, and product category for the years December 31, 2018 and 2017.

5. **Variable Interest Entities**

A variable interest entity ("VIE") is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support or (ii) has equity investors who lack the characteristics of a controlling financial interest. A VIE is consolidated by its primary beneficiary. The primary beneficiary has both the power to direct the activities that most significantly impact the entity's economic performance and the obligation to absorb losses or the right to receive benefits from the entity that could potentially be significant to the VIE.

If Milestone Scientific determines that it has operating power and the obligation to absorb losses or receive benefits, Milestone Scientific consolidates the VIE as the primary beneficiary. Milestone Scientific's involvement constitutes power that is most significant to the entity when it has unconstrained decision-making ability over key operational functions within the entity.

Because Milestone Scientific has a variable interest in Milestone China, it considered the guidance in ASC *810,* "Consolidation" as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

Power Criterion: The power to direct the activities that most significantly impact the entity's economic performance; and
Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE

Milestone Scientific does not have the ability to control the activities that most significantly impact Milestone China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of Milestone China to the CEO and a group of significant shareholders, including the Milestone China CEO, of Milestone China which have the power to direct the activities that most significantly impact the economic performance of Milestone China. Management has concluded that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and continues to be accounted for under the equity method. See Note H.

6. Cash and Cash Equivalents

Milestone Scientific considers all highly liquid investments purchased with an original maturity of *three* months or less to be cash equivalents.

7. **Accounts Receivable**

Milestone Scientific sells a significant amount of its product on credit terms to its major distributors. Milestone Scientific estimates losses from the inability of its customers to make payments on amounts billed. Most credit sales are due within 90 days from invoicing. There have not been any significant credit losses incurred to date. As of December 31, 2018 and 2017, accounts receivable was recorded, net of allowance for doubtful accounts of $10,000.

8. **Product Return and Warranty**

Milestone Scientific generally does *not* accept non-defective returns from its customers, except for certain customers that can return factory sealed purchases (inventory) that still remain in their locations at the time of termination of their Distributor Agreement. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Warranty Policy. Returns *not* within the Warranty Policy are evaluated and the customer is charged for the repair.

9. **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, slow moving, defective, and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirements. As of December 31, 2018 and 2017, inventory was recorded net of a valuation allowance for slow moving and defective inventory of approximately $763,000 and $220,000, respectively.

10. **Equity Method Investments**

Investments in which Milestone Scientific can exercise significant influence, but do *not* control, are accounted for under the equity method of accounting and are included in the long-term assets on the Consolidated Balance Sheets. Under this method of accounting, Milestone Scientific's share of the net earnings or losses of the investee is presented below the income tax line on the Consolidated Statements of Operations. Milestone Scientific evaluates its equity method investments whenever events or changes in circumstance indicate that the carrying amounts of such investments *may* be impaired. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period.

11. **Furniture, Fixture and Equipment**

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

12. **Intangible Assets – Patents and Developed Technology**

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

13. Impairment of Long-Lived Assets

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

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

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

14. **Shipping and Handling Costs**

Milestone Scientific includes shipping and handling costs, if any, in cost of goods sold. These costs are paid by or billed to customers at the time of shipments. Domestic and international shipments are FOB warehouse; therefore, *no* costs are incurred by Milestone Scientific.

15. **Research and Development**

Research and development costs, which consist principally of new product development costs payable to *third* parties, are expensed as incurred. Advance payments for the research are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

16. **Income Taxes**

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

At December 31, 2018 and 2017, we had no uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Consolidated Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2015, 2016, and 2017 years are subject to audit by federal and state jurisdictions.

17. **Basic and diluted net loss per common share**

Basic earnings (loss) per common share is computed by dividing the net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. In periods where there is net income, we apply the two-class method to calculate basic and diluted net income (loss) per share of common stock, as our Series A Convertible Preferred Stock is a participating security. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. In periods where there is a net loss, the two-class method of computing earnings per share does not apply as our Series A Convertible Preferred Stock does not contractually participate in our losses. We compute diluted net income (loss) per common share using net income (loss) as the “control number” in determining whether potential common shares are dilutive, after giving consideration to all potentially dilutive common shares, including stock options, warrants, during the period and potential issuance of stock upon the conversion of our Series A Convertible Preferred Stock issued and outstanding during the period, except where the effect of such securities would be antidilutive.

The Company did not include any portion of outstanding options, warrants or convertible preferred stock in the calculation of diluted loss per common share because all such securities are anti-dilutive for all periods presented. The application of the two-class method of computing earnings per share under general accounting principles for participating securities is not applicable during these periods because those securities do not contractually participate in its losses.

Since Milestone Scientific had net losses for 2018 and 2017, the assumed effects of the exercise of potentially dilutive outstanding stock options, warrants and convertible preferred stock were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 3,203,553 and 3,710,335 at December 31, 2018 and 2017, respectively.

