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, 2016

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 MKT

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

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

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

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

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

As of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non- affiliates of the issuer was $42,784,395. This amount is based on the closing price of $2.80 per share of the registrant's common stock as of such date, as reported on the NYSE MKT.

As of March 31, 2017 the registrant has a total of 30,679,353 shares of Common Stock, $0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE
None

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FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K are "forward-looking statements" (within the meaning of the Private Securities Litigation Reform Act of 1995) regarding the plans and objectives of management for future operations. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Milestone Scientific Inc. ("Milestone Scientific") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Milestone Scientific's plans and objectives are based, in part, on assumptions involving the continued expansion of business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific. Although Milestone Scientific believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. In light of 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

Item 1. Description of Business

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

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of *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 a number of other disciplines. The dental instruments are sold in the United States and in over 47 countries abroad. To date there have been no medical instruments sold in the United States and limited amounts sold internationally, although certain medical instruments have obtained CE mark approval and now can be marketed and sold in most European countries. Milestone Scientific's products are manufactured by a third-party contract manufacturer.

In May 2014, Milestone Scientific completed a private placement (the "May 2014 Financing"), which raised aggregate gross proceeds $10 million, from the sale of $3 million of our common stock, $.001 par value per share ("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), convertible into common stock at $2.37 per share (as adjusted to date) on May 14, 2019, or $1.50 per share if certain conditions are not met; both subject to anti-dilution adjustment.

In July 2014, Milestone Scientific acquired all of the outstanding shares of an inactive Florida corporation and changed its name to Wand Dental, Inc. ("Wand Dental"). In September 2014, that corporation was merged into a Delaware corporation, retaining the same name and capitalization. On July 1, 2014, Wand Dental was capitalized with cash and the contribution by Milestone Scientific of its dental business and related dental assets including the exclusive license of Milestone Scientific's patents, trademarks, and technology for use in the dental marketplace.

On June 1, 2015, our common stock was listed on the NYSE MKT LLC ("NYSE MKT") under the ticker symbol "MLSS".

In June 2016, we raised an additional $2.0 million of gross proceeds in a private placement of one million shares of common stock, at a price of $2.00 per share, to the same investors that participated in the May 2014 financing.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we exchanged one share of common stock for every two outstanding shares of Milestone Medical (described below) common stock, a previously consolidated variable interest entity. As a result of the exchange program, at December 31, 2016, Milestone Scientific owned approximately 91% of Milestone Medical.

In July 2016, Milestone Scientific raised gross proceeds of $250,000 in a registered direct offering of 104,200 shares of common stock at $2.40 per share. The transaction was covered by the prospectus supplement, filed with the United States Securities and Exchange Commission ("SEC") on July 22, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

In July 2016, Milestone Scientific filed for 510(k) marketing clearance with the United States Food and Drug Administration ("FDA") Milestone Medical's epidural anesthetic injections instrument. This clearance is necessary to begin commercialization of these medical instruments in the United States.

In December 2016, we received notification from the FDA that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, out did not adequately document that the device met the equivalency standard required for 510(k) clearance. Following consultation with the FDA Office of Device Evaluation, we intend to provide additional data, which could include a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the device. An HFV Study demonstrates the ease of use of a product. The cost to generate this incremental data is estimated to be approximately $100,000.

In December 2016, we 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. The public offering price for each share and related warrant was $1.50. 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. The gross proceeds from this offering, including proceeds from partial exercises of the over-allotment option, were approximately $3,200,000, before deducting underwriting discounts and commissions and other offering expenses. This offering was covered by the prospectus supplement, filed with the SEC on December 16, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

As of December 31, 2016, Milestone Scientific's financial statements are consolidated to include the accounts of its wholly-owned and majority-owned subsidiaries including, Wand Dental, Milestone Advanced Cosmetic Systems, Inc., ("Milestone Advance Cosmetic"), and Milestone Medical Inc. ("Milestone Medical"). Milestone Education LLC ("Milestone Education") is a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements as of January 1, 2016.

BUSINESS

Background

Since its inception, Milestone Scientific has engaged in pioneering proprietary, innovative, computer-controlled injection technologies and solutions for the medical and dental markets. Milestone Scientific has focused its resources on redefining the worldwide standard of care for injection techniques by making the experience more comfortable for the patient and by reducing the anxiety and stress of administering injections for the healthcare provider.

Milestone Scientific and its technology are widely recognized by key opinion leaders, industry experts and medical and dental practitioners as the noted leader in the emerging, high growth, computer-controlled injection industry; and remains intent on expanding the use and application of its proprietary, patented technologies to achieve greater operational efficiencies, enhanced patient safety and therapeutic adherence, and improved quality of care within a broad range of medical disciplines.

In 1997, Milestone Scientific first introduced *The Wand*® (*CompuDent*® instrument) and the disposable *Wand*® handpiece. *CompuDent*® provides painless injections for all routine dental treatments, including implants, root canals, crowns, fillings and cleanings. Milestone Scientific's Computer-Controlled Local Anesthetic Delivery (C-CLAD) instrument handpiece does not look or feel like a syringe.

Milestone Scientific expanded its product offerings with the introduction of its *CompuMed*® advanced injection instrument, designed for use in a wide range of applications within the medical industry, including cosmetic surgery, hair restoration surgery, podiatry, colorectal surgery, nasal and sinus surgery, dermatology and orthopedics, among others.

In 2007, Milestone Scientific received FDA 510(k) clearance for the marketing and sale of its *STA Single Tooth Anesthesia System*® instruments (dental instrument). Milestone Scientific introduced the instrument to the market in February 2007 and this instrument is currently being marketed throughout the world.

Central to Milestone Scientific's intellectual property platform and current product development strategy is its patented CompuFlo® technology for the precise delivery of medicaments**.** The CompuFlo® pressure/force Computer-Controlled Local Anesthetic Delivery (C-CLAD) technology is an advanced, patented and FDA-approved medical 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 flow rate continues to provide the CompuDent® benefits of painless injections, while its DPS Dynamic Pressure Sensing Technology® 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. The 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, pressure feedback can prevent the suffusion of tissue outside the intended target area, a vitally important characteristic in the injection of chemotherapeutics and other toxic substances.

The CompuFlo® technology consists of two critical elements. One element is the ability to determine exit pressure In Situ (in the injection site tissue) at the tip of the needle. This minimizes tissue damage (and eliminates the pain of the injection) because the flow rate and pressure of the injection are controlled. The other critical element of the technology is an integrated injection database of algorithms that have been defined which allow for the measurement of the exit pressure. This database of algorithms contains 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.

The *CompuFlo*® technology also consists of a disposable injection handpiece that provides for precise tactile control during the injection, an electromechanical (computer-controlled) fluid delivery instrument and the ability to record data from the injection event. As confirmed by numerous noted medical and dental experts within academia and the clinical practice arenas, *CompuFlo*® has 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.

On September 14, 2004, Milestone Scientific was issued United States Patent No. 6,786,885 for the *CompuFlo*® technology, entitled "Pressure/Force Computer Controlled Drug Delivery Instrument with Exit Pressure." Proprietary software, working with an innovative technology, allows the instrument to continuously monitor and control the exit pressure of fluid and/or medication during an injection. This same technology also enables doctors to accurately identify different tissue types based on exit pressure during an injection. The technology has numerous applications in both medicine and dentistry, including epidural and intra-articular injections.

In December 2004, the United States Patent Office issued a "Notice of Allowance" for patent protection on two additional critical elements of the *CompuFlo*® automated drug delivery technology: "Drug Delivery Instrument with Profiles" and "Pressure/Force Computer Controlled Drug Delivery with Automated Charging".

In December 2005, Milestone Scientific submitted a pre-market notification to the FDA on its *CompuFlo*® technology, which was subsequently cleared by the FDA in July of 2006. This initial submission was critical for Milestone Scientific's continuing efforts to develop and commercialize this important technology. Milestone Scientific has identified a number of potential applications for *CompuFlo*®, including single-tooth dental injections, self-administered drug delivery, osteoarthritis joint pain management and epidurals.

Given Milestone Scientific's experience and established brand awareness within the dental industry, it elected to focus its initial product development efforts on the integration of *CompuFlo*® into its legacy computer-controlled dental injection instrument. As a result, Milestone Scientific developed the industry's first solution for painlessly administering a single-tooth injection as the only injection necessary for achieving anesthesia, foregoing the need to administer a traditional nerve branch block. This instrument, which also utilizes a disposable handpiece, was trademarked the "S*TA Single Tooth Anesthesia System ®".*

After receiving FDA 510(k) approval for the marketing and sale of the STA Instrument, Milestone Scientific introduced the instrument to market in February 2007 at the Chicago Dental Society's 143rd Midwinter Meeting. The patented STA Instrument incorporates the "pressure feedback" elements of Milestone Scientific's patented *CompuFlo*® technology, thereby allowing dentists to administer injections accurately and painlessly into the periodontal ligament space, effectively anesthetizing a single tooth. This injection is of significant value in that it allows the dentist to profoundly anesthetize the tooth within one or two minutes, versus up to 15-18 minutes for a block injection to take effect. Utilizing the STA Instrument single tooth injection, the patient will suffer neither pain nor collateral anesthesia in the cheek, lips or tongue at any time. The STA Instrument is capable of performing all of the injections that can be done with a conventional dental syringe, including the palatal-anterior superior alveolar, anterior middle superior alveolar and inferior alveolar nerve block. The STA Instrument achieves these injections predictably and reliably.

Initial market response to the STA Instrument following its commercial debut in February 2007 proved to be less than robust. Moreover, at that time, Milestone Scientific had granted exclusive United States and Canadian distribution and marketing rights for the STA Instrument to Henry Schein, Inc. ("Henry Schein"), the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets. Following several months of lackluster sales and after making critical senior management changes, Milestone Scientific initiated an in-depth market study to reassess its positioning and marketing strategies for the STA Instrument. The insight gained from this study led management to redefine and implement a new messaging platform, created to emphasize key benefits that Milestone Scientific discovered are of most value to dental professionals. This new product messaging was launched in January 2008 and has remained in constant review.

In the spring of 2009, Milestone Scientific signed a distribution and marketing agreement with China National Medicines Corporation, dba Sinopharm, which is China's largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and China's largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. The distribution and marketing agreement with China National Medicines was terminated in September 2014. Proximate to that time, we entered into a new distribution and marketing agreement with Milestone China Ltd. ("Milestone China") to be our distributor for the STA Instruments and handpieces in China. Milestone Scientific owns forty (40%) percent of Milestone China.

In early October 2012, the State Food and Drug Administration ("CFDA") of the People's Republic of China approved our *STA Single Tooth Anesthesia System*® *Instrument.* However, the CFDA's approval of the *Wand*® handpieces was received in May 2014 and the distribution of these handpieces in China began in the fourth quarter of 2014.

According to a 2011 report published by the U.S. Department of Commerce, titled "China's Emerging Markets: Opportunities in the Dental and Dental Lab Industry," China's dental market lags behind other healthcare services and has largely been neglected in the past. In fact, a CS Market Research report indicates that 50% of adults and 70% of children out of China's estimated 1.3 billion plus population have tooth decay problems and over 90% have periodontal disease. (See Shuyu Sun & Seth Pierrepont. The Dental Equipment Market Over in China, CS Market Research (Sept. 20, 2005) and Opportunities Abound for Dental Care in China, CHINA BRIEFING (February 27, 2015)). However, with increasing affluence of the Chinese population, as well as increasing attention towards personal care, demand for dental services has been growing. Market research firm Freedonia agrees, noting that demand for dental products in China is expected to climb due primarily to escalating personal income levels and government programs promoting awareness of the benefits of good oral care.

Shortly before the end of the second quarter of 2009, Milestone Scientific elected to refine its international marketing strategy to gain greater access to and penetration of the international dental markets. The revised sales strategy provides for increasing hands-on oversight and support of its existing international distribution network, while also attracting new distributors throughout Europe, Asia and South America.

In November 2012, Milestone Scientific signed an exclusive distributor and marketing agreement with a well-known US domestic manufacturer and distributor, for the sale and distribution of the STA instrument and handpieces in the United States and Canada. The marketing initiative included participation in US 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. The exclusive distributor and marketing agreement was converted to a non-exclusive agreement on December 31, 2016.

In January of 2015, Milestone Scientific added a President, a full-time CEO for Wand Dental, a Senior Business Brand Manager, and a Senior Manager of Project Management. This increase in staffing was to support the growth of our initiative in our *CompuFlo*® software for anticipated new medical and dental instruments.

In September 2016, Milestone Scientific added a senior Vice President of Marketing and Sales to focus on the medical sector of our business.

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. We believe that this exclusive arrangements will be more effective than previous arrangements relying on Wand Dental's appearances at dental shows and catalog sales.

***CompuFlo*® Advanced Injection Technology – Core Technology**

Our next significant intellectual property was the development of our proprietary patented CompuFlo® technology for the precise delivery of anesthetics and other medicaments into various tissues and bodily cavities. The CompuFlo® technology has been FDA approved and allows the practitioner to precisely regulate and control the flow rate of the injectable material while receiving visual and audible in-tissue pressure feedback, allowing the practitioner to determine the tissue into which the injectable material is being delivered. The CompuFlo® technology encompasses the painless delivery benefits of the CompuDent® while allowing the practitioner to know which tissues have been penetrated and to inject medicaments precisely into the desired location. With CompuFlo®, the injection of chemotherapeutics and other toxic substances outside the targeted area can be avoided. The instruments developed using the CompuFlo® also provide a digital record of the time and amount of anesthetic or medicament injected.

Our first system utilizing the *CompuFlo*® technology was our STA instrument and related handpiece for the dental market. The STA instrument and handpiece continue to provide all of the benefits of the *CompuDent*® system while better facilitating single tooth anesthesia (now generally performed with a high pressure spring loaded gun-like instrument) by allowing the practitioner to monitor and precisely control pressure, rate and volume. Instruments using the *CompuFlo*® technology can be used to inject a wide variety of liquid medicaments as well as anesthetics. We believe *CompuFlo*® avoids the negative side effects from the use of traditional hypodermic drug delivery injection instruments, 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 been capable of controlling flow rate, we believe the ability to accurately and precisely control pressure has been unobtainable until the development of *CompuFlo*®.

The next systems utilizing the *CompuFlo*® technology we developed were instruments for administering epidural injections and intra-articular related disposable and an instrument for administering hyaluronic acid and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions.

Our epidural injection instrument using *CompuFlo*® pressure sensing technology 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 extraligamentary tissue. In studies utilizing the *CompuFlo*® technology the epidural space has been correctly identified 100% of the time. Knowing the precise location of a needle during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes, in the absence of fluoroscopy, who identify the epidural space by relying on the subjective perception of loss of resistance to saline.

