

MILESTONE SCIENTIFIC INC.
Form 10-K
April 06, 2016

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, 2015

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
State or other jurisdiction of
Incorporation or organization
220 South Orange Avenue, Livingston, NJ 07039

13-3545623
(I.R.S. Employer
Identification No.)

(Address of principal executive offices)

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-K

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, 2015, the last business day of Milestone Scientific Inc.'s most recently completed second fiscal quarter, the aggregate market value of the common stock held by non – affiliates of the issuer was \$25,888,742. This amount is based on the closing price of \$3.40 per share of Milestone Scientific's common stock as of such date, as reported on the NYSE MKT.

As of April 6, 2016 the registrant has a total of 21,687,164 shares of Common Stock, \$0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

MILESTONE SCIENTIFIC Inc.

Form 10-K Annual Report

TABLE OF CONTENTS

PART I

Item 1.	<u>Description of Business</u>	4
Item 1A.	<u>Risk Factors</u>	13
Item 1B.	<u>Unresolved Staff Comments</u>	16
Item 2.	<u>Description of Property</u>	16
Item 3.	<u>Legal Proceedings</u>	16
Item 4.	<u>Mine Safety Disclosure</u>	16

PART II

Item 5.	<u>Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities</u>	17
Item 6.	<u>Selected Financial Data</u>	17
Item 7.	<u>Management's Discussion and Analysis or Plan of Operations</u>	18
Item 7A.	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	24
Item 8.	<u>Financial Statements</u>	24
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	24
Item 9A.	<u>Controls and Procedures</u>	25
Item 9B.	<u>Other Information</u>	25

PART III

Item 10.	<u>Directors, Executive Officers, Promoters and Control Persons and Corporate Governance; Compliance with Section 16 (a) of the Exchange Act</u>	26
Item 11.	<u>Executive Compensation</u>	29
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	32
Item 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	33
Item 14.	<u>Principal Accounting Fees and Services</u>	34

PART IV

Item 15.	<u>Exhibits and Financial Statement Schedules</u>	35
----------	---	----

SIGNATURES

38

EXHIBITS

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. 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 Inc.’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 Inc. Although Milestone Scientific Inc. 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 Inc. or any other person that the objectives and plans of Milestone Scientific Inc. will be achieved. Milestone Scientific Inc. 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 Inc. and Milestone Medical Inc.) unless the context otherwise indicates.

Milestone Scientific has rights to the following trademarks: CompuDent®, CompuMed®, CompuFlo®, The Wand®, The Wand Plus®, The SafetyWand®, Dynamic Pressure Sensing Technology®, STA Single Tooth Anesthesia,TM(STA Instrument, instruments and handpieces. Milestone Scientific was incorporated in the State of Delaware

In July 2014, Milestone Scientific acquired all of the 750,000 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 received Milestone Scientific’s dental business and related dental assets including the exclusive license of Milestone Scientific’s, patents, trademarks, and technology for use in the dental marketplace. Wand Dental is consolidated into Milestone Scientific.

On June 1, 2015, Milestone Scientific’s listed its common stock on the NYSE MKT LLC (NYSE MKT) under the ticker symbol MLSS.

As of December 31, 2015, Milestone Scientific consolidated the financial statements of Milestone Medical Inc. (“Milestone Medical”) into its financial statements as a variable interest entity. Milestone Medical is a 49.98% owned subsidiary of Milestone Scientific, which develops, commercializes, manufactures and markets epidural and intra-articular injection medical instruments (see Note F to the Consolidated Financial Statements).

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 energy and 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. And, what’s more, it works better than a syringe, resulting in a more pleasant experience for the patient and practitioner.

Milestone Scientific subsequently expanded its product offerings with the introduction of the 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) Pre-market clearance for marketing and sale of the STA 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 Dynamic Pressure Sensing® capability provides visual and audible in-tissue pressure feedback, identifying tissue types to the healthcare provider. This pressure feedback extends the benefit of painlessness from anesthetics with known viscosities to a wide range of liquid drugs and other medicaments with varying viscosities and flow rates. Dynamic Pressure Sensing 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 U.S. Food and Drug Administration (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 new instrument, which also provides for use of a disposable handpiece, was trademarked the "STA Single Tooth Anesthesia Instrument"TM now more commonly known as The Wand[®] STA Instrument.

After receiving FDA 510(k) Pre-market Notification acceptance 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 143^d

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 U.S. and Canadian distribution and marketing rights for the STA Instrument to Henry Schein, Inc., 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 an Exclusive 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 the country's largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone Scientific a blanket purchase order for 12,000 STA instruments and related handpieces to be delivered over 36 months, thereby marking Milestone Scientific's initial penetration into China's emerging dental market. The agreement was terminated in September 2014 and a new distributor, Milestone China Ltd. became the distributor for the STA Instruments and handpieces in China. Milestone China is owned forty (36) percent by Milestone Scientific.

In early October 2012, the State Food and Drug Administration (SFDA) of the People's Republic of China approved Milestone Scientific's Single Tooth Anesthesia System (STA System). Unfortunately, the SFDA bifurcated approval of the STA Systems from The Wand® handpieces. CFDA, (previously the SFDA), approval of The Wand® handpieces was received in May 2014 and the distribution of these handpieces has begun in China

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, CS Market Research reports that "of China's 1.3 billion plus population, 50% of the adults and 70% of the children are estimated to have decayed tooth problems, and over 90% have periodontal disease." 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 new 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 will include participation in U.S. 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 U.S. and Canada. The exclusive distributor and marketing agreement was converted to a non-exclusive agreement on December 31, 2015. In addition, on January 1, 2016 Henry Schein was added as an additional non-exclusive distributor of the STA instruments and handpieces in the United States and Canada.

In May of 2014, Milestone Scientific completed a private placement, which raised gross proceeds in the total of \$10 million, for