18. **Fair Value of Financial Instruments**

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

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

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of an input to the fair value measurement requires judgment and *may* affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

19. **Stock-Based Compensation**

Milestone Scientific accounts for stock-based compensation under ASC Topic *718,* Share-Based Payment. ASC Topic *718* requires all share-based payments to employees, including grants of employee stock options, to be recognized in the Statements of Operations over the service period, as an operating expense, based on the grant-date fair values.

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model. See note L.

20. **Recent Accounting Pronouncements**

In February 2016, the FASB issued a new standard Accounting Standards Update ("ASU ") No.2016-02, "Leases"(Topic 842). The new standard is intended to increase transparency and comparability among organizations to recognize lease assets and liabilities on the balance sheet and disclose key information about leasing arrangements. It will be effective for fiscal years beginning after December 15, 2018. The adoption of this standard will not have a material effect on the Company's financial position, results of operations and cash flows.

In June 2016, the FASB issued a new standard ASU No.2016-13, "Financial Instruments – Credit Losses" (Topic 326).: The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2018.

Milestone Scientific will adopt this standard in 2019, the adoption of this ASU will have immaterial effect on its financial position, results of operations and cash flows. In July 2017, the FASB issued a new standard ASU No.2017-11, "Earnings Per Share" (Topic 260), "Distinguishing Liabilities from Equity" (Topic 480), "Derivatives and Hedging" (Topic 815). The new standard provides guidance relating to equity-linked instruments that include certain features. It will be effective for public entities for fiscal years and interim periods, beginning after December 15, 2018. Milestone Scientific has adopted this standard in December 2018, the adoption of this ASU will have immaterial effect on its presentation within the statement of cash flows.

NOTE D — NOTES RECEIVABLE

In June 2017, Milestone Scientific entered into an agreement for the sale of its forty percent (40%) interest in Milestone China (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 was payable in quarterly installments of $125,000 and was secured by the Milestone China Shares until full repayment. In addition, the purchaser was 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 was accounted for as a secured financing and Milestone Scientific continued to account for its relationship with Milestone China under the equity method of accounting. A note receivable was presented on the Company's consolidated balance sheet along with a deferred gain from financing transaction of $1,400,000. The carrying value of the forty (40%) percent investment in Milestone China at the transaction date was zero.

As of March 2, 2018, the promissory note was in default. In April 2018, Milestone Scientific entered into a Release, Assignment and Termination Agreement (the "Termination Agreement") with the issuer of the promissory note, pursuant to which, Milestone Scientific repaid the $250,000 payment made by the issuer and the issuer returned the Milestone China Shares to Milestone Scientific and cancelled the promissory note. Because of the Termination Agreement and related repayment made by Milestone Scientific, the Company derecognized the outstanding note receivable balance of $1,150,000 and the related deferred gain from financing transaction of $1,400,000. No gain or loss was recognized on the transaction.

NOTE E — INVENTORIES

Inventories consist of the following:	December 31, 2018	December 31, 2017
Dental finished goods, net	$1,609,000	$2,846,272
Medical finished goods, net	188,133	475,285
Component parts and other materials	123,918	57,652
Total inventories	$1,921,051	$3,379,209

At December 31, 2018, a reserve for slow moving medical finished goods of $454,183 and damaged slow moving dental finished goods of $309,196 was recorded. At December 31 ,2017 a reserve for slow moving medical finished goods of $220,000 was recorded. The reserve for the medical finished goods was provided due to the delay in commercialization of the intra-articular medical instrument.

NOTE F — ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA inventory purchases and epidural replacements parts. The balance of the advances as of December 31, 2018 and 2017 is approximately $649,000 and $697,000 respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE G – CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Education was a *50%* owned subsidiary of Milestone Scientific which began operations in *2013* to provide training and education to dentists throughout the world. Approximately *84%* of the revenue earned by Milestone Education is from services performed for Milestone Scientific as of *December 31, 2018* and *2017.* Because of this dependency and relationship, we determined that Milestone Scientific had the power to direct the activities that most significantly impact Milestone Education's economic performance, and therefore Milestone Education is consolidated in our financial statements. Milestone Scientific purchased the remaining *50%* of Milestone Education in *September 2018* for a nominal purchase price of *$8,020.*

NOTE H – INVESTMENT IN AND TRANSACTIONS WITH UNCONSOLIDATED SUBSIDIARIES

Milestone China Ltd.

Ownership

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.

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 was payable in quarterly installments of $125,000 until paid in full and was secured by the Milestone China Shares until full repayment. In addition, pursuant to such note, the purchaser was precluded from selling all or substantially all its assets prior to repayment of the note. The 10-year option agreement provided 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. A note receivable is presented on the Company's balance sheet, along with a deferral from financing transaction ($1,400,000) as of December 31, 2017. The carrying value of the forty (40%) percent investment at the transaction date was zero.