Precisely controlling in-tissue pressure increases 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 epidural injections, intra-articular injections and numerous organ, subcutaneous and intramuscular injections.

We believe that our intra-articular injection instrument will be 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 hyaluronic acid or other medicament into that space. The *CompuFlo*® technology has been successful in administering hyaluronic acid and other medicaments into the intra-articular space in both small and large joints using its computer-controlled pressure sensing capabilities in an independent animal study.

Both the epidural and intra-articular instruments have obtained CE mark approval and may now be marketed and sold in most European countries and many other countries accepting CE approved instruments. In the United States, we have completed required testing for the epidural instrument for birthing and pain management and have submitted the favorable results of these tests to the FDA. We expect to receive FDA approval of our epidural instrument by the end of the second quarter 2017 and of our intra-articular instrument some time later in 2017; however we are unable to provide any assurances when approval will be received, if ever. Upon FDA approval, we intend to establish an international marketing network of independent distributors for the devices, although a limited number of European and near-east distributors have already been appointed.

In December 2016, we received notification from the FDA that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, we did not adequately document that the device met the equivalency standard required for 510(k) clearance. Following consultation with the FDA Office of Device Evaluation, we intend to provide additional data, which could include a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the device. An HFV Study demonstrates the ease of use of a product. The cost to generate this incremental data is estimated to be approximately $100,000.

At earlier stages of development are potential products, using our *CompuFlo*® technology for less painful injections into the eye and for the subcutaneous injection of fillers and other substances in the dermatology market. In the self-injectable market there are a number of 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 the *CompuFlo*® technology, using pressure sensing capabilities, can serve as a painless subcutaneous injection method for these self-administered drugs. A significant reduction in pain during delivery should have a positive impact on compliance, which is a major consideration when physicians are treating patients. In addition, the ability to record the injection will allow for significantly enhanced monitoring of the patient.

Instruments Platform-Medical and Dental

Milestone Scientific has developed and brought to market a highly differentiated portfolio of industry innovations. Milestone Scientific’s proprietary solutions have succeeded in elevating the innovation in the professional dental arena. The product portfolio includes:

STA Single Tooth Anesthesia System® Instrument

The *STA Single Tooth Anesthesia System® Instrument* (or STA Instrument) is a patented, computer-controlled local anesthesia delivery instrument that incorporates the “pressure feedback” elements of Milestone Scientific’s patented *CompuFlo*® technology, thereby allowing dentists to administer injections accurately into the periodontal ligament space, effectively anesthetizing a single tooth. While the periodontal ligament injection has been available for some time, there has been no effective technology that allows dentists to easily perform the procedure painlessly, safely and predictably until now. With this STA Instrument dentists can easily and predictably anesthetize a single tooth root in one minute as the primary and sole injection, as compared to a general blocking injection with a waiting time of up to 18 minutes (or longer if the blocking injection needs to be re-administered) before proceeding to perform a procedure on the targeted tooth. An instrument which allows dentists to effectively anesthetize a single tooth will greatly enhance the productivity of dental practices and, when combined with the painless injection capabilities already present in the *CompuDent*® instrument, such an instrument should provide a compelling value in the marketplace. The STA Instrument will generate recurring revenues from per-patient disposable handpieces.

Since its market introduction in the spring of 2007, the STA Instrument has received favorable reviews and awards from the dental industry. In July 2007, noted industry publication Dentistry Today featured the STA Instrument as one of the "Top 100 Products in 2007," helping to promote much broader recognition of the instrument and validating STA's value proposition for dentists and patients, alike. In early 2008, Medical Device & Diagnostic Industry magazine distinguished the STA Instrument 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 STA was one of only two winning products that serve dental practitioners. In December 2008, Milestone Scientific continued to win broad acclaim for the STA Instrument 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 STA Instrument was also named as a Dental Products Report "Top 100 2008 Product of Distinction." Additionally, the STA Instrument was named one of Dentistry Today's "Top 100 Products" for the third consecutive year in 2010.

CompuDent®

CompuDent® is Milestone Scientific's proprietary, patented Computer-Controlled Local Anesthetic Delivery (C-CLAD) instrument and predecessor of the STA Instrument. CompuDent® delivers anesthesia at a precise and consistent rate below a patient's pain threshold. Over the years, CompuDent® has been widely heralded as a revolutionary instrument, considered one of the major advances in dentistry in the 20^{th} Century. The instrument has been favorably evaluated in more than 50 peer reviewed or independent clinical research reports. CompuDent®, including its ergonomically designed single-use handpieces (The Wand®), provides numerous, well documented benefits:

- CompuDent® minimizes the pain associated with palatal, mandibular block and all other injections, resulting in a more comfortable injection experience for the patient;
- the pencil grip used with The Wand® handpieces allows unprecedented tactile sense and accurate control;
- new injections made possible with the CompuDent® technology eliminate collateral numbness of the tongue, lips and facial muscles;
- bi-directional rotation of The Wand® handpieces eliminates needle deflection resulting in greater success and more rapid onset of anesthesia in mandibular block injections;
- the use of a single patient use, disposable handpieces minimizes the risk of cross contamination; and
- The ergonomic design of The Wand® handpieces makes an injection easier and less stressful to administer, lowering the risk of carpal tunnel syndrome.

Despite *CompuDent*® many benefits, including the administration of less painful and more comfortable injections, dentists in the United States have been slow to give up the use of traditional syringes. Dentists have all been trained to use syringes in dental school and often have become accustomed to and are comfortable with their use during many years of clinical practice, in spite of the obvious reluctance and/or fear of the patient in relation to injections administered by hypodermic syringe. There are approximately 40 million dental phobics, those people afraid to visit a dentist, in the United States. Therefore, Milestone Scientific believes there is a disconnect in the way dentists perceive their patients' attitudes toward injection by hypodermic syringe. The CompuDent® is used today by thousands of dentists around the world, many of whom have long since abandoned the over 150-year old syringe.

CompuMed®

CompuMed® is a patented computer-controlled injection instrument geared to the needs of the medical market and providing benefits similar to *CompuDent*®. *CompuMed*® allows many medical procedures, now requiring intravenous sedation, to be performed with only local anesthesia due to dramatic pain reduction. Also, dosages of local anesthetic can often be significantly reduced, thus reducing side effects, accelerating recovery times, lowering costs and eliminating potential complications. *CompuMed*® has accumulated clinical evidence demonstrating benefits from use in colorectal surgery; podiatry; dermatology, including surgery for the removal of basal cell carcinomas and other oncological dermatologic procedures; nasal and sinus surgery, including rhinoplasty; hair transplantation and cosmetic surgery, among others. The *CompuMed*® is being replaced by instruments that include *CompuFlo*® technology geared to specific medical disciplines.

The Wand®

Our first commercial product, the *CompuDent®,* and its associated disposable *The Wand®* handpiece for the dental market is intended to allow the dentist to provide painless injections for virtually all dental procedures, including routine cleanings and fillings, as well as more sophisticated implants, root canals and crowns. New injections made possible by the *CompuDent®* 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 pencil grip used with The Wand® handpieces provides the practitioner with unprecedented tactile sense and accurate control and allows bi-directional rotation eliminating needle deflection, resulting in a greater success rate. Since the *Wand®* handpiece does not look like a typical syringe it also reduces patient anxiety and offers the possibility of curing dental phobia of which 40 million Americans suffer (see the Colgate Oral Care website). The *CompuDent®* instrument is considered one of the major advances in dentistry in the 20th Century and has been favorably evaluated in more than 50 peer reviewed or independent clinical research reports, which we have reviewed.

Competition

Milestone Scientific's proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) instruments 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. Upon commercial introduction and sale, Milestone Medical's epidural injection instrument will also compete with APAD, a computer controlled injection instrument which claims to be able to reliably identify the epidural space.

Milestone Scientific's instruments compete on the basis of their performance characteristics and the benefits provided to the practitioner, patient and the dental business operations. Clinical studies have shown that the instruments reduce fear, pain and anxiety for many patients, and Milestone Scientific believes that they can reduce practitioner stress levels, as well. Milestone Scientific's newest product introduction, the STA Instrument, can be used for all dental injections that can be performed with a traditional dental syringe. Moreover, the STA Instrument can also be used for new and modified dental injection techniques that cannot be performed with traditional syringes. These new techniques allow for faster procedures shortening chair-time, minimizing the numbing of the lips and facial muscles, enhancing practice productivity, reducing stress and virtually eliminating pain and anxiety for both the patient and the dentist.

Milestone Scientific faces intense competition from many companies in the medical and dental device industry, possessing substantially greater financial, marketing, personnel, and other resources. Most competitors have established reputations, stemming from their success in the development, sale, and service of competing dental products. Further, rapid technological change and research may affect the products. Current or new competitors could, at any time, introduce new or enhanced products with features that render the products less marketable or even obsolete. Therefore, Milestone Scientific must devote substantial efforts and financial resources to improve existing products, bring products to market quickly, and develop new products for related markets. In addition, the ability to compete successfully requires that Milestone Scientific establish an effective distribution network with a strong marketing plan. Historically, Milestone Scientific has been unsuccessful in executing the marketing plans for its products, primarily due to resource constraints. New products must be approved by 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 the products less marketable or obsolete, or, that Milestone Scientific will succeed in improving the existing products, effectively develop new products, or obtain required regulatory approval for those products.

Patents and Intellectual Property

Milestone Scientific holds the following U.S. utility and design patents:

Computer Controlled Drug Delivery Systems	U.S. Patent Number	Date of Issue
Dental Anesthetic and Delivery Injection Unit	6,022,337	2/8/2000
Cartridge Holder for Injection Device	6,132,414	10/17/2000
Dental Anesthetic Delivery Injection Unit	6,152,734	11/28/2000
Pressure/Force Computer Controlled Drug Delivery System	6,200,289	3/13/2001
Dental Anesthetic and Delivery Injection Unit with Automated Rate Control	6,652,482	11/25/2003
Pressure/Force Computer Controlled Drug Delivery System with Exit Pressure	6,786,885	9/14/2004
Pressure/Force Computer Controlled Drug Delivery System with Automated Charging	6,887,216	5/3/2005
Drug Delivery System with Profiles	6,945,954	9/20/2005
Cartridge Holder for Anesthetic and Delivery Injection Device	D558,340	12/25/2007
Design for Drive Unit for Anesthetic	D566,265	4/8/2008
Design for Drive Unit for Anesthetic	D579,540	10/28/2008
Drug Infusion Device with Tissue Identification Using Pressure Sensing	7,449,008	11/11/2008
Computer Controlled Drug Delivery Systems with Pressure Sensing	7,618,409	11/17/2009
Hand Piece for Fluid Administration	7,625,354	12/1/2009
Self-Administration Injection System	7,740,612	6/22/2010
Computer controlled drug delivery system with dynamic pressure sensing	7,896,833	3/1/2011
Injection Device Adapter	D741,811	10/27/2015
Epidural Injection Device	D765,832	9/6/2016
Device and Method for Identification of a Target Region	9,504,790	11/29/2016
Engineered Sharps Injury Protection Devices		
Handpiece for Injection Device with a Retractable and Rotating Needle	6,428,517	8/6/2002
Safety IV Catheter Device	6,726,658	4/27/2004
Safety IV Catheter Infusion Device	6,905,482	6/14/2005
Handpiece for Injection Device with a Retractable and Rotating Needle	6,966,899	11/22/2005

During the 2016 and 2015 fiscal years, Milestone Scientific expended on a consolidated basis $1,270,471 and $100,856, respectively, on research and development activities.

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.

In the event that 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.

Government Regulation

The FDA cleared the *CompuDent*® instrument and its disposable handpieces for marketing in the United States for dental applications in July 1996; the *CompuMed*® instrument for marketing in the United States for medical applications in May 2001; and *Safety Wand*® for marketing in the United States for dental applications in September 2003. For us to commercialize other products in United States, Milestone Scientific would have to submit additional 510(k) applications to the FDA. Milestone Scientific received FDA 510(k) approval for the STA Instrument in August 2006.

The manufacture and sale of medical devices and other medical products are subject to extensive regulation by the FDA pursuant to the 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 a number of 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 FDC Act in May 1976, the FDA classified medical devices in commercial distribution into one of three classes. This classification is based on the controls necessary to reasonably ensure the safety and effectiveness of the medical devices. Class I devices are those devices whose safety and effectiveness can reasonably be ensured through general controls, such as adequate labeling, pre-market notification, and adherence to the FDA's Quality Instrument Regulation ("QSR"), also referred to as "Good Manufacturing Practices" ("GMP") regulations. Some Class I devices are further exempted from some of the general controls. Class II devices are those devices whose safety and effectiveness reasonably can be ensured through the use of 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.

If a manufacturer or distributor can establish that a proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not required pre-market approval, the manufacturer or distributor may seek FDA marketing clearance for the device by filing a 510(k) Pre-market Notification. The 510(k) Pre-market Notification and the claim of substantial equivalence may have to be supported by various types of data and materials, including test results indicating that the device is as safe and effective for its intended use as a legally marketed predicate device. Following submission of the 510(k) 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. At this time, 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 make a determination regarding substantial equivalence. Such determination or request for additional information could delay market introduction of products and could have a material adverse effect on our business, financial condition and results of operations. 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.

Though the STA Instrument, *CompuDent*®, *Safety Wand*® and *CompuMed*® have received FDA marketing clearance, there can be no assurance that any of the other products 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 and could have a material adverse effect on our business, financial condition and results of operations.

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, as a result 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, the officers or employees. Any action by the FDA could result in disruption of operations for an undetermined amount of time.

In March 2012, Milestone Scientific received approval for *The Wand*® and the *STA Single Tooth Anesthesia System* ® *Instrument* from ANVISA in Brazil. In June 2007, Milestone Scientific received a CE mark for the marketing of the STA Instrument in Europe. In June 2003 Milestone Scientific received a CE mark for the marketing of the *Safety Wand*® and *The Wand*® handpieces with needle in Europe. In July 2003, Milestone Scientific obtained regulatory approval to sell *CompuDent*® and its handpieces in Australia and New Zealand.

As of May 2014, China National Medicines received the appropriate registration approval from the regulatory body in China, therefore, shipment of STA handpieces began in China. In the fourth quarter of 2014, the distribution agreement with China National Medicines was terminated and Milestone China Ltd. (owned 40% by Milestone Scientific) became the authorized distributor of the STA instruments and handpieces in China.