As of March 2, 2018, the promissory note was in default. In April 2018, Milestone Scientific entered into a Release, Assignment and Termination Agreement (the "Termination Agreement") with the issuer of the promissory note, pursuant to which, Milestone Scientific repaid the $250,000 payment made by the issuer and the issuer returned the Milestone China Shares to Milestone Scientific and cancelled the promissory note. Because of the Termination Agreement and related repayment made by Milestone Scientific, the Company derecognized the outstanding note receivable balance of $1,150,000 and the related deferred gain from financing transaction of $1,400,000. No gain or loss was recognized on the transaction.

Related Party Transactions

Milestone China is Milestone Scientific's exclusive distributor in China. During 2017 and prior to the payment default during 2018 Milestone Scientific agreed to sell inventory to Milestone China and its agent. During 2018, Milestone Scientific recognized $900,000 of related party sales of handpieces and instruments to Milestone China and its agent. Milestone Scientific had $2,071,000 of related party sales of handpieces and instruments to Milestone China and its agent for twelve months ended December 31, 2017.

As of December 31, 2018, Milestone Scientific had recorded deferred revenues and deferred costs associated with sales to Milestone China and it's agents of $0.1 million and $0.5 million , respectively. As of December 31, 2017, Milestone Scientific recorded deferred revenues and deferred costs associated with sales to Milestone China and it's agents of $ 1.7 million and $1.1 million, respectively.

During 2018 Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and it's agents which increased to $ 2.8 million at the time of the payment arrangement. The payment terms required $200,000 payments per month beginning in July 2018 through November 2018 and a balloon payment of approximately $1,425,000 during December 2018. During 2018 Milestone Scientific

only collected $900,000 under the payment arrangement. Due to the default on the arrangement and Milestone China's liquidity constraints, Milestone Scientific halted shipments to Milestone China. The Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a reserve against the related deferred cost of $1.25 million.

Gross Profit Deferral

Due to timing differences of when the inventory sold to Milestone China is recognized and when Milestone China sells the acquired inventory to third parties, an elimination of the profit is required as of the balance sheet date. In accordance with ASC 323 Equity Method and Joint Ventures, Milestone Scientific has deferred 40% of the gross profit associated with recognized revenue from sales to Milestone China until that product is sold to third parties.

At December 31, 2018 and 2017, the deferred profit was $421,800 and $751,500, respectively, which is included in deferred profit, related party in the consolidated balance sheets. For twelve months ended December 31, 2018 and 2017, Milestone Scientific recorded a loss and income on equity investment of $329,700 and $120,510, respectively, for product sold by Milestone China to third parties.

Equity Method Disclosures

As of December 31, 2018, and December 31, 2017, Milestone Scientific's investment in Milestone China was $0. As of December 31, 2018, and December 31, 2017, Milestone Scientific's share of cumulative losses of Milestone China were $3,380,388 and $3,147,470, respectively, which have been suspended.

The following table includes summarized financial information (unaudited) of Milestone China:

	December 31, 2018	December 31, 2017
Assets:	(unaudited)	(unaudited)
Current assets	$10,587,648	$13,127,422
Non-current assets	4,603,485	3,213,520
Total assets:	$15,191,133	$16,340,942
Liabilities:		
Current liabilities	17,696,033	18,468,937
Stockholders' deficit	(2,504,900)	(2,127,995)
Total liabilities and stockholders’ deficit	$15,191,133	$16,340,942

	December 31, 2018	December 31, 2017
	(unaudited)	(unaudited)
Net sales	$7,598,998	$1,394,760
Cost of goods sold	3,539,138	477,200
Gross profit	4,059,860	917,560
Other expenses	(4,642,154)	(5,975,360)
Net Losses	$(582,294)	$(5,057,800)

NOTE I— FURNITURE, FIXTURES AND EQUIPMENT

	2018	2017
Furniture, Fixtures and Equipment consist of the following:		
Leasehold improvements	$24,734	$24,734
Office furniture and equipment	134,948	134,947
Molds	7,200	7,200
Trade show displays	143,357	143,357
Computers and software	278,766	270,904
Tooling Safety Wand	125,022	125,022
Tooling equipment-STA & Wand	11,100	11,100
EPI and IA Instruments	82,362	82,363
STA Trials Instruments	63,752	63,752
Total	871,241	863,379
Less accumulated depreciation	(788,684)	(721,619)
Total	$82,557	$141,760

Depreciation expense was *$66,604* and *$62,474* for the years ended *December 31, 2018* and *2017,* respectively.