Product Liability

Failure to use any of the products in accordance with recommended operating procedures could potentially result in health hazards or injury. Failures of the products to function properly could subject Milestone Scientific to claims of liability. Milestone Scientific maintains liability insurance in an amount that Milestone Scientific believes is adequate. However, there can be no assurance that the insurance coverage will be sufficient to pay product liability claims brought against Milestone Scientific. 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.

Employees

As of December 31, 2016, Milestone had a total 17 full-time employees consisting of two executive officers of Milestone Scientific, a director of clinical affairs, a director of engineering, a senior vice president of marketing, a senior project manager, three customer service representatives, two accountants, four clinical hygienist, a quality engineer, and an administrative manager. Milestone Scientific also has a consultant who serves as a Director of Clinical Affairs and a business development consultant.

Global Advisory Board

We have a Global Advisory Board (GAB), which is staffed by highly qualified consultants with the background and expertise we need to carry out our long-term business objectives. Our GAB members work with our management team in the planning, development and execution of business strategies to commercialize our epidural and other medical instruments on a worldwide basis. It reviews, and advises management on our progress in research and clinical development as well as new scientific perspectives. The GAB is composed of well-respected, experienced leaders with diverse expertise and knowledge in a variety of areas, including developing partnerships with medical and healthcare organizations in the United States and around the world, public health, clinical research and trial management, US healthcare policy, and business development.

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:

Milestone Scientific does not have a consistent history of profitable operations. Continuing losses could exhaust capital resources and force Milestone Scientific to discontinue operations.

For the years ended December 31, 2016 and 2015, revenues were approximately $10.5 million and $9.4 million, respectively. Milestone Scientific has a net loss of approximately $5.9 million for year ended December 31, 2016 and a net loss of approximately $5.4 million for year ended December 31, 2015. In addition, Milestone Scientific has had losses for each year since the commencement of operations with the exception of 2013. Milestone Scientific had an accumulated deficit of approximately $73 million at December 31, 2016. At December 31, 2016, Milestone Scientific had cash and cash equivalents approximately $3.6 million, and working capital of approximately $7.7 million. Dental revenues are projected to improve in the upcoming 12 months due to the new exclusive distribution arrangement for its dental products for the United States and Canada with Henry Schein and increase dental revenues from out China business sector. To further reduce our expenditures, Milestone Medical expenses related to FDA clearance for the epidural and intra-articular instruments can be controlled as required to meet our budget. By limiting the FDA related expenses and increasing the dental instrument and handpieces revenue through the new distribution agreement, management believes that Milestone Scientific will have sufficient cash to meet all of its anticipated obligations over the next twelve months from the filing date of this Form 10-K.

Milestone Scientific management continues to examine all areas of the business to manage our cash flow. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue based upon management's assessment of present contracts and reductions in operating expenses.

We cannot become successful unless we gain greater market acceptance for our products and technology.

As with any new technology, there is substantial risk that the marketplace will not accept the potential benefits of this technology or be unwilling to pay for any cost differential with the existing technologies. Market acceptance of *CompuDent*®, STA Instrument, *The Safety Wand*®, *CompuMed*® and *CompuFlo*® depends, in large part, upon the ability to educate potential customers of the product's distinctive characteristics and benefits and will require substantial marketing efforts and expense. More than 47,000 of the STA Instrument and its predecessors have been sold worldwide since 1998. Since being introduced to market in February 2007, more than 20,000 of the STA Instrument have been sold. Milestone Scientific cannot assure that its current or proposed products will obtain enough of a broad based acceptance practitioners or that any of the current or proposed products will be able to compete effectively against current and alternative products.

Our limited distribution channels must be expanded in order to become successful.

Future revenues depend on Milestone Scientific's ability to market and distribute its computer-controlled injection products successfully. Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016, we established new exclusive distribution arrangements for our dental products for the United States and Canada with Henry Schein. Under these arrangements we will, for the first time, have a semi-dedicated independent sales force visiting dentists. We believe that these arrangements will be more effective than previous arrangements which primarily relied on appearances at dental shows and catalog sales. To be successful, Milestone Scientific will need to engage additional distributors, on a worldwide bases provide for their proper training and ensure adequate customer support. Milestone Scientific cannot assure that it will be able to hire and retain an adequate sales force and modify management or engage suitable distributors, or that the sales efforts or distributors will be able to successfully market and sell the products.

Excessive returns under the June 2016 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.

Our near-term prospects are dependent on the marketing success of our epidural anesthetic injections and intra-articular injection instruments in the EU community. If we fail to successfully commercialize these instruments in the EU, our business and prospects would be harmed significantly.

Our near-term prospects are dependent upon our success in marketing our epidural anesthetic injections and intra-articular injection instruments in the EU community where we have previously received CE approval. There can be no assurance that we will be able to successfully commercialize these products in the EU. If we fail to successfully commercialize these products in the EU, our business and prospects would be harmed significantly.

Our prospects are dependent on FDA approval of our epidural anesthetic injections instrument to permit marketing in the United States If we fail to obtain the regulatory approvals necessary to sell this instrument in the United States, or upon approval, fail to successfully commercialize this instrument in the United States, our business and prospects would be harmed significantly.

Our prospects are dependent upon our receipt of FDA approval of our epidural anesthetic injections instrument. We have filed a 510(k) application with respect to this instrument with the FDA and approval, which will permit us to commence marketing of the instruments in the United States, is pending. There can be no assurance that we will obtain the FDA approvals necessary to sell our epidural anesthetic injections instrument in the United States. In addition, even if we obtain such regulatory approvals, there can be no assurance that we will be able to successfully commercialize this product in the United States. If we fail to obtain the regulatory approvals necessary to sell this instrument or fail to successfully commercialize this product in the United States, our business and prospects would be harmed significantly.

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.

Our planned operations in the developing world could cause us to incur additional costs and risks associated with doing business in developing markets.

We are seeking to operate in the developing world (e.g., China), which would make us vulnerable to political, economic and social instability in such areas. Many areas of the developing world have experienced political, economic and social uncertainty in recent years, including an economic crisis characterized in some cases by increased inflation, high domestic interest rates, negative economic growth, reduced consumer purchasing power and high unemployment. Political, economic and social instability in these countries may have an adverse effect on our business, financial condition and results of operations.

We participate in a highly competitive environment.

The medical device industry is characterized by rapid technological change, changing customer needs and frequent new product introductions. Our products may be rendered obsolete as a result of future innovations. We face intense competition from other manufacturers. Some of our competitors may be larger than we are and may have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe that price competition will continue among products developed in our markets. Our competitors may develop or market technologies and products that are more effective or commercially attractive than any we are developing or marketing. Our competitors may succeed in obtaining regulatory approval and introducing or commercializing products before we do. Such developments could have a significant negative effect on our business, financial condition and results of operations. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

Our success depends upon the development of new products and product enhancements, which entails considerable time and expense.

We place a high priority on the development of new products to add to our product portfolio, as well as on the development of enhancements to our existing products. Product development involves substantial expense and we cannot be certain that a completed product will generate sufficient revenue for our business to justify the resources that we devote to research and development related to such product. The time and expense required to develop new products and product enhancements is difficult to predict and we cannot guarantee that we will succeed in developing, introducing and marketing new products and product enhancements. Our inability to successfully develop and introduce new or enhanced products on a timely basis or at all, or to achieve market acceptance of such products, could materially impair our business.

We are dependent on adequate protection of our patent and proprietary rights.

We rely on patents, trade secrets, trademarks, copyrights, know-how, license agreements and contractual provisions to establish and protect our intellectual property rights. However, these legal means afford us only limited protection and may not adequately protect our rights or remedies to gain or keep any advantages we may have over our competitors. We cannot guarantee that others may not independently develop the same or similar technologies or otherwise obtain access to our technology and trade secrets. Our competitors, many of which have substantial resources and may make substantial investments in competing technologies, may apply for and obtain patents that will prevent, limit, or interfere with our ability to manufacture or market our products. Further, while we do not believe that any of our products or processes interfere with the rights of others, third parties may nonetheless assert patent infringement claims against us in the future.

Costly litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how we own, to defend us against claimed infringement of the rights of others or to determine the ownership, scope, or validity of our proprietary rights and the rights of others. Any claims of infringement against us may involve significant liabilities to third parties, could require us to seek licenses from third parties and could prevent or delay us from manufacturing, selling or using our products. The occurrence of such litigation or the effect of an adverse determination in any of this type of litigation could have a material adverse effect on our business, financial condition and results of operations.

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 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 similar to 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. States had until March 31, 2013 to enact or amend their false claims laws modeled after the federal False Claims Act for review and approval to receive a greater portion of any recovery.

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 starting in 2012 to record any transfers of value to physicians and teaching hospitals beginning in August 2013 and to report to the Centers for Medicare and Medicaid Services starting in 2014 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. If we receive FDA clearance to market our epidural anesthetic injections and/or our intra-articular injection instruments in the United States, 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 system. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. 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 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 the purpose of 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.

We depend on two principal manufacturers. If Milestone Scientific cannot maintain its existing relationships or develop new ones, it may have to cease operations.

Milestone Scientific and its subsidiary has informal arrangements with the manufacturer of the STA Instrument, *CompuDent*® and *CompuMed*® and with one of the principal manufacturers of the handpieces, for those items, respectively. Pursuant to the informal arrangements, they manufacture these instruments and handpieces under specific purchase orders without minimum purchase commitment. Milestone Scientific has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum purchase commitments. Milestone Scientific has been supplied by the manufacturer of the STA Instrument, *CompuDent*® and *CompuMed*® epidural and intra-articular instruments since the commencement of production in 1998, the manufacturer of its handpieces since 2003. However, termination of the manufacturing relationship with any of these manufacturers could significantly and adversely affect the 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 or not as a result or termination of the relationship, would have a material adverse effect on our financial condition, business and results of operations.

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, Milestone Scientific cannot assure 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.

Milestone Scientific relies on the continuing services of its Chief Executive Officer and Director of Clinical Affairs.

Milestone Scientific depends on the personal efforts and abilities of its 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 Chief Executive Officer. However, the loss of his services or the services of its Director of Clinical Affairs, on whom Milestone Scientific maintains no insurance, could have a materially adverse effect on the business.

The market price of Milestone Scientific's common stock has been volatile and may continue to fluctuate significantly because of various factors, some of which are beyond Milestone Scientific's control.

Milestone Scientific's stock price has been extremely volatile, fluctuating during the last two years between $4.00 and $1.27. The market price of common stock could continue to fluctuate significantly in response to a variety of factors, some of which may be beyond Milestone Scientific's control.

Milestone Scientific is controlled by a limited number of stockholders.

Milestone Scientific's principal stockholders, Leonard Osser, Gian Domenico Trombetta, K. Tucker Andersen, and Robert Gintel beneficially own approximately 50% of the issued and outstanding shares of common stock. As a result, they have the ability to exercise substantial control over Milestone Scientific's affairs and corporate actions requiring stockholder approval, including electing directors, selling all or substantially all of the assets, merging with another entity or amending its certificate of incorporation. This de facto control could delay, deter or prevent a change in control and could adversely affect the price that investors might be willing to pay in the future for Milestone Scientific's securities.

Future sales or the potential for sale of a substantial number of shares of common stock could cause the trading price of common stock to decline and could impair Milestone Scientific's ability to raise capital through subsequent equity offerings.

Sales of a substantial number of shares of common stock in the public markets, or the perception that these sales may occur, could cause the market price of the stock to decline and could materially impair its ability to raise capital through the sale of additional equity securities. At December 31, 2016, Milestone Scientific had outstanding options to purchase 1,736,994 shares of common stock at prices ranging from $0.75 to $3.89 per share with a weighted average exercise price of $1.85. Holders of these options are given the opportunity to profit from a rise in the market price of the common stock and are likely to exercise their securities at a time when Milestone Scientific would be able to obtain additional equity capital on more favorable terms. Thus, the terms upon which Milestone Scientific will be able to obtain additional equity capital may be adversely affected, since the holders of outstanding options and warrants can be expected to exercise them at a time when Milestone Scientific would, in all likelihood, be able to obtain any needed capital on terms more favorable than the exercise terms provided by such outstanding securities. The market price of the common stock has been volatile and may continue to fluctuate significantly because of various factors, many of which are beyond Milestone Scientific's control.

Adherence to Sarbanes-Oxley Act and SEC rules concerning internal controls may be so costly that 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, 2016. 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 2005, Milestone Scientific hired an outside consultant to assist with the development and implementation of the necessary internal controls and reporting procedures. In 2016 and 2015, Milestone Scientific utilized the outside consultant on a quarterly basis to review compliance with the internal controls over financial reporting. This expense amounted to approximately $20,000 and $14,000 in 2016 and 2015, respectively and the cost is expected to continue in 2017.

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Property

The headquarters for Milestone Scientific is located at 220 South Orange Ave, Livingston, New Jersey. Milestone Scientific leases approximately 7,625 square feet of office space. The lease term expires January 31, 2020 at a monthly cost of $12,522. Additionally, Milestone Scientific has other smaller insignificant leases ending through 2017. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

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

Item 3. Legal Proceedings

At the present time, 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 MKT under the symbol “MLSS”. Prior to its listing on the NYSE MKT, Milestone’s common stock traded on the OTC Market on the OTCQB market tier under the same symbol. The following table sets forth the high and low sales prices of Milestone’s common stock for the periods presented.

2016	HIGH	LOW	**2015**	HIGH	LOW
First Quarter	$ 2.54	$ 1.27	First Quarter	$ 3.00	$ 2.35
Second Quarter	$ 3.10	$ 1.70	Second Quarter	$ 4.00	$ 2.42
Third Quarter	$ 2.96	$ 1.94	Third Quarter	$ 3.52	$ 2.55
Fourth Quarter	$ 2.19	$ 1.29	Fourth Quarter	$ 3.20	$ 2.16

Holders

As of March 29, 2017, we had approximately 130 stockholders of record of our common stock. We believe that we have approximately 1,737 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 J – STOCKHOLDERS’ EQUITY, to the audited 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.

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 MKT on June 1, 2015 and trades under the symbol "MLSS". We have developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of *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 a number of other disciplines. The dental instruments are sold in the United States and in over 47 countries abroad. There have been no medical instruments sold in the United States and limited amounts sold internationally as of the reporting date, although certain medical instruments have obtained CE mark approval and now can be marketed and sold in most European countries. Milestone Scientific's products are manufactured by a third-party contract manufacturer.

In 2016, Milestone Scientific remained focused on advancing efforts to achieve our three primary objectives; those being:

- Obtaining the 510(k) marketing clearance with the United States Food and Drug Administration ("FDA") for the epidural and intra articular instruments.
- Enhancing our global reach by partnering with distribution companies in the medical sector; and
- Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the STA Single Tooth Anesthesia System® Instrument (STA Instrument).

STA Instrument Growth

Since its market introduction in early 2007, the STA Instrument and prior C-CLAD products have been used to deliver over 66 million safe, effective and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

Global Distribution Network

United States and Canadian Market

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

To date, Henry Schein has endeavored to accomplish the goals set forth in the exclusive distribution agreement for *The Wand*® STA instrument and handpieces, including training of its exclusive products sales specialists. Specifically, 25 exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand*® STA instrument and handpieces and all 25 are currently in the field selling the instrument. Henry Schein also plans to train an additional two to three dedicated customer service representatives to support dentists across North America through its exclusive product sales customer call center.

Henry Schein's exclusive products sales specialist team, which is comprised of 25 products sales specialists and supported by over 1,000 field service representatives, will exclusively market and distribute *The Wand*® STA instrument and handpieces, together with a select group of other devices in the United States and Canada. Our agreement with Henry Schein has minimum purchase order requirements to maintain exclusivity in the third through tenth year of the term of the agreement.

International Market

On the global front, we also have granted exclusive marketing and distribution rights for the STA Instrument to select dental suppliers in various international regions in Asia, Africa, South America and Europe. They include Istrodent in South Africa and Unident 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 *STA Single Tooth Anesthesia System*® (STA System). In May 2014, the CFDA also approved the STA handpieces for sale in China.

In September 2014, Milestone Medical received CE clearance to distribute their epidural and intra-articular instruments in European Community (EU). Milestone Medical is actively pursuing distributors for the instrument in the EU community. 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.

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. Since September 2014, we have an established exclusive distribution arrangement with Milestone China for the distribution of the STA Instrument in China, which has led to the placement of our dental instruments in clinics serving major cities in China. Milestone China purchases STA Instruments from us for cash as required. We believe that Milestone China will make a positive impact on the dental and future medical business opportunities in China and other parts of Asia.

In China, where the dental market lags behind other health care services and has largely been neglected in the past, a CS Market Research report indicates that 50% of adults and 70% of children out of China's estimated 1.3 billion plus population have tooth decay problems and over 90% have periodontal disease. (See Shuyu Sun & Seth Pierrepont. *The Dental Equipment Market Over in China*, CS Market Research (Sept. 20, 2005) and *Opportunities Abound for Dental Care in China,* CHINA BRIEFING (February 27, 2015)). With increasing affluence and increasing attention towards personal care, the provision of dental services has been growing rapidly. We expect this will lead to both increased sales of dental instruments and our single-use handpieces.

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

	Years Ended December 31,			
	2016		2015	
DOMESTIC				
Instruments	$ 852,148	27.5%	$ 623,195	17.8%
Handpieces	2,102,394	67.9%	2,799,785	79.8%
Other	143,762	4.6%	83,362	2.4%
Total Domestic	$ 3,098,304	100.0%	$ 3,506,342	100.0%
INTERNATIONAL				
Instruments	$ 3,264,633	44.2%	$ 2,062,556	34.5%
Handpieces	4,063,811	55.1%	3,836,002	64.1%
Other	55,257	0.7%	86,669	1.4%
Total International	$ 7,383,701	100.0%	$ 5,985,227	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	$ 3,098,304	29.6%	$ 3,506,342	36.9%
International	$ 7,383,701	70.4%	$ 5,985,227	63.1%
Total Product Sales	$ 10,482,005	100.0%	$ 9,491,569	100.0%

Milestone Scientific earned gross profit of 60% and 68% in the years ended December 31, 2016 and 2015, respectively. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses. Although Milestone Scientific anticipates expending funds for research and development in 2017, these amounts will vary based on the operating results for each quarter.

In 2017, Milestone Scientific plans to support increased sales and marketing activity through our current distributors and through newly appointed distributors of the STA instruments and handpieces in the international market. In the United States and Canada, Milestone Scientific will continue the utilization of independent hygienists for training individual practitioners and group practices domestically, refined and directed advertising to dental professionals, continue to develop Key Opinion Leaders (KOL) and support and broaden our global distribution network.

Current Product Platform

See Item 1. Description of Business.

Summary of Critical Accounting Policies and Significant Judgments and Estimates

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

The preparation of these 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 readily apparent 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 B to the consolidated financial statements included elsewhere in this report, Milestone Scientific believes that the following accounting policies and significant judgments and estimates are most critical in understanding and evaluating the reported financial results.

Assessment of our Ability to Continue as a Going Concern

Our management has made various estimates in assessing our ability to continue as a going concern as of the report date of our Friedman LLP's, our independent auditor's, report included in this Form 10-K. These estimates include, an increase in the revenues generated by Wand Dental as a result of the new distribution agreement with Henry Schein, an increase in the revenues generated by Milestone China, a reduction in our profit margins due to the nature of the distribution relationships with both Henry Schein and Milestone China, and reduction our selling, general and administrative costs for one-time expenses incurred during 2016. Based on this assessment, management believes that our cash on hand, accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-K.

Accounts Receivable

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

Inventories

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

Impairment of Long-Lived Assets

Milestone Scientific reviews long-lived assets for impairment whenever events or circumstances (i.e. a triggering event) indicate that the carrying amounts may not be recoverable. The carrying value of the assets is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets. Milestone Scientific adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. There have been no impairment indicators or triggering events and therefore, no impairment reviews have been performed for the period ending December 31, 2016.

Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to domestic distributors on the date of shipment for essentially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific will recognize revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. Shipments to international distributors are FOB warehouse, therefore revenue is recognized upon the shipment of the goods. In all cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone Scientific has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period. The instrument sales and hand piece sales are sold separately and not bundled and, as such, there are no multiple element assessments or determinations for revenue recognition.

Results of Operations

The following table sets forth for the consolidated results of operations for the year ended December 31, 2016 compared to 2015 as a percentage of revenues. In 2015, the consolidated statement of operations do not include in the revenue and expenses of Milestone Medical and Milestone Education both of which were previously equity investments until they were determined as of December 31, 2015 and January 1, 2016, respectively, to be variable interest entities for which Milestone Scientific is the primary beneficiary. The trends suggested by this table may not be indicative of future operating results:

	Year Ended December 31,			
	2016		2015	
Revenue				
Product sales, net	$ 10,482,005	100%	$ 9,491,569	100%
Cost of products sold	4,175,533	40%	3,048,260	32%
Gross profit	6,306,472	60%	6,443,309	68%
Selling, general and administrative expenses	11,549,961	110%	9,399,201	99%
Research and development expenses	1,270,471	12%	100,856	1%
Total operating expenses	12,820,432	122%	9,500,057	100%
Loss from operations	(6,513,960)	(62)%	(3,056,748)	(32)%
Other (expenses)	(5,088)	(0)%	(5,347)	(0)%
Interest expense	1,285	0%	3,838	0%
Loss before provision for income tax and equity in net earnings of equity investments	(6,517,763)	(62)%	(3,058,257)	(32)%
Provision for income tax	19,101	0%	(36,157)	(0)%
Loss before equity in net earnings of equity investments	(6,498,662)	(62)%	(3,094,414)	(33)%
Loss on earnings from Milestone Medical	-	0%	(2,019,211)	(21)%
Income (Loss) on earnings from Education Joint Venture	-	0%	(7,846)	(0)%
Loss on earnings from China Joint Venture	(795,827)	(8)%	(418,432)	(4)%
Loss in equity investments	(795,827)	(8)%	(2,445,489)	(26)%
Net Loss	(7,294,489)	(70)%	(5,539,903)	(58)%
Net loss attributable to noncontrolling interests	(1,347,982)	(13)%	(72,381)	(1)%
Net loss attributable to Milestone Scientific Inc.	$ (5,946,507)	(57)%	$ (5,467,522)	(58)%

Year ended December 31, 2016 compared to year ended December 31, 2015

Total revenues for the twelve months ended December 31, 2016 and 2015, principally dental revenues, were approximately $10.5 and $9.4 million, respectively. The total revenue increased by approximately $1 million or 10%, which was principally related to the increase in instrument and handpiece sales to China.

Domestic sales decreased by approximately $408,000 in 2016. In the fourth quarter of 2016, Henry Schein did not purchase instruments and handpieces as they continued to introduce our instrument to the market and sell down their existing inventory. International sales in 2016 increased by approximately $1.4 million over the same period in 2015 principally due to a shipment of STA Instruments and handpieces to Milestone China. However, we believe that the June 2016 exclusive distribution agreement with Henry Schein will lead to increased domestic sales in 2017 as the product and sales force training has been substantially completed as of December 31, 2016.

Selling, general and administrative expenses for twelve months ended December 31, 2016 were approximately $11.5 million versus $9.4 million in 2015. The increase of approximately $2.1 million is predominantly due to the consolidation of Milestone Medical commencing on December 31, 2015 which had $ 2.5 million in SG&A expenses in 2016 versus $ 3.0 million in SG&A expenses in 2015 which was included within Loss on Earnings from Milestone Medical in the consolidated statement of operations. In 2015, Milestone Medical was accounted for under the equity method, until December 2015 when it was determined that Milestone Medical did not have sufficient capital at risk to support its activities without financial support from Milestone Scientific and therefore consolidated (See Note E to the consolidated financial statements).

Research and development expenses for the twelve months ended December 31, 2016 and 2015 were approximately $1.3 million and $100,000, respectively. In 2015, Milestone Medical incurred $792,000 of research and development expenses that were included in a single line item on loss on earning for Milestone Medical for reporting purposes. Giving the effect to the Milestone Medical research development expenses on a consolidated basis in 2015, the comparable amount of research and development cost would be $892,000.

The loss from operations for the twelve months ended December 31, 2016 and 2015 was approximately $6.5 million and $3.1 million, respectively, an increase of approximately $3.4 million. The increase in loss from operations in 2016 is primarily the result of the consolidation of Milestone Medical in 2016.

The loss on earnings from the China Joint Venture was approximately $796,000 and $418,000 for the twelve months ended December 31, 2016 and 2015, respectively, an increase of approximately $378,000. The increase in loss on earnings from the China Joint Venture is primarily due to the China Joint Venture being in its initial operating and expansion cycle in China.

Liquidity and Capital Resources

At December 31, 2016, Milestone Scientific had cash and cash equivalents of approximately $3.6 million, total current assets of approximately $12.7 million and working capital of approximately $7.7 million. We believe that our cash on hand, accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-K.

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. For the twelve months ended December 31, 2016 and 2015, we had negative cash flows from operating activities of approximately $5.4 million and $2.9 million, respectively.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for the year ended December 31, 2013. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through increases in revenues based upon management's assessment of present contracts, and current negotiations and reductions in operating expenses. Milestone Scientific believes that clearance to commercialize its epidural and intra-articular instruments will improve our capital raising opportunities and financial condition. Although there can be no assurances on the timing and ultimate outcome, management believes that FDA clearance for Milestone Medical's 510(k) epidural application may occur by the end of the second quarter of 2017.

Milestone Scientific believes that the June 2016 exclusive distribution agreement with Henry Schein will improve its dental revenues in 2017. To further reduce Milestone Scientific's expenditures, Milestone Medical is carefully managing expenses related to obtaining FDA clearance for the epidural and intra-articular instruments. By limiting the FDA related expenses and increasing the dental instrument revenue through the new distribution agreement and performing a cash flow projection of the consolidated company and its subsidiaries, management believes that Milestone Scientific will have resources to fund its operations over the next 12 months from the filing date of this Form 10-K.

Our consolidated balance sheet included in this report reflects an increase of approximately $890,000 in current assets from 2015 to 2016. This increase in current assets was primarily due to increases in the amount due from related party, deferred cost, and inventories of an aggregate of approximately $2.6 million, offset by decreases in cash and cash equivalents, accounts receivable and advances on contracts of approximately $1.8 million.

Current liabilities increased by approximately $1.4 million from approximately $3.7 million to approximately $5.0 million. The increase is primarily due to an increase in accounts payable and deferred revenue from a related party, as result of consolidating Milestone Medical at December 31, 2016.

In June 2016, we raised an additional $2.0 million of gross proceeds in a private placement of one million shares of common stock, at a price of $2.00 per share, to the same investors that participated in the May 2014 Financing.

In July 2016, Milestone Scientific raised gross proceeds of $250,000 in a registered direct offering of 104,200 shares of common stock at $2.40 per share. The transaction was covered by the prospectus supplement, filed with the SEC on July 22, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

In December 2016, we 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 warrant was $1.50. 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. The gross proceeds from this offering, including proceeds from partial exercises of the over-allotment option, were approximately $3.2 million, before deducting underwriting discounts and commissions and other offering expenses. This offering was covered by a prospectus supplement, filed with the SEC on December 16, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

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, 2016, expected on the liquidity and cash flows in future periods, is as follows:

	Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years
Operating lease obligations	$ 658,730	$ 163,965	$ 339,198	$ 155,567
Purchase obligations (1)	$ 1.577,042	$ 1,409,162	$ 167,880	$ -
Total	$ 2,235,772	$ 1,573,127	$ 507,078	$ 155,567

(1) Purchase obligations include agreements for the purchase of instruments and handpieces.

Recent Accounting Pronouncements

See "Note B - Summary of Significant Accounting Policies" to the 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 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 Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of December 31, 2016 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 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, 2016. 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, 2016.

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, 2016 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

Item 9B. Other Information

None.

PART III

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

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

The current executive officers and directors of Milestone Scientific and their respective ages as of March 31, 2017 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leslie Bernhard (1) (2) (3)	72	Chairman of the Board and Director	2003
Leonard Osser	69	Chief Executive Officer and Director	1991
Joseph D'Agostino	65	Chief Financial Officer and Chief Operating Officer	
Leonard Schiller (1) (2) (3)	76	Director	1997
Gian Domenico Trombetta	56	Director	2014
Edward J. Zelnick, M.D. (1) (3)	71	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 March 31, 2017:

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

Leslie Bernhard, Chairman of the Board

Leslie Bernhard has been serving as Milestone Scientific's non-executive Chairman of the Board since October 2009. In addition, Ms. Bernhard has also 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. (OTC Markets: UPGI), 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.

Leonard Osser, Chief Executive Officer and Director

Leonard Osser has been Milestone Scientific's Chief Executive Officer and a director since September 2009. Prior to that, he served as Milestone Scientific's Chairman from 1991 until September of 2009, and during that time, from 1991 until 2007, was also Chief Executive Officer of Milestone Scientific. In September 2009, he resigned as Chairman of Milestone Scientific, but remained a director, and assumed the position of Chief Executive Officer. From 1980 until the consummation of Milestone Scientific's public offering in November 1995, Mr. Osser was primarily engaged as the principal owner and Chief Executive Officer of U.S. Asian Consulting Group, Inc., a New Jersey-based provider of consulting services specializing in distressed or turnaround situations in both the public and private markets. Mr. Osser's knowledge of our business and background with us since 1980 provides the Board with valuable leadership skills and insight into our business and accordingly, the expertise needed to serve as one of our directors.