NOTE J — PATENTS

	December 31, 2018				December 31, 2017			
	Cost	Impairment	Accumulated Amortization	Net	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	$*1,377,863*	$-	$*(942,590*)	$*435,273*	$*1,377,863*	$-	$*(787,821*)	$*590,042*
Epidural-Apad acquired patents	*2,639,647*	*(1,539,794*)	*(1,099,853*)	-	*2,639,647*	-	*(439,941*)	*2,199,706*
Total	$*4,017,510*	$*(1,539,794*)	$*(2,042,443*)	$*435,273*	$*4,017,510*	$-	$*(1,227,762*)	$*2,789,748*

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was $814,681 and $510,676 for the year ended December 31, 2018 and 2017, respectively. The annual amortization expense expected to be recorded for existing intangibles assets for the years 2019 through 2023 is approximately $53,000, $53,000, $53,000, $47,000 and $33,000.

On July 13, 2017, Milestone Scientific consummated an Asset Purchase Agreement (the "Agreement") with APAD Octrooi B.V. and APAD B.V. (each, a "Seller" and collectively, the "Sellers") pursuant to which Milestone Scientific acquired certain patent rights and other intellectual property rights related to the Sellers' computer-controlled injection instrument (the "Purchased Assets") accounted for as an asset acquisition. On the closing date, Milestone Scientific issued to the Sellers an aggregate of 1,646,358 shares of its common stock, valued at approximately $2,486,000 for the Purchased Assets which shares are subject to certain post-closing upward or downward adjustments not to exceed twenty-five percent of the initial shares as of the purchase date or 250,000 Euros, as defined in the agreement. In 2018 Milestone Scientific finalized the payment for the APAD patents with the issuance of 244,959 shares at a cost of $286,601. The patents purchased in the amount of approximately $2,639,000 have been capitalized and were amortized over their three-year estimated useful life.

During 2018, the Company determined that the APAD Patents purchased in 2017 will not be further developed or commercialized before their estimated useful life expires . As such, Management has determined that these assets have been impaired and a charge of approximately $1.5 million was recorded.

NOTE K — STOCKHOLDERS' EQUITY

ISSUANCE COMMON STOCK

In December 2016, Milestone Scientific completed an underwritten public offering of 2,000,000 shares of common stock and warrants to purchase up to 1,592,775 shares of common stock, including 92,775 additional warrants pursuant to a partial exercise of the over-allotment option granted to the underwriters. Each share of common stock was sold in combination with a warrant to purchase 0.75 shares of common stock. The public offering price for each share and related .75 share warrant was $1.50 for gross proceeds of $3,000,000. The warrants have a three-year term and an exercise price of $2.55 per share. In January 2017, the underwriter exercised a portion of its over-allotment option to purchase an additional 123,700 shares of common stock at the public offering price of $1.499 per share for gross proceeds of approximately $186,000.

PREFERRED STOCK

In May of 2014, Milestone completed a private placement, which raised gross proceeds in the total of $10 million, from the sale of $3 million of Milestone Scientific common stock (two million shares at $1.50 per share) and $7 million of our Series A Convertible Preferred Stock ("preferred stock") (7,000 shares at $1,000 per share). These shares are convertible, at the option of the holder, into the number of shares of common stock equal to the stated value divided by $2.545, subject to anti-dilution adjustments, at any time before May 14, 2019. These shares are mandatorily convertible on May 14, 2019, into the number of shares of common stock equal to the stated value divided by $2.545 per share or $1.50 per share if the common stock does not trade at $3.15 for period of time, as defined by the agreements, both subject to anti-dilution adjustment. The conversion ratio and anti-dilution adjustment becomes effective if a triggering events occur such as; issuance of stock dividends or distributions, subdivisions, splits, issuance of stock purchase rights, debt and distributions, cash dividends or distributions, self-tender offers and exchange offers, rights plans and issuance below the conversion price, as defined in the Investment Agreement. Generally, each share of preferred stock entitles the holder to vote together with the holders of Milestone Scientific common stock, as a single class, on all matters submitted for the approval of the holders of Milestone Scientific common stock and has the number of votes equal to the number of shares of our common stock into which they are then convertible. In addition, preferred stock is also entitled to share, pair passu, in any cash dividends declared on Milestone Scientific common stock on a converted basis.

SHARES TO BE ISSUED

As of December 31, 2018, and 2017, there were 1,908,813 and 1,374,931 shares, respectively, whose issuance has been deferred under the terms of an employment agreements with the Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. Such shares will be issued to each party upon termination of their employment. As of December 31, 2018, and 2017, there were 561,752 and 26,316 shares, respectively, that will be issued in 2019 to non employee for services rendered. The number of shares was fixed at the date of grant and were fully vested upon grant date.

SHARES RESERVED FOR FUTURE ISSUANCE

At December 31, 2018 and 2017, there were 5,315,974 and 5,111,582 shares reserved for future issuance and 2,845,409 and 3,710,335 shares underlying other vested stock options and warrants outstanding, respectively.