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

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

Leonard M. Schiller, Director

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

Gian Domenico Trombetta, Director

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

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 Doctorate 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 Leonard M. Schiller, Leslie Bernhard and Edward J. Zelnick, M.D. (the "Independent Directors") are independent as that term is defined in the listing standards of the NYSE MKT. As disclosed above, Leslie Bernhard, Edward J. Zelnick, M..D. and Leonard M. Schiller are members of the Audit Committee and Nominating Committee and are independent for such purposes. Leonard M. Schiller and Leslie Bernhard are members of the Compensation Committee and are independent for such purposes.

In determining director independence, the Board considered the stock awards to the Independent Directors for the year ended December 31, 2016, disclosed in "Item 11 – Executive Compensation – Director Compensation" above, and determined that such awards were compensation for services rendered to the Board and therefore did not impact their ability to continue to serve as Independent Directors.

Milestone Scientific's Board of Directors has established a compensation, audit and 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 of 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. Ms. Bernhard is independent, as that term is defined in the listing standards of the NYSE MKT.

The Nominating Committee has dual responsibilities. The Nominating Committee will assist the board by identify 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 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. 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, 2016.

Code of Ethics

Milestone Scientific has adopted a code of ethics that applies to its directors, principal executive officer, principal financial officer and other persons performing similar functions. This code of ethics is filed herewith as an exhibit to this annual report and is posted on Milestone Scientific's web site at www.milestonescientific.com. Milestone Scientific will also provide a copy of the Code of Ethics to any person without charge, upon written request addressed to the Chief Financial Officer, Joseph D'Agostino at the principal executive office, located at 220 South Orange Avenue, Livingston, NJ 07039.

Item 11. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2016 and 2015 by Milestone Scientific's (i) CEO and (ii) two most highly compensated executive officers other than the CEO who was serving as an executive officer at the end of the 2016 fiscal year and whose salary as determined by Regulation S-K, Item 402, exceeded $100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the "Named Executive Officers").

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary	Bonuses		Option Awards (2)	Other Compensation		Total
Leonard A. Osser								
Chief Executive Officer	2016	$ 300,000	$ 400,000	(1)	$ 442,019	$ 238,030	(1)	$ 1,380,049
	2015	$ 300,000	$ 400,000	(1)	$ 101,245	$ 236,267	(1)	$ 1,037,512
Gian Domenico Trombetta								
Chief Executive Officer - Wand Dental Inc	2016	$ 279,999	$ 160,000	(4)	$ 221,743	$ -		$ 661,742
	2015	$ 340,000	$ 80,000	(4)	$ 161,992	$ -		$ 581,992
Joseph D'Agostino								$ -
Chief Financial Officer	2016	$ 171,600	$ 80,000	(4)	$ 222,344	$ 35,144	(3)	$ 509,088
	2015	$ 171,600	$ 114,500	(4)	$ 174,413	$ 44,996	(3)	$ 505,509

1. Recognition of $400,000 of bonuses for the years ended December 31, 2016 and 2015, respectively, of which $150,000 in 2016 and $200,000 in 2015, were deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. In accordance with Mr. Osser's employment agreement, one half of his annual bonus is paid in cash and one half in common stock. Other compensation represents payments made for health insurance coverage, pension plan, and car allowance.

2. The amounts in this column reflect the fair value of the options on the date of grant. For details used in the assumption calculating the fair value of the option reward, see Note B to the Financial Statements for the year ended December 31, 2016 and 2015, which is located on pages F-9 through F-14 of this Report. Compensation cost is generally recognized over the vesting period of the award. See the table below entitled Outstanding Equity Awards at December 31, 2016.

3. Other compensation represents payments made for health insurance coverage and car allowance.

4. One half of the bonus for 2016 was deferred and will be paid in common stock upon the termination of their employment from Milestone Scientific. The 2015 bonuses were deferred in full and will be paid common stock upon the termination of their employment from Milestone Scientific.

Employment Contracts

As of September 1, 2009, Milestone Scientific entered into a five-year employment agreement with Leonard Osser as its chief executive officer (CEO). The term of the 2009 agreement is 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. 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). The options shall vest and become exercisable to the extent of one-third of the shares covered at the end of each of the first three years following the date of grant, but shall only be exercisable while the CEO is employed by Milestone Scientific or within 30 days after the termination of his employment.

In accordance with the employment contract, 855,810 shares of common stock are to be paid out at the end of the contract in settlement of $980,906 at December 31, 2016 and 776,862 shares of common stock are to be paid out at the end of the contract in settlement of $830,985 at December 31, 2015 of accrued deferred compensation and, accordingly, such shares have been classified in stockholders' equity with the common stock classified as to be issued.

The 2009 employment agreement suspended the previous 2008 employment with 40-months remaining in its term. In March 2014, the 2009 agreement was amended to extend its remaining term to 120-months.

On December 1, 2016, Wand Dental and Gian Domenico Trombetta entered into an Amended and Restated Employment Agreement, pursuant to which Mr. 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, Mr. 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; which term automatically renews for a one-year period, from September 1st through August 31st of each successive year, unless prior to June 1st of the then current term 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.

Objective of Executive Compensation Program

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

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

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

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

Annual CEO compensation consists of a base salary component and periodic stock option grants. It is the Compensation Committee's intention to set totals for the CEO for cash compensation sufficiently high enough to attract and retain a strong motivated leadership team, but not so high that it creates a negative perception with the other stakeholders. The CEO receives stock option grants under the stock option plan. The number of stock options granted to the executive officer is made on a discretionary rather than a formula basis by the Compensation Committee. The CEO's current and prior compensation is considered in setting future compensation. In addition, Milestone Scientific reviews the compensation practices of 28 other companies. To some extent, the compensation plan is based on the market and the companies that compete for executive management. The elements of the plan (e.g., base salary, bonus and stock options) are similar to the elements used by many companies. The exact base pay, stock option grant, and bonus amounts are chosen in an attempt to balance the competing objectives of fairness to all stakeholders and attracting and retaining executive managers.

Outstanding Equity Awards at December 31, 2016

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, 2016.

	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	855,809	$ 1,198,133
	248,448	-	$ 1.65	12/31/2018		
	83,333		$ 0.75	1/9/2017		
	144,033	41,152	$ 2.38	11/20/2019		
	31,836	25,470	$ 3.49	6/20/2020		
	27,663	55,325	$ 1.89	2/4/2021		
	57,143	114,286	$ 1.93	11/10/2021		
Total	**665,789**	**236,233**			**855,809**	**$ 1,198,133**
Gian Domenico Trombetta	44,260	88,520	$ 1.89	2/4/2021	66,390	$ 92,946
Total	**44,260**	**88,520**			**66,390**	**$ 92,946**
Joseph D'Agostino	116,520	33,334	$ 2.09	11/11/2019	166,201	$ 232,681
	38,315	10,947	$ 2.03	11/20/2019		
	66,666	-	$ 1.50	12/31/2018		
	78,126	-	$ 1.28	12/31/2017		
	44,380	44,380	$ 1.72	2/4/2021		
Total	**344,154**	**88,661**			**166,201**	**$ 232,681**

1. Represents stock option grants at fair market value on the date of grant.
2. Issuance of the shares of common stock has been deferred until the termination of his employment with Milestone Scientific in accordance with the terms of his respective employment arrangement.
3. Based on the closing price per share of $1.40 as reported on the NYSE MKT on December 31, 2016.

Director Compensation

NAME	Fees Earned or Paid in Cash ($)	Total ($)
Leslie Bernhard	$ 36,000	$ 36,000
Leonard Schiller	$ 36,000	$ 36,000
Edward J. Zelnick, M.D.	$ 33,000	$ 33,000

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 31, 2017, 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	3,777,118	(3)	11.77%
Joseph D'Agostino	1,625,465	(4)	5.21%
Leslie Bernhard	-		0.00%
Leonard Schiller	185,158	(5)	*%
Edward J. Zelnick, M.D.	8,750	(6)	*%
Gian Domenico Trombetta	6,176,558	(7)	18.29%
All directors & executive officers as group (6 persons)	11,773,049	(8)	32.84%
K. Tucker Andersen	3,241,050		10.59%
Tom Cheng	1,562,599		5.11%
Debra Ginsberg	1,605,000	(9)	5.25%
* Less than 1%			

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

2. A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 31, 2017, 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 31, 2017 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 31, 2017 and the number of shares underlying options exercisable and convertible securities convertible within 60 days from March 31, 2017 held by the beneficial owner.

3. Includes 2,293,706 shares held by Mr. Osser or his family, 886,865 shares to be issued at the termination of his employment agreement, and 596,547 shares subject to common stock options with the following per share exercise prices: 73,333 at $1.49, 230,044 at $1.65 and 130,315 at $2.38, 31,837 at $3.49, 51,533 at $1.89, 57,143 at $1.93 and 22,342 at $1.77.

4. Includes 1,044,117 shares held by Mr. D'Agostino, 191,046 shares to be issued at the termination of his employment, and 390,302 shares subject to common stock options with the following per share exercise prices: 78,126 shares at $1.28, 66,666 shares at $1.50; 116,666 shares at $2.09; 38,314 at $2.03, 73,967 at $1.72 and 16,563 shares at $1.61.

5. Includes 179,533 shares held by Mr. Schiller and 5,625 shares subject to common stock warrants exercisable at $2.55 per share.

6. Includes 5,000 shares held by Dr. Zelnick and 3,750 shares subject to common stock warrants exercisable at $2.55 per share.

7. Includes 116,079 shares to be issued at the termination of his employment, 106,893 shares subject to common stock options with the following per share exercise prices: 73,767 at $ 1.89 and 33,126 at $1.61, and 5,953,586 shares held directly by BP4 S.r.l. ("BP4") of which 2,953,586 shares are issuable upon the conversion of $7 million of preferred stock at $2.37 per share, as adjusted to date. Innovest S.p.A. ("Innovest") is the controlling shareholder of BP4 and Mr. Trombetta is a controlling shareholder and director of Innovest, and, as such, is deemed to have voting and investment power over the securities held by BP4. Mr. Trombetta disclaims beneficial ownership of all securities held by BP4.

8. Includes an aggregate of 1,103,117 shares of common stock underlying outstanding options, 1,193,990 shares of common stock issuable upon termination of employment and 2,953,586 shares of common stock issuable upon the conversion of $7 million of preferred stock at $2.37 per share.

9. The information with respect to their 5% shareholder has been derived from the Schedule 13G files with the SEC on February 1, 2017, reporting beneficial ownership as of December 31, 2016.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes, as of December 31, 2016, 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	Weighted-average exercise price of outstanding options	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)	1,663,661	$ 1.94	1,485,229
Total	1,736,994		1,485,229

(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 2016.

(2) The 2011 Plan, as amended, provides for awards of restricted common stock and options to purchase up to a maximum 4,000,000 shares of common stock and expires in June 2021. Options may be granted to employees, directors and consultants of Milestone Scientific for the purchase of shares of common stock at a price not less than the fair market value of common stock on the date of grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. For the year ended December 31, 2016, 327,778 shares were exercised.

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

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

Tom Cheng, is a controlling shareholder of a major supplier of handpieces to Milestone Scientific. Milestone Scientific purchased $3,025,249 and $2,698,522 from this supplier for the years ended December 31, 2016 and 2015, respectively.

Item 14. Principal Accounting Fees and Services

Effective July 18, 2016, our Audit Committee engaged Friedman LLP ("Friedman") to replace Baker Tilly Virchow Krause, LLP ("Baker Tilly") as our new principal accounting firm. The aggregate fees billed by our principal accounting firms for the years ended December 31, 2016 and 2015 are as follows:

	2016	2015
Audit Fees and Audit Related fees	$ 291,500 (1)	$ 277,000
Tax Fees	30,000	
Total Fees	$ 321,500	$ 277,000

* Includes fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Qs or services that are reasonably related to the performance of the audit or normally provided in connection with statutory and regulatory filings.

(1) The audit fees in 2016 includes $180,000 of fees incurred with Friedman and $93,500 of fees billed by Baker Tilly.

Audit Committee Pre-Approval Policies and Procedures

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Report:

1. Financial Statements. See Index to Financial Statements on page F-1.

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

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

Exhibit NO.	Description
3.1	Restated Certificate of Incorporation of Milestone filed on September 6, 2013 (11)
3.2	Form of Certificate of Designation filed on April 18, 2014 (12)
3.3	Certificate of Correction to the Certificate of Designation filed on May 12, 2014 (13)
3.4	By-laws of Milestone (1)
4.1	Specimen stock certificate (2)
4.2	Form of warrant agreement, including form of warrant (4)
4.3	Form of Common Stock Purchase Warrant issued in the 2016 Public Offering (16)
10.1	Lease dated November 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (3)
10.2	Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (4)
10.4	Employment Agreement with Leonard Osser, dated September 1, 2009** (6)
10.5	2011 Equity Compensation Plan (7)
10.6	Amendment to the Employment Agreement with Leonard Osser, dated March 6, 2013** (11)
10.7	Master Supply and Distribution Agreement, dated July 3, 2013, between Milestone Scientific Inc and Tri-anim Health Services, Inc (9)
10.8	Amendment to the Employment Agreement with Leonard Osser, effective March 17, 2014** (10)
10.9	Agreement with Mark Hochman, dated July 2015 (13)
10.1	Investment Agreement, dated April 15, 2014, between Milestone Scientific Inc. and BP4 S.p.A. (12)
10.11	Exclusive Distribution and Supply Agreement, dated as of June 20, 2016, among Milestone Scientific Inc., Wand Dental, Inc. and Henry Schein, Inc. (14)
10.12	Amended and Restated Employment Agreement, dated December 1, 2016, between Wand Dental Inc. and Gian Domenico Trombetta (15)
21.1	List of Subsidiaries (12)
23.1	Consent of Friedman, LLP*
23.2	Consent of Baker Tilly Virchow Krause, LLP*
31.1	Rule 13a-14(a) Certification-Chief Executive Officer*
31.2	Rule 13a-14(a) Certification-Chief Financial Officer*
32.1	Section 1350 Certifications-Chief Executive Officer***
32.2	Section 1350 Certifications-Chief Financial Officer***
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*

* Filed herewith.