NOTE L — STOCK OPTION PLANS

The 2004 Stock Option Plan provided for the grant of options to purchase up to 750,000 shares of Milestone Scientific's common stock. Options may be granted to employees, officers, directors and consultants of Milestone Scientific for the purchase of common stock at a price not less than the fair market value of the common stock on the date of the grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. There were no shares available for grant at December 31, 2018 or 2017 under this plan.

In June 2011, the stockholders of Milestone Scientific approved the 2011 Stock Option Plan (the "2011 Plan") which originally provided for stock options to our employees, directors and consultants and incentive and non-qualified stock options to purchase up to 2,000,000 shares of common stock and was later amended in 2016 to increase the maximum number of shares reserved for grant to 4,000,000. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant.

Milestone Scientific recognizes compensation expense over the requisite service period and in the case of performance-based options over the period of the expected performance. For the twelve months ended December 31, 2018 and 2017, Milestone Scientific recognized $398,301 and $636,058 of total employee compensation cost, respectively. As of December 31, 2018 and 2017, there was $263,974 and $603,979 of total unrecognized compensation cost related to non- vested options, respectively. Milestone Scientific expects to recognize these costs over a weighted average period of 1.75 years and 3.04 years as of December 31, 2018 and 2017, respectively.

A summary of option activity for employees under the plans and changes during the years ended December 31, 2018 and 2017 is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Options outstanding December 31, 2016	1,511,995	1.74	2.97	102,605
Granted	1,806,741	1.82	4.69	25,610
Exercised during 2017	(83,333)	0.75	-	-
Forfeited or expired	(1,250,068)	-	-	-
Options outstanding December 31, 2017	1,985,335	1.74	3.04	25,160
Exercisable, December 31, 2017	1,317,441	1.84	2.46	8,537
Granted	-	-	-	-
Exercised during 2018	-	-	-	-

Forfeited or expired	(315,114)	1.50	-	-
Options outstanding December 31, 2018	1,670,221	1.71	2.40	-
Exercisable, December 31, 2018	1,317,632	1.79	2.15	-

The weighted-average fair value of the options granted during *2018* and *2017* was estimated at $0 and *$1.73* respectively, on the date of grant. The fair value for *2018* and *2017* was determined using the Black-Scholes option-pricing model with the following assumptions:

	2018	2017	
Volatility	-	81.23%-97.24%	
Risk-free interest	-	1.4%-2.2%	
Expected Life	-	2-5 years	
Dividend yield	-	0	%
Forfeiture Rate	-	6	%

A summary of option activity for non-employees under the plans and changes during the years ended *December 31, 2018* and *2017,* is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Options outstanding December 31, 2016	224,999	2.53	5.32	-
Granted	-	-	-	-
Exercised during 2017	-	-	-	-
Forfeited or expired	-	-	-	-
Options outstanding December 31, 2017	224,999	2.53	4.32	-
Exercisable, December 31, 2017	23,067	2.22	4.38	-
Granted	8,333	0.75	4.33	
Exercised during 2018	-	-	-	-
Forfeited or expired	(200,000)	2.55	-	-
Options outstanding December 31, 2018	33,332	1.87	2.94	-
Exercisable, December 31, 2018	27,777	2.10	2.66	-

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model at the date of grant. For the twelve months ended December 31, 2018 and 2017, Milestone Scientific recognized $10,720 and $9,384 expense related to non-employee options, respectively.

NOTE M–EMPLOYMENT CONTRACT AND CONSULTING AGREEMENTS

Employment Contracts

As of September 1, 2009, Milestone Scientific entered into a five-year employment agreement with Leonard Osser as its then Chief Executive Officer (the "2009 Agreement"). The terms of the 2009 Agreement are automatically extended for successive one-year periods unless prior to August 1 of any year, either party notifies the other that he or it chooses not to extend the term. Under the 2009 Agreement, the CEO receives base compensation of $300,000 per year. In addition, the CEO, may earn annual bonuses up to an aggregate of $400,000, payable one half in cash and one half in common stock, contingent upon achieving targets set for each year by the Compensation Committee. In addition, if in any year of the term of the agreement the CEO earns a bonus, he shall also be granted five-year stock options to purchase twice the number of bonus shares earned. Each such option is to be exercisable at a price per share equal to the fair market value of a share on the date of grant 110% of the fair market value if the CEO is a 10% or greater stockholder on the date of grant). On the grant date one-third of options are vested, the remaining options shall

be vested over a 3 years period, with one- third vesting each year on the grant date but shall only be exercisable while the CEO is employed by Milestone Scientific or within 30 days after the termination of his employment. In addition, the CEO also receives other compensation represents payments made for health insurance coverage $4,900 and car allowance $7,200, pension payment $203,111.

In accordance with the 2009 Agreement, 1,055,135 shares of common stock were to be paid out at the end of the term in settlement of $1,205,707 of deferred compensation accrued at December 31, 2018 and 886,866 shares of common stock are to be paid out at the end of the contract in settlement of $1,030,875 of deferred compensation accrued at December 31, 2017 and, accordingly, such shares have been classified in stockholders' equity with the common stock classified as to be issued.