** Indicates management contract or compensatory plan or arrangement.

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

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

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
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2017

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Date	Title
/s/ Leonard Osser Leonard Osser	March 31, 2017	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Joseph D'Agostino Joseph D'Agostino	March 31, 2017	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)
/s/ Leonard Schiller Leonard Schiller	March 31, 2017	Director
/s/ Leslie Bernhard Leslie Bernhard	March 31, 2017	Chairman and Director
/s/ Gian Domenico Trombetta Gian Domenico Trombetta	March 31, 2017	Director
/s/ Edward J. Zelnick, M.D. Edward J. Zelnick, M.D.	March 31, 2017	Director

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

For the Years ended December 31, 2016 and 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Milestone Scientific Inc. and subsidiaries as of December 31, 2016, and the related consolidated statement of operations, consolidated statement of changes in stockholders' equity and cash flows for the year ended December 31, 2016. Milestone Scientific Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Milestone Scientific Inc. as of December 31, 2016, and the results of its operations and its cash flow for the year ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ Friedman LLP

East Hanover, New Jersey
March 31, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders, Audit Committee and Board of Directors
Milestone Scientific Inc.
Livingston, NJ

We have audited the accompanying consolidated balance sheet of Milestone Scientific Inc. as of December 31, 2015, and the related consolidated statements of operations stockholders' equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting.

Our audit included consideration of its internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Milestone Scientific Inc. as of December 31, 2015 and the results of its operations and cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Baker Tilly Virchow Krause, LLP

New York, New York
April 6, 2016

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,602,229	$ 4,194,384
Accounts receivable, net of allowance for doubtful accounts of $10,000 as of December31, 2016 and $5,000 as of December 31, 2015	802,384	1,437,401
Account receivable from related party	2,083,610	356,400
Other receivable	10,000	58,140
Inventories	4,602,719	4,258,094
Advances on contracts	700,900	1,215,128
Deferred cost	620,041	-
Prepaid expenses and other current assets	291,929	304,604
Total current assets	12,713,812	11,824,151
Investment in Milestone Education LLC	-	16,346
Furniture, fixtures & equipment net of accumulated depreciation of $659,144 as of December 31, 2016 and $566,477 as of December 31, 2015	159,026	235,935
Patents, net of accumulated amortization of $717,086 as of December 31, 2016 and $646,388 as of December 31, 2015	660,457	715,540
Other assets	17,355	17,355
Total assets	$ 13,550,650	$ 12,809,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,576,259	$ 2,088,268
Accrued expenses and other payables	1,436,262	1,555,567
Deferred revenue	1,001,800	-
Total current liabilities	5,014,321	3,643,835
Commitments and Contingencies		
Stockholders' Equity		
Series A convertible preferred stock, par value $.001, authorized 5,000,000 shares, 33,333 shares held in the treasury, and 7,000 shares issued and outstanding as December 31, 2016 and December 31, 2015	7	7
Common stock, par value $.001; authorized 50,000,000 shares; 30,457,224 shares issued, 1,270,481 shares to be issued and 30,423,891 shares outstanding as of December 31, 2016; 21,720,497 shares issued, 963,451 shares to be issued and 21,687,164 shares outstanding as of December 31, 2015	31,720	22,685
Additional paid-in capital	82,761,503	78,632,383
Accumulated deficit	(73,381,491)	(67,434,984)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	8,500,223	10,308,575
Noncontrolling interest	36,106	(1,143,083)
Total Equity	8,536,329	9,165,492
Total liabilities and stockholders' equity	$ 13,550,650	$ 12,809,327

See Notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2016 AND 2015

	2016	2015
Revenue		
Product sales, net	$ 10,482,005	$ 9,491,569
Cost of products sold	4,175,533	3,048,260
Gross profit	6,306,472	6,443,309
Selling, general and administrative expenses	11,549,961	9,399,201
Research and development expenses	1,270,471	100,856
Total operating expenses	12,820,432	9,500,057
Loss from operations	(6,513,960)	(3,056,748)
Other (expenses)	(5,088)	(5,347)
Interest income	1,285	3,838
Loss before provision for income tax and equity in net earnings of equity investments	(6,517,763)	(3,058,257)
Provision for income tax	19,101	(36,157)
Loss before equity in net earnings of equity investments	(6,498,662)	(3,094,414)
Loss on earnings from Milestone Medical	-	(2,019,211)
Income (Loss) on earnings from Education Joint Venture	-	(7,846)
Loss on earnings from China Joint Venture	(795,827)	(418,432)
Loss in equity investments	(795,827)	(2,445,489)
Net Loss	(7,294,489)	(5,539,903)
Net loss attributable to noncontrolling interests	(1,347,982)	(72,381)
Net loss attributable to Milestone Scientific Inc.	$ (5,946,507)	$ (5,467,522)
Net loss per share applicable to common stockholders—		
Basic	$ (0.22)	$ (0.26)
Diluted	$ (0.22)	$ (0.26)
Weighted average shares outstanding and to be issued—		
Basic	26,966,988	21,429,993
Diluted	26,966,988	21,429,993

See Notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2016 AND 2015

	Preferred Stock		Common Stock						
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, December 31, 2014	7,000	$ 7	22,379,447	$ 22,380	$ 77,504,415	$ (61,967,462)	$ 394,528	$ (911,516)	$ 15,042,352
Consolidation of Milestone Medical	-	-	-	-	-	-	(1,965,230)	-	(1,965,230)
Stock based compensation	-	-	-	-	637,108	-	-	-	637,108
Capital contribution from noncontrolling interest	-	-	-	-		-	500,000	-	500,000
Common stock issued for payment of consulting services	-	-	41,365	41	119,959	-	-	-	120,000
Common stock issued for payment of employee compensation	-	-	17,817	18	49,982	-	-	-	50,000
Common stock to be issued to employee for bonuses	-	-	29,865	29	99,971	-	-	-	100,000
Common stock issued to employee for exercise of stock options	-	-	200,000	200	199,800	-	-	-	200,000
Exercise of stock options for consultants	-	-	16,666	17	21,148	-	-	-	21,165
Net loss	-	-	-	-		(5,467,522)	(72,381)	-	(5,539,903)
Balance, December 31, 2015	7,000	$ 7	22,685,160	22,685	78,632,383	(67,434,984)	(1,143,083)	(911,516)	9,165,492
Consolidation of Milestone Education	-	-			-	-	16,346	-	16,346
Stock based compensation	-	-	-	-	580,347	-	-	-	580,347
Common stock to be issued to employee for compensation			14,181	14	29,986	-	-	-	30,000
Common stock to be issued to employee for stock program			31,053	31	58,969	-	-	-	59,000
Common stock issued to employee for exercise of stock options			327,778	328	137,172	-	-	-	137,500
Common stock issued for payment of consulting services			270,526	263	504,150	-	-	-	504,413
Common stock to be issued to employee for bonuses			259,765	260	539,240	-	-	-	539,500
Sale of Common Stock - Private Placement			1,104,200	1,104	2,223,896	-	-	-	2,225,000
Sale of Common Stock - Public Offering			2,000,000	2,000	2,571,220				2,573,220
Common Stock exchanged for Milestone Medical Inc.			5,035,042	5,035	(2,515,860)	-	2,510,825	-	-
Net loss	-	-				(5,946,507)	(1,347,982)	-	(7,294,489)
Balance, December 31, 2016	7,000	$ 7	31,727,705	$ 31,720	$ 82,761,503	$ (73,381,491)	$ 36,106	$ (911,516)	$ 8,536,329

See Notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2016 AND 2015

	2016	2015
Cash flows from operating activities:		
Net loss	$ (7,294,489)	$ (5,539,903)
Adjustments to reconcile net loss to net cash (used in) by operating activities		
Depreciation expense	92,667	27,947
Amortization of patents	70,699	69,428
Common stock and options for compensation, consulting and vendor services	1,850,760	1,128,274
Equity loss on Milestone Medical Inc.	-	2,019,211
Equity loss on Education joint venture	-	7,846
Equity loss on China joint venture	795,827	348,651
Changes in operating assets and liabilities:		
Increase (Decrease) in accounts receivable	635,017	(207,248)
Increase in due from related party	(1,727,210)	-
Decrease (Increase) in other receivable	48,515	(58,140)
Increase in inventories	(509,462)	(875,034)
Decrease (Increase) to advances on contracts	514,228	(450,407)
Increase in deferred cost	(620,041)	-
Decrease to prepaid expenses and other current assets	12,675	192,601
(Increase) in other assets	-	(2,670)
Increase in accounts payable	486,348	173,068
Decrease in accrued expenses and other payables	(755,915)	220,038
Increase in deferred revenue	1,001,800	-
Net cash (used in) operating activities	(5,398,581)	(2,946,338)
Cash flows from investing activities:		
Purchases of intangible assets	(15,615)	(9,939)
Purchases of property and equipment	(15,344)	(67,581)
Consolidation of variable interest entity	39,165	(3,649,751)
Net cash provided by (used in) investing activities	8,206	(3,727,271)
Cash flows from financing activities:		
Net proceeds on private placement offering	2,225,000	-
Net proceeds on public offering	2,573,220	-
Capital contribution from noncontrolling interest	-	500,000
Net cash provided by investing activities	4,798,220	500,000
Net (decrease) in cash and cash equivalents	(592,155)	(6,173,609)
Cash and cash equivalents at beginning of year	4,194,384	10,367,993
Cash and cash equivalents at end of year	$ 3,602,229	$ 4,194,384
Supplemental disclosure of cash flow information:		
Net assets acquired from variable interest entity	$ 16,346	$ 566,775

See Notes to Consolidated Financial Statements

NOTE A — ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

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

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of 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 a number of other disciplines. The dental instruments are sold in the United States and in over 47 countries abroad. There have been no medical instruments sold in the United States and limited amounts sold internationally as of the reporting date, although certain medical instruments have obtained CE mark approval and now can be marketed and sold in most European countries. Milestone Scientific's products are manufactured by a third-party contract manufacturer.

In May of 2014, Milestone Scientific completed a private placement (the "May 2014 Financing"), which raised aggregate gross proceeds $10 million, from the sale of $3 million of our common stock, $.001 par value per share ("common stock") (two million shares at $1.50 per share) and $7 million of our Series A Convertible Preferred Stock (7,000 shares at $1,000 per share), convertible into common stock at $2.37 per share (as adjusted to date) on May 14, 2019, or $1.50 per share if certain conditions are not met; both subject to an anti-dilution adjustment.

On June 1, 2015, we listed our common stock on the NYSE MKT LLC ("NYSE MKT") under the ticker symbol "MLSS".

In June 2016, Milestone Scientific raised an additional $2.0 million of gross proceeds in a private placement of one million shares of common stock, at a price of $2.00 per share, to the same investors that participated in the May 2014 Financing.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we exchanged one share of common stock for every two outstanding shares of Milestone Medical (described below) common stock, a previously consolidated variable interest entity. As a result of the exchange program, at December 31, 2016, Milestone Scientific owned approximately 91% of Milestone Medical.

In July 2016, Milestone Scientific filed for 510(k) marketing clearance with the United States Food and Drug Administration ("FDA") Milestone Medical's epidural anesthetic injections instrument. This clearance is necessary to begin commercialization of these medical instruments in the United States.

In December 2016, Milestone Scientific received notification from the FDA that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, it did not adequately document that the device met the equivalency standard required for 510(k) clearance. Following consultation with the FDA Office of Device Evaluation, we intend to provide additional data, which could include a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the device. An HFV Study demonstrates the ease of use of a product. The cost to generate this incremental data is estimated to be approximately $100,000.

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. The public offering price for each share and related warrant was $1.50. 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. The gross proceeds from this offering, including proceeds from partial exercises of the over-allotment option, were approximately $3,200,000, before deducting underwriting discounts and commissions and other offering expenses. This offering was covered by the prospectus supplement, filed with the SEC on December 16, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

As of December 31, 2016, Milestone Scientific's financial statements are consolidated to include the accounts of its wholly-owned, majority-owned subsidiaries variable interest entity including, Wand Dental, Inc., a Delaware corporation ("Wand Dental"), Milestone Advanced Cosmetic Systems, Inc. ("Milestone Advanced Cosmetic"), Milestone Medical Inc. ("Milestone Medical") and Milestone Education LLC ("Milestone Education"). Milestone Education are variable interest entity for which Milestone Scientific is the primary beneficiary. All significant, intra-entity transactions and balances have been eliminated in the consolidation. (See Note E to the Consolidated Financial Statements).

Milestone Scientific has incurred operating losses and negative cash flows from operating activities since its inception, except for 2013. Milestone Scientific is actively pursuing the generation of increased revenue, positive operating income and cash flow from operations. The previous equity financings provided Milestone Scientific with the opportunity to continue to develop medical instruments and aggressively market its already commercialized dental instruments throughout the world. Management believes its cash on hand and remaining net current assets are sufficient to meet its obligations over the next twelve months from the filing of this form 10K. Milestone Scientific may need to raise additional capital prior to management's expected generation of sustainable positive cash flow from operating activities.

NOTE B — 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, Milestone Advanced Cosmetic and Milestone Medical. Milestone Education is a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. Prior to December 31, 2015, Milestone Medical was accounted for as an equity investment (See Note E). All significant, intra-entity transactions and balances have been eliminated in the consolidation.

2. Reclassifications

Certain reclassifications have been made to the 2015 financial statements to conform to the consolidated 2016 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

3. 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.

Milestone Scientific is the primary beneficiary of Milestone Medical as of December 31, 2015 (see Note E) and Milestone Education as of January 2016. Accordingly, the assets and liabilities of Milestone Medical and Milestone Education are included in the accompanying consolidated financial statements.

Because Milestone Scientific had an increasing variable interest in Milestone China, it further considered the guidance in Accounting Standard Codification ("ASC") 810 as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. As Milestone China's equity at risk and voting rights were not proportional to their economic interest, Milestone China was determined to be a VIE. 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 management 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 majority shareholder/CEO of Milestone China. As majority shareholder, majority holder of voting rights, and the active CEO, the 53% investor has 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 F).

4. 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.

5. 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. A majority of credit sales are due within ninety days from invoicing. There have not been any significant credit losses incurred to date.

6. Product Return and Warranty

Milestone Scientific generally does not accept non-defective returns from its customers. 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.

7. 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 requirements.

8. Equity Method Investments

Investments in which Milestone Scientific has the ability to 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.

9. 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 five to seven years. The costs of maintenance and repairs are charged to operations as incurred.

10. Intangible Assets - Patents

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. Although certain patents have not yet been approved, the costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. If the applicable patent application is ultimately rejected, the remaining unamortized balance will be expensed in the period in which Milestone Scientific receives notice of such rejection. Patent defense costs, to the extent applicable are expensed as incurred. Patent applications filed and patents obtained in foreign countries are subject to the laws and procedures that differ from those in the United States. Patent protection in foreign countries may be different from patent protection under United States laws and may not be favorable to Milestone Scientific. Milestone Scientific also attempts to protect the proprietary information through the use of confidentiality agreements and by limiting access to its facilities. There can be no assurance that the program of patents, confidentiality agreements and restricted access to the facilities will be sufficient to protect the proprietary technology.

11. Impairment of Long-Lived Assets

Milestone Scientific reviews long-lived assets for impairment whenever events or circumstances (i.e. a triggering event) indicate that the carrying amounts may not be recoverable. The carrying value of the assets is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets. Milestone Scientific adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. There have been no impairment indicators or triggering events and therefore, no impairment reviews have been performed in the period ending December 31, 2016.

12. Revenue Recognition

Revenue from product sales is recognized, net of discounts and allowances to domestic distributors, on the date of shipment for substantially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific recognizes revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. Shipments to international distributors are FOB warehouse, therefore revenue is recognized on shipment of the goods. In all cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone Scientific has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period. Instrument and hand pieces are not bundled but rather sold separately and, as such, there are no multiple element determinations in connection with the revenue recognition.

13. Shipping and Handling Costs

Milestone Scientific includes shipping and handling costs in cost of goods sold. These costs are billed to customers at the time of shipment for domestic shipments. International shipments are FOB warehouse, therefore no costs are incurred by Milestone Scientific.

14. 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.

15. 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.

16. Basic and diluted net loss per common share

Milestone Scientific presents "basic" earnings (loss) per common share applicable to common stockholders and, if applicable, "diluted" earnings (loss) per common share applicable to common stockholders pursuant to the provisions of Statement of Financial Accounting Standards ASC Topic 260. Basic earnings (loss) per common share is calculated by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding and to be issued during each period. The calculation of diluted earnings per common share is similar to that of basic earnings per common share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if all potentially dilutive common shares, such as those issuable upon the exercise of stock options, warrants, and the conversion of debt were issued during the period.

Since Milestone Scientific had net losses for 2016 and 2015, the assumed effects of the exercise of potentially dilutive outstanding stock options and warrants were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 3,329,769 and 1,427,769 at December 31, 2016 and 2015, respectively.

17. Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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**.**

18. Fair Value of Financial Instruments

Fair Value Measurements: We follow the provisions of ASC 820, Fair Value Measurements and Disclosures related to financial assets and liabilities that are being measured and reported on a fair value basis. 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 has the ability to 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 a particular 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 weighted-average fair value of the options granted during 2016 and 2015 was estimated as $1.70 and $3.01, respectively, on the date of grant. The fair value for 2016 and 2015 was determined using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2016	2015
Volatility	181%	167%
Risk-free interest	0.99%	1.73%
Expected Life (in years)	5	5
Dividend yield	0%	0%
Forfeiture Rate	6%	6%

20. **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. The FASB continues to release guidance clarifying certain aspects of the revenue guidance. We do not believe that this new accounting pronouncement will have a material impact on our financial statements.

In August 2014, the FASB issued a new standard Accounting Standards Update ("ASU") No.2014-15, "Presentation of Financial Statements – Going Concern" (Subtopic 205-40).The new standard is intended to enhance the disclosure as it relates to management's assessment of the abilities to continue as a going concern. The standard will be effective for the annual period ending after December 15, 2016. Milestone Scientific adopting this standard with its annual reporting as December 31, 2016.

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. We do not believe that this new accounting pronouncement will have a material impact on our financial statements.

In February 2016, the FASB issued a new standard 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 and for interim periods within fiscal years beginning after December 15, 2020. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In March 2016, the FASB issued a new standard ASU No.2016-07, "Investments - Equity Method and Joint Ventures" (Topic 323): The new standard is intended to eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an in increase in the level of ownership or degree of influence, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect all of the previous periods that the investment was held. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2016. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In March 2016, the FASB issued a new standard ASU No.2016-07, "Investments - Equity Method and Joint Ventures" (Topic 323): The new standard is intended to eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an in increase in the level of ownership or degree of influence, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect all of the previous periods that the investment was held. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2016. Milestone Scientific does not believe that this new accounting pronouncement will have a material impact on our financial statements.

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 is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In August 2016, the FASB issued a new standard ASU No.2016-15, “Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Disbursements” (Topic 230). The new standard provides guidance as to the conformity of presentation of certain cash receipts and disbursements. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

NOTE C — INVENTORIES

	December 31	
	2016	2015
Inventories consist of the following:		
Finished goods	$ 4,573,667	$ 4,252,612
Component parts and other materials	29,052	5,482
Total	$ 4,602,719	$ 4,258,094

NOTE D — ADVANCES ON CONTRACTS

Milestone Scientific has entered into fixed arrangements with a contract manufacturer to manufacture STA Instruments and handpieces, *CompuDent*®. The contract manufacturer bills Milestone Scientific as the work progresses and it is Milestone Scientific’s policy to record these billings as advances on contracts. These advances are reclassified into inventory when the contract manufacturer ships the product and title passes to Milestone Scientific. The balance of the advances as of December 31, 2016 and 2015 are $700,900 and $1,215,128, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE E – CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Medical

As of December 31, 2016, Milestone Medical is approximately 91% owned by Milestone Scientific. Milestone Medical was established to develop and commercialize intra-articular and epidural drug delivery instruments, utilizing an exclusive royalty-free license to Milestone Scientific's CompuFlo technology. The license was contributed by Milestone Scientific for its initial 50% ownership in Milestone Medical in September, 2011.

Since its initial investment in Milestone Medical, Milestone Scientific had accounted for the investment in accordance with the equity method of accounting. However, during 2015, Milestone Scientific provided short term bridge financing to Milestone Medical in anticipation of the completion of a secondary stock offering in Poland. In December 2015, Milestone Medical suspended this capital raise efforts meriting re-consideration of the initial accounting for the investment as an equity method investment. In April 2016, Milestone Medical cancelled the uplisting of its shares to the Poland Warsaw Stock Exchange.

As a result of the change in circumstances around the proposed offering in December 2015 by Milestone Medical, Milestone Scientific reevaluated its relationship with Milestone Medical and Milestone Medical's status as a VIE and determined that Milestone Medical did not have sufficient capital at risk to support its activities without additional financial support from Milestone Scientific. Since the factors giving rise to concluding that Milestone Medical is a VIE happened proximate to the end of fiscal year 2015, the date for measuring the consolidation of Milestone Medical was deemed to be December 31, 2015.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which it would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. As there was no change in control, the acquisition of the non-controlling interest is reflected as an equity transaction with the carrying value of the non-controlling interest adjusted to reflect Milestone Scientific's increased ownership interest in the subsidiary. As a result of these exchanges, Milestone Scientific owns approximately 91% of Milestone Medical at December 31, 2016.

Milestone Education LLC

Milestone Education is a 50% owned subsidiary of Milestone Scientific which began operations in 2013 to provide training and education to dentists throughout the world. Milestone Scientific accounted for its investment in Milestone Education using the equity method of accounting through December 31, 2015. Approximately 81% of the revenue earned by Milestone Education is from services performed for Milestone Scientific as of December 31, 2016. As a result of this relationship, we determined that we have the power to direct the activities that most significantly impact Milestone Education's economic performance, and that it is a VIE and should be consolidated in the financials of Milestone Scientific effective January 2016.

The financial information in the table below summarizes the combined results of operations of Milestone Scientific and its subsidiaries, including Milestone Medical and Milestone Education, on a pro forma basis as though the companies had been combined as of the beginning of the earliest period presented. The pro forma financial information is presented for informational purposes only and is not indicative of the result of operations that would have been achieved if the consolidation had taken place at the beginning of the period presented.

	December 31, 2015 Pro Forma (unaudited)
Revenue	
Sales	$ 9,624,375
Cost of products sold	3,061,299
Gross Profit	6,563,076
Selling, general and administrative expenses	12,781,813
Research and development expenses	892,255
Operating expenses	13,674,068
Loss from operations	(7,110,992)
Other expenses	(6,845)
Interest income	3,846
Loss before provision for income tax and equity in net earnings of equity investments	(7,113,991)
Provision for Income Tax	(36,157)
Loss before equity in net earnings of equity investments	(7,150,148)
Loss on earnings from China Joint Venture	(418,432)
Loss in equity investments	(418,432)
Net loss	(7,568,580)
Less: Net loss attributable to the noncontrolling interests	(2,101,056)
Net loss attributable to Milestone Scientific Inc.	$ (5,467,524)

NOTE F – INVESTMENT IN UNCONSOLIDATED SUBSIDIARIES

Advance Ocular Science SA

Advanced Ocular Sciences SA (“Advanced Ocular”) is an entity organized to develop an instrument that delivers injections into the eyes. Advanced Ocular is a shell company as of December 31, 2016. Milestone Scientific owns 25% of this entity. During 2015, Milestone Scientific advanced $78,798 for marketing and strategy planning to Advanced Ocular and they, or their organizers, are obligated to repay this advance once a public offering of Advanced Ocular equity is approved and funded in Poland during 2016. No public offering was completed in Poland as of December 31, 2016.

As such, Milestone Scientific has written-off the $78,798 advanced to Advanced Ocular as of December 31, 2016. Advance Ocular was not included in the consolidated financial statements at December 31, 2016 as no investment has been made by Milestone Scientific. The suspended losses approximated $19,700 at December 31, 2016.

Milestone China Ltd.

In June 2014, Milestone Scientific invested $1 million through the contribution of 772 STA instruments (at a distributor price of approximately $1,296 per instrument) for a forty percent (40%) ownership in Milestone China. In 2014, the instruments were shipped and were recorded as an investment in Milestone China at the cost of the inventory contributed. In January 2016, Milestone Scientific contributed 308 STA instruments with a retail value of approximately $400,000 ($1,296 per instrument) to Milestone China which increased Milestone Scientific's investment by approximately $165,000 which represents the cost of the instruments. This did not increase Milestone Scientific's percentage of ownership since the contribution was proportionate to contributions from other shareholders.

Milestone Scientific recorded a loss on its investment in Milestone China of $795,827 and $418,432 for the twelve months ended December 31, 2016, and, 2015, respectively. Milestone Scientific' investment in Milestone China was $0 as of December 31, 2016 and 2015. Milestone Scientific had suspended losses on its investment in Milestone China of $1,124,350, and $215,347 as of December 3, 2016 and 2015.

Milestone Scientific had $3,425,000 of related party revenue for sales of instruments and handpieces during the twelve months ended December 31, 2016 to Milestone China. Milestone Scientific recorded deferred revenues and cost associates with sales to Milestone China of $1,001,800 and $620,041, respectively as of December 31, 2016. Milestone China owes $2,714,600 to Milestone Scientific for STA instruments and handpieces shipped in 2016, which is included in due from related party at December 31, 2016. During 2015, Milestone Scientific shipped $507,000 in handpieces and $938,304 in instruments to Milestone China Ltd.

Milestone Scientific recognizes the total revenue and costs of goods sold at the time the shipment of instruments and handpieces to Milestone China. However, due to timing differences of when the inventory is sold to Milestone China and when Milestone China sells the acquired inventory to third parties, elimination of the intra-entity profit is required as of the balance sheet date. In accordance with ASC 323 Equity Method and Joint Ventures, Milestone Scientific has deferred the gross profit associated with inventory shipped to Milestone China that has not been sold to third parties. The deferred profit of $630,990 and $ 69,781, as of December 31, 2016 and 2015, respectively is included in the loss from Milestone China within the Consolidated Statements of Operations and presented in due from related parties in the Consolidated Balance Sheets. Milestone Scientific received payment of $1.7 million of the amount outstanding at December 31, 2016 subsequent to year end.

The following table includes summarized financial information of Milestone China:

	December 31, 2016 (unaudited)	December 31, 2015 (unaudited)
Assets:		
Current Assets	$ 9,362,198	$ 772,999
Non -Current Assets	2,467,547	903,766
Total Assets:	11,829,745	1,676,765
Liabilities:		
Current Liabilities	9,900,611	580,613
Stockholders' equity	1,929,134	1,096,152
Total liabilities and stockholders' equity	$ 11,829,745	$ 1,676,765

	December 31, 2016 (unaudited)	December 31, 2015 (unaudited)
Net Sales	$ 1,126,484	$ 2,303,660
Cost of Goods Sold	976,106	2,096,569
Gross Profit	150,378	207,091
Other Expenses	(2,834,980)	(1,342,357)
Net Losses	$ (2,684,602)	$ (1,135,266)

NOTE G— FURNITURE, FIXTURES AND EQUIPMENT

	December 31	
	2016	2015
Furniture, Fixtures and Equipment consist of the following:		
Leasehold improvements	$ 24,734	$ 24,734
Office furniture and equipment	135,802	134,948
Molds	7,200	7,200
Trade show displays	143,357	136,029
Computers and software	224,840	217,265
Tooling Safety Wand	125,022	20,377
Tooling equipment-STA & Wand	11,100	115,745
EPI and IA Instruments	82,363	82,362
STA Trials Instruments	63,752	63,752
Total	818,170	802,412
Less accumulated depreciation	(659,144)	(566,477)
Total	$ 159,026	$ 235,935

Depreciation expense was $92,226 and $27,947 for the years ended December 31, 2016 and 2015, respectively.

NOTE H — PATENTS

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 10 to 20 years, with a weighted average amortization period of 12 years. Amortization expense amounted to $70,699 in 2016 and $69,428 in 2015.

NOTE I — STOCKHOLDERS' EQUITY

ISSUANCES COMMON STOCK

In June 2016, Milestone Scientific raised an additional $2.0 million of gross proceeds in a private placement of one million shares of common stock, at a price of $2.00 per share, to the same investors that participated in the May 2014 Financing.

In July 2016, Milestone Scientific raised gross proceeds of $250,000 in a registered direct offering of 104,200 shares of common stock at $2.40 per share. The transaction was covered by the prospectus supplement, filed with the United States Securities and Exchange Commission ("SEC) on July 22, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

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. The gross proceeds from this offering, including proceeds from partial exercises of the over-allotment option, were approximately $3,200,000, before deducting underwriting discounts and commissions and other offering expenses of $426,780.

ISSUANCES OF 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), convertible into common stock at $2.37 per share (as adjusted to date) on May 14, 2019, or $1.50 per share unless certain conditions are not met both subject to anti-dilution adjustment. 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, pari passu, in any cash dividends declared on Milestone Scientific common stock on as converted basis.