On December 1, 2016, Wand Dental and Gian Domenico Trombetta (“Trombetta”) entered into an Amended and Restated Employment Agreement (the “Agreement”), pursuant to which Trombetta receives base compensation of $280,000 per year and is eligible to receive annual bonuses in the sole discretion of the Compensation Committee. Pursuant to the Agreement, Trombetta will continue to serve as the Chief Executive Officer of Wand Dental for a period of one-year beginning on September 1, 2016 through August 31, 2017 (the “Employment Term”). The Employment Term automatically renews for a one-year period, from September 1st through August 31st of each successive year (each a “Renewal Term”), unless prior to June 1st of the Employment Term or any Renewal Term, as applicable, either party notifies the other that he or it chooses not to extend the term of employment in accordance with the terms of the Agreement.

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 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 2, 2017, Milestone Scientific accepted the resignation of the then CEO, Daniel Goldberger. Subsequent to that date, Mr. Goldberger through his attorney advised Milestone Scientific's attorneys, that Mr. Goldberger was entitled, based on the circumstances he asserted with respect to his resignation after acceptance of such resignation, to his basic salary ($300,000) for one year and certain other benefits (health and disability insurance for one year ($30,000 estimated) and a car allowance of $1,200 per month), in accordance with his employment contract dated July 10, 2017.

In February 2018, Milestone Scientific and Daniel Goldberger, the Company's former President and Chief Executive Officer, who resigned effective October 2, 2017, signed a Settlement and Release Agreement with respect to Mr. Goldberger's leaving the Company. The gross settlement was $175,000, which was paid in full as of December 31, 2018.

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.

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. All previous compensation expense recorded to the date of the resignation, related to the stock options, was reversed as of the resignation date.

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 agreed to accept *25,000* shares of Milestone Scientific stock for her services as Interim Chief Executive Officer in-lieu of the *100,000* shares she was previously awarded.

On December 19, 2017 the Board of Directors appointed Leonard Osser Interim Chief Executive Office, replacing Leslie Bernhard. Mr. Osser will enter into a similar employment contract that he received in 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 and will not receive or earn any compensation under those agreements until he is no longer Interim Chief Executive Officer.

NOTE N — INCOME TAXES

Due to Milestone Scientific's history of operating losses, a full valuation allowances have been provided for all of Milestone Scientific's deferred tax assets At December 31, 2018 and 2017, no recognition was given to the utilization of the remaining net operating loss carry forwards in each of these periods.

Deferred tax attributes resulting from differences between financial accounting amounts and tax bases of assets and liabilities at December 31, 2018 and 2017 are as follows:

	2018	2017
Allowance for doubtful accounts	$3,000	$3,000
Warranty reserve	29,000	20,000
Impaired Assets	435,000	5,000
Inventory Reserve	551,000	
Capital Gains	-	45,000
Deferred officers' compensation	715,000	636,000
Depreciation and Amortization	345,000	181,000
Deferred revenue		478,000
Net operating loss carryforward	16,500,000	15,116,000
Subtotal	18,578,000	16,484,000
Valuation allowance	(18,578,000)	(16,484,000)
Non-current deferred tax asset	$-	$-

The deferred tax asset, before valuation allowance, has been calculated on rates anticipated to be effect when the temporary differences reverse. Accordingly, based on the change in Federal tax rates promulgated in December 2017, effective January 1, 2018, the Company utilized a Federal rate of 21% and accordingly existing deferred tax assets upon the tax law act being signed into law on December 22, 2017, the Company revalued its deferred tax assets which resulted in a tax provision charge of $8,677,000, offset by a corresponding decrease in the valuation allowance.

As of December 31, 2018, federal net operating loss carry-forwards are approximately $65,300,000. As of December 31, 2017, and Milestone Scientific has federal net operating loss carry-forwards of approximately $60,000,000, which is comprised solely of losses attributable Milestone Scientific and its subsidiaries. Net operating losses will be available to offset future taxable income, if any, through December 2038. As of December 31, 2018, state net operating losses were approximately $30,800,000. As of December 31, 2017 Milestone, Scientific has state net operating loss carry-forwards of approximately $26,000,000. Net operating losses will be available to offset future taxable income, if any, through December 2038.

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

As of December 31, 2018, and 2017, state tax liability was approximately $24,000 and $19,000 respectively. Such expense was recognized in the accompanying consolidated financial statements.

Accounting for uncertainties in income taxes prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition. At December 31, 2018 and 2017, we had no uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2015, 2016, and 2017 years are subject to audit by federal and state jurisdictions.