SHARES TO BE ISSUED

As of December 31, 2016 and 2015, there were 1,270,481 and 963,451 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. 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, 2016 and 2015 there were 4,600,250 and 2,391,220 shares reserved for future issuance and 3,329,769 and 1,427,769 shares underlying other stock options and warrants outstanding, respectively. At December 31, 2016 and 2015 there were 1,270,481 shares and 963,451 shares, respectively, reserved for issuance in settlement of deferred compensation to officers of Milestone Scientific.

NOTE J — 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, 2016 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. Such future share issuances are included in the above noted shares reserved for future issuances. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant.

In May 2016, Milestone Scientific's stockholders approved the following amendments to the 2011 Plan:

i. Renaming of the 2011 plan to the “Milestone Scientific Inc., 2011 Equity Compensation Plan”
ii. Providing for awards of restricted common stock; and
iii. Increasing the maximum number of shares of common stock reserved for grants under the 2011 Plan from 2,000,000 to 4,000,000.

Milestone Scientific recognizes compensation expense on a straight line basis 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, 2016 and 2015 respectively, Milestone Scientific recognized $579,103 and $637,108 of total employee compensation cost, respectively. As of December 31, 2016 and 2015, there was $678,842 and $1,167,865 of total unrecognized compensation cost related to nonvested options, respectively. Which Milestone Scientific expects to recognize these cost over a weighted average period of 2.58 years and 2.78 years as of December 31, 2016 and 2015, respectively.

A summary of option activity for employees under the plans and changes during the year ended December 31, 2016, is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Outstanding January 1, 2015	1,472,130	0.79	2.88	1,430,231
Exercisable, December 31, 2015	1,036,185	1.10	2.75	1,244,074
Granted	157,306	3.01	4.18	
Exercised during 2015	(200,000)	1.00	-	-
Forfeited or expired	(10,000)	1.00	-	-
Outstanding December 31, 2015	1,419,436	1.56	2.79	1,220,338
Exercisable, December 31, 2015	1,041,680	1.29	2.41	1,135,819
Granted	520,337	1.79	4.38	-
Exercised during 2016	(327,778)	.75	-	-
Forfeited or expired	(100,000)	2.35	-	-
Outstanding December 31,2016	1,511,995	1.74	2.97	102,605
Exercisable, December 31, 2016	1,054,202	1.65	2.51	102,605

A summary of option activity for non-employees under the plans as of December 31, 2016 and 2015, and changes during the year ended is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Outstanding, January 1, 2015	16,666	1.27	0.62	17,166
Exercisable, January 1, 2015	16,666	1.27	0.62	17,166
Granted	8333	2.70	4.83	22,499
Exercised	(16,666)	1.27	-	-
Outstanding, December 31, 2015	8,333	2.70	4.83	-
Exercisable, December 31, 2015	2,777	2.70	4.83	-
Granted	216,666	2.53	-	-
Exercised	-	-	-	-
Outstanding, December 31, 2016	224,999	2.53	5.32	-
Exercisable, December 31, 2016	14,734	2.72	4.36	-

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. In accordance with the provisions of FASB ASC 505, Milestone Scientific will re-measure the value of the grant at each presentation date unless there is a significant disincentive for non-performance or until performance has been. For the twelve months end December 31, 2016, Milestone Scientific recognized $25,346 expense related to non-employee options. For the twelve months end December 31, 2015, Milestone Scientific recognized $7,050 expense related to non-employee options. As of December 31, 2016, there was a total of $678,842 of unrecognized compensation cost related to non-vested options, which Milestone Scientific expects to recognize over a weighted average period of 2.49 years.

NOTE K–EMPLOYMENT CONTRACT AND DEFERRED COMPENSATION

Employment Contracts

As of September 1, 2009, Milestone Scientific entered into a five-year employment agreement with Leonard Osser as its Chief Executive Officer (the "2009 Agreement"). The term of the 2009 Agreement is 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). The options shall vest and become exercisable to the extent of one-third of the shares covered at the end of each of the first three years following the date of grant, but shall only be exercisable while the CEO is employed by Milestone Scientific or within 30 days after the termination of his employment. In 2012 the CEO waived the option component of his bonus for that year.

In accordance with the 2009 Agreement, 855,810 shares of common stock are to be paid out at the end of the term in settlement of $980,906 of deferred compensation accrued at December 31, 2016 and 735,369 shares of common stock are to be paid out at the end of the contract in settlement of $730,985 of deferred compensation accrued at December 31, 2015 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.

NOTE L — INCOME TAXES

Due to Milestone Scientific®€™s history of operating losses, a full valuation allowances has been provided for all of Milestone Scientific®€™s deferred tax assets at December 31, 2016 and 2015, no recognition was given to the utilization of the remaining net operating loss carryforwards.

Deferred tax attributes resulting from differences between financial accounting amounts and tax bases of assets and liabilities at December 31, 2016 and 2015 are as follows:

	2016	2015
Current assets		
Allowance for doubtful accounts-short term	$ 4,000	$ 2,000
Warranty reserve	36,000	43,000
Deferred officers compensation	395,000	643,000
Subtotal	435,000	688,000
Valuation allowance	(435,000)	(688,000)
Non-current assets		
Depreciation and amortization	$ 135,000	$ 149,000
Net operating loss carryforward	18,456,000	16,160,000
Federal tax effect of state deferred tax assets	-	(117,000)
Subtotal	18,591,000	16,192,000
Valuation allowance	(18,591,000)	(16,192,000)

As of December 31, 2016, federal net operating loss carryforwards are approximately $51,807,000. As of December 31, 2015 and Milestone Scientific has federal net operating loss carryforwards of approximately $46,875,000, 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 2036. As of December 31, 2016 state net operating losses were approximately $10,047,000. As of December 31, 2015 Milestone Scientific has state net operating loss carryforwards of approximately $3,771,000. Net operating losses will be available to offset future taxable income, if any, through December 2036.

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

For the year ended December 31, 2016 and 2015, state tax liability was approximately $13,000 and $62,000. Such expense was recognized in the accompanying consolidated financial statements.

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

	2016	**2015**
Statutory rate	34%	34%
State income tax - all states	6%	6%
Non-deductible stock based compensation	3%	-
	43%	40%
Current year valuation allowance	(43%)	(40%)
Benefit for income taxes	0%	0%

Accounting for Uncertain Tax Positions:

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 also provides guidance on derecognition, classification, interest and penalties, disclosure and transition. At December 31, 2016, and 2015, 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 2013, 2014, and 2015 years are subject to audit by federal and state jurisdictions.

NOTE M — PRODUCT SALES AND SIGNIFICANT CUSTOMERS AND VENDORS

Milestone Scientific's consolidated dental sales by product and by geographical region are as follows:

	Years Ended December 31,			
	2016		2015	
DOMESTIC				
Instruments	$ 852,148	27.5%	$ 623,195	17.8%
Handpieces	2,102,394	67.9%	2,799,785	79.8%
Other	143,762	4.6%	83,362	2.4%
Total Domestic	$ 3,098,304	100.0%	$ 3,506,342	100.0%
INTERNATIONAL				
Instruments	$ 3,264,633	44.2%	$ 2,062,556	34.5%
Handpieces	4,063,811	55.1%	3,836,002	64.1%
Other	55,257	0.7%	86,669	1.4%
Total International	$ 7,383,701	100.0%	$ 5,985,227	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	$ 3,098,304	29.6%	$ 3,506,342	36.9%
International	$ 7,383,701	70.4%	$ 5,985,227	63.1%
Total Product Sales	$ 10,482,005	100.0%	$ 9,491,569	100.0%

Milestone Scientific has informal arrangements with the manufacturer of the STA, CompuDent® and CompuMed® instruments, one of the principal manufacturers for those instruments pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. In March 2016, Milestone Scientific entered into a new purchase commitment for delivery of 3,000 instruments. An advance an aggregate of $656,752 was recorded at December 31, 2016. Consequently, advances on contracts have been classified as current at December 31, 2016 and 2015.

For the year ended December 31, 2016, Milestone Scientific had two customers (distributors, one is a related party) that purchased approximately 58% (31% and 27%), of its net product sales. Accounts receivable for the two major customers amounted to approximately $2,994,686, or 85% of gross accounts receivable for the years ended December 31, 2016. For the year ended December 31, 2015, Milestone Scientific had two customers (distributors, one is a related party) that purchased approximately 33% (15% and 15%), of its net product sales. Accounts receivable for the three major customers amounted to approximately $1,100,000, or 69% of gross accounts receivable for the years ended December 31, 2015.

NOTE N – RELATED PARTIES

Milestone Scientific has a manufacturing agreement with one of its principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders, but without minimum purchase commitments. Purchases of handpieces from this vendor in China were $3,025,249 and $2,698,522 during the years ended December 31, 2016 and 2015 respectively. All other purchases from other suppliers were not significant for the period. Milestone Scientific Inc owed $1,235,052 and $716,519 to this supplier as of December 31, 2016 and 2015, respectively.

Milestone Scientific has $3,245,000 of related party revenue for sales of instruments and handpieces during the twelve months ended December 31, 2016 to Milestone China. Milestone Scientific recorded deferred revenues and cost associates with the sales to Milestone China $1,001,800 and $620,041 as of December 31, 2016. Milestone China owes $2,714,600 to Milestone Scientific for STA instruments and handpieces shipped in 2016, which is included in due from related party at December 31, 2016. During 2015, Milestone Scientific shipped $507,000 in handpieces and $938,304 in instruments to Milestone China Ltd.

Milestone Scientific recognizes the total revenue and costs of goods sold at the time the shipment of instruments and handpieces to Milestone China. However, due to timing differences of when the inventory is sold to Milestone China and when Milestone China sells the acquired inventory to third parties, elimination of the intra-entity profit is required as of the balance sheet date. In accordance with ASC 323 Equity Method and Joint Ventures, Milestone Scientific has deferred the gross profit associated with inventory shipped to Milestone China that has not been sold to third parties. The deferred profit of $630,990 and $ 69,781, as of December 31, 2016 and 2015, respectively is included in the loss from Milestone China within the Consolidated Statements of Operations and presented in due from related parties in the Consolidated Balance Sheets. Milestone Scientific received payment of $1.7 million of the amount outstanding at December 31, 2016 subsequent to year end.

In June 2016, Milestone Scientific raised an additional $2.0 million of gross proceeds in a private placement of one million shares of common stock, at a price of $2.00 per share, to Innovest, a related party.

In August 2013, a stockholder of Milestone Scientific entered a three-year agreement with Milestone Scientific to provide financial and business strategic services. The fee for these services are $100,000 annually.

NOTE O — COMMITMENTS AND OTHER

(1) Lease Commitments

The headquarters for Milestone Scientific is located at 220 South Orange Ave, Livingston, New Jersey. Milestone Scientific leases approximately 7,625 square feet of office space. The lease term expires January 31, 2020 at a monthly cost of $12,522. Additionally, Milestone Scientific has other smaller insignificant leases ending through 2017. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

Aggregate minimum rental commitments under noncancelable operating leases are as follows:

	Year Ending December 31,
2017	150,264
2018	150,264
2019	161,532
2020	152,142
	$ 614,202

For the years ended December 31, 2016 and 2015, respectively, rent expense amounted to $133,657and $121,866 respectively.

(2) Contract Manufacturing Arrangement

Milestone Scientific has informal arrangements for the manufacture of its product, The *STA Single Tooth Anesthesia System*® instrument is manufactured for Milestone Scientific by Tricor Systems, Inc. pursuant to specific purchase orders. The STA and the Wand® Handpiece with Needle is supplied to Milestone Scientific by a contractor in the United States, which arranges for its manufacture with two factories in China.

The termination of the manufacturing relationship with any of the above 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, whether or not as a result of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations.

(3) Other Commitments

Milestone Scientific's employment agreement with its Chief Executive Officer provides for payments of $203,111 per year for five years to the executive, or as he directs such payments, to a third party to fund his acquisition of, or contribution to, an annuity, pension, or deferred distribution plan; or for an investment for the benefit of the executive and his family. For the twelve months ended December 31, 2016 and 2015 approximately $203,111 and $236,963 was charged to expense, respectively to fund this obligation.

The technology underlying the *SafetyWand*® 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. The Director of Clinical Affairs was granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant 8,333 shares of common stock upon the issuance of each additional patent relating to 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 $526,737 and $442,763 for the twelve months ended December 31, 2016 and 2015, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $275,000 and $185,751 for the twelve months ended December 31, 2016 and 2015, respectively.

NOTE P — 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 Q — SUBSEQUENT EVENTS

In January 2017, in connection with Milestone Scientific public offering of shares in December 2016, the underwriter of the offering exercised a portion of its over-allotment option and purchased an additional 123,700 shares of common stock at the public offering price of $1.499 per share. The gross proceeds to Milestone Scientific from this exercise was approximately $186,000 before deducting underwriting discounts and commissions and other offering expenses.

In January 2017, Milestone Scientific continued its Milestone Medical exchange program and exchanged 1,065,084 shares of Milestone Medical shares for 532,542 shares of Milestone Scientific common stock. Giving effect to the exchange, Milestone Scientific now owns approximately 96% of the shares in Milestone Medical.

In February 2017, the Company issued a purchase order to its supplier for 2,000 STA instruments in the amount of $1.4 million which are expected to be delivered beginning in the third quarter of 2017.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 No. 333-209466 and Form S-8 File No. 333-134245 and No. 333-40413 of Milestone Scientific Inc. of our report dated March 31, 2017 relating to our audit of the consolidated financial statements of Milestone Scientific Inc. as of December 31, 2016, which appear in this Form 10-K.

/s/ Friedman LLP

East Hanover, New Jersey
March 31, 2017

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-209466) and Form S-8 (File No. 333-134245 and File No. 333-40413) of Milestone Scientific Inc. and Subsidiary of our report dated April 6, 2016, which appears on page F-3 of this annual report on Form 10-K for the year ended December 31, 2016.

/s/ Baker Tilly Virchow Krause, LLP

New York, New York

March 31, 2017

Exhibit 31.1

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

I, Leonard Osser, certify that:

1. I have reviewed this annual report on Form 10-K of Milestone Scientific Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2017

/s/ Leonard Osser
Leonard Osser
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Joseph D'Agostino, certify that:

1. I have reviewed this annual report on Form 10-K of Milestone Scientific Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2017

/s/ Joseph D'Agostino
Joseph D'Agostino
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the annual report of Milestone Scientific Inc (the "Company") on Form 10-K for the period ending December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard Osser, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company

Dated: March 31, 2017

/s/ Leonard Osser
Leonard Osser
Chief Executive Officer
(Principal Executive Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the annual report of Milestone Scientific Inc (the "Company") on Form 10-K for the period ending December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph D'Agostino, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company

Dated: March 31, 2017

/s/ Joseph D'Agostino
Joseph D'Agostino
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.