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

	2018		2017	
Statutory rate	21	%	34	%
State income tax-all states	7	%	6	%
Non-deductible Stock based compensation	0	%	0	%
Deferred provision for effect of change in Federal rate	0	%	164	%
	28	%	204	%
Valuation allowance	-28	%	-204	%
Effective tax rate	0	%	0	%

NOTE O — SEGMENT AND GEOGRAPHIC DATA

We conduct our business through *two* reportable segments: dental and medical. These segments offer different products and services to different customer base. The following tables present information about our reportable and operating segments:

	Years Ended December 31,	
Sales		
Net Sales:	**2018**	**2017**
Dental	$9,502,276	$11,279,886
Medical	119,800	2,000
Total net sales	$9,622,076	$11,281,886
Operating Income (Loss):	**2018**	**2017**
Dental	$1,373,178	$3,127,570
Medical	(2,611,231)	(2,389,145)
Corporate	(6,761,282)	(5,972,743)
Total operating loss	$(7,999,335)	$(5,234,318)
Depreciation and Amortization:	**2018**	**2017**
Dental	$16,474	$17,305
Medical	24,492	26,950
Corporate	840,319	528,895
Total depreciation and amortization	$881,285	$573,150
Income (loss) before taxes and equity in earnings of affiliates:	**2018**	**2017**
Dental	$1,363,662	$3,136,167

Medical	(2,704,630)	(2,391,082)
Corporate	(6,658,152)	(5,975,035)
Total loss before taxes and equity in earnings of affiliate	$(7,999,120)	$(5,229,950)

The following table presents information about our operations by geographic area as *December 31, 2018* and *2017.* Net sales by geographic area are based on the respective locations of our subsidiaries

	2018		
	Dental	Medical	Total
Domestic US / Canada:			
Device	$491,375	$32,500	$523,875
Handpieces	4,211,243	-	4,211,243
Other	96,088	-	96,088
Total Domestic US / Canada	$4,798,706	$32,500	$4,831,206
International Rest of the World:			
Device	$1,292,844	$81,000	$1,373,844
Handpieces	2,444,639	6,100	2,450,739
Other	66,087	200	66,287
Total International Rest of the World	$3,803,570	$87,300	$3,890,870
International China:			
Device	$109,374	$-	$109,374
Handpieces	790,626	-	790,626
Other	-	-	-
Total International China	$900,000	$-	$900,000
Total Product Sales	$9,502,276	$119,800	$9,622,076

The following table presents information about our operations by geographic area as *December 31, 2018* and *2017.* Net sales by geographic area are based on the respective locations of our subsidiaries

	2017		
	Dental	Medical	Total
Domestic US / Canada:			
Device	$914,495	$-	$914,495
Handpieces	4,346,664	-	4,346,664
Other	78,550	-	78,550
Total Domestic US / Canada	$5,339,709	$-	$5,339,709
International Rest of the World:			
Device	$1,427,016	$-	$1,427,016
Handpieces	2,325,622	2,000	2,327,622
Other	116,539	-	116,539
Total International Rest of the World	$3,869,177	$2,000	$3,871,177
International China:			
Device	$643,600	$-	$643,600
Handpieces	1,425,600	-	1,425,600
Other	1,800	-	1,800
Total International China	$2,071,000	$-	$2,071,000

Total Product Sales	$11,279,886	$2,000	$11,281,886

Total Assets:	**December 31, 2018**	**December 31, 2017**
Dental	$5,169,944	$10,255,144
Medical	328,208	655,513
Corporate	902,816	4,718,130
Total assets	$6,400,968	$15,628,787

NOTE P -- CONCENTRATIONS

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, *CompuDent* and *CompuMed* devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current at December 31, 2018 and 2017. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations.

For the twelve months ended December 31, 2018, an aggregate of approximately 53% of Wand Dental's net product sales were to two customers/distributors (one of which, Milestone China, is a related party), 43% and 10% respectively. For the twelve months ended December 31, 2017, an aggregate of approximately 70% of Milestone Scientific's net product sales were to two customer/distributors (one of which, Milestone China, is a related party), 51% and 19% respectively.

Accounts receivable for the major customer/distributors amounted to approximately or 82%, or 49% and 33% of Milestone Scientific's gross accounts receivable as of December 31, 2018. Accounts receivable, including related party accounts receivable, for the major customer/distributors (one of which, Milestone China, is a related party), amounted to approximately $2,555,000, or 78% of Milestone Scientific's accounts receivable, as of December 31, 2017. As of December 31, 2018, Milestone China owed $1,917,990 to Milestone Scientific. Due to the delinquent nature of the scheduled payments and Milestone China's further liquidity constraints, Milestone Scientific reduced accounts receivable, related party and deferred revenue, related party by $1,817,990 at December 31, 2018. Additionally, Milestone Scientific recorded a reserve of $1,250,928 against the associated deferred cost, related party.

NOTE Q -- RELATED PARTY TRANSACTIONS

United Systems

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were $1.2 million and $2.1 million for the years ended December 31, 2018 and 2017, respectively. As December 31, 2018 and 2017, Milestone Scientific owed this manufacturer $1.3 million and $1.0 million, respectively, which is included in accounts payable, related party on the consolidated balance sheets. In February 2019, Milestone Scientific board of directors granted United Systems (controlling shareholder, Tom Cheng) 285,714 shares of stock at $.35 or $100,000 for consulting services. These shares were included in shares to be issued at December 31, 2018.

During 2018 Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of December 31, 2018, Wand Dental has deferred royalty income of $342,540 that will be recognized at the earlier of when payment of the royalties is received from United Systems or when collectability is deemed to be assured and is included in accounts receivable, related party and deferred revenue, related party on the consolidated balance sheets.

Also, during the year ended December 31, 2018, a Distribution Agreement between Wand Dental and United Systems was formed. Under the Distribution agreement United Systems purchased 1,000 STA instruments in June 2018, for delivery to Milestone China. Due to the related party nature and collectability concerns Wand Dental has deferred the sale. As of December 31, 2018, Milestone Scientific had recorded deferred revenues and deferred costs associated with the sale to United Systems of $750,000 and $686,365, respectively. Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and it’s agents which increased to $ 2.8 million at the time of the payment arrangement. The payment terms required $200,000 payments per month beginning in July 2018 through November 2018 and a balloon payment of approximately $1,425,000 during December 2018. During 2018 Milestone Scientific only collected $900,000 under the payment arrangement. Due to the default on the arrangement and Milestone China’s liquidity constraints, Milestone Scientific halted shipments to Milestone China. The Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a reserve against the related deferred cost of $1.25 million which includes the sale to United Systems. See Note H.

Milestone China

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. See note H for a description of related party transactions with Milestone China.

Other

In *August 2016,* K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a *three*-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were $100,000 for years ended December 31, *2018* and *2017,* respectively.

In *January 2017,* Milestone Scientific entered into a *twelve*-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific, to provide consulting services. This agreement will renew for successive *twelve*-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were $80,000 for years ended December 31, *2018* and *2017,* respectively.

The Director of Clinical Affairs’ royalty fee was approximately $465,000 and $554,000 for the years ended December 31, 2018 and 2017, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $186,000 and $275,000 for the years ended December 31, 2018, and 2017, respectively. As of December 31, 2018, and 2017 Milestone Scientific owed the Director Clinical Affairs for royalties of approximately $364,000 and $162,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

NOTE R — COMMITMENTS

(*1*) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, CompuDent® and CompuMed® devices, pursuant to which they manufacture these products under specific purchase orders but without

any long-term contract or minimum purchase commitment. In January 2018, Wand Dental entered into a new purchase commitment for the delivery of 2,000 devices beginning in the third quarter of 2018, Milestone Scientific's purchase commitment for this purchase order was $873,400 at December 31, 2018, however an advance of $596,724 was recorded against this purchase order. At December 31, 2018 Milestone Scientific still owes $259,801 related to this purchase order. An advance of approximately $649,000 and $697,000 was recorded at December 31, 2018 and 2017, respectively.

(*2*) Other Commitments

The technology underlying the Safety Wand® and *CompuFlo*®, and an improvement to the controls for *CompuDent*® were developed by the Director of Clinical Affairs and assigned to Milestone Scientific. Milestone Scientific purchased this technology pursuant to an agreement dated *January 1, 2005.* The Director of Clinical Affairs will receive additional payments of *2.5%* of the total sales of products using certain of these technologies, and *5%* of the total sales of products using certain other of the technologies until the expiration of the last patent covering these technologies. If products produced by *third* parties use any of these technologies (under license from us) then the Director of Clinical Affairs will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license.

The Director of Clinical Affairs' royalty fee was approximately $465,000 and $554,000 for the years ended December 31, 2018 and 2017, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $186,000 and $275,000 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017 Milestone Scientific owed the Director Clinical Affairs for royalties of approximately $364,000 and $162,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

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.

NOTE S — PENSION PLAN

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

NOTE T — SUBSEQUENT EVENTS

In February 2019, Milestone Scientific consummated a public offering and a private placement of Common Stock. The public offering generated gross proceeds of approximately $2.0 million for the issuance of 5,715,000 shares of common stock and warrants to purchase 1,428,000 shares of common stock. The warrants term is 5 years and they are exercisable at $.50. Subsequent to the public offering the underwriter exercised its overallotment option and paid approximately $198,000 for 567,400 additional shares.

Also, in February 2019, the Company generated gross proceeds from a private placement of approximately $250,000 for 714,286 shares of common stock and warrants to purchase 178,594 shares of common stock from Bp4 S.p.A., a principal stockholder of Milestone Scientific, that exercised its right to participate on a pro-rata basis on the recent public offering. Bp4's CEO is a director of Milestone Scientific and also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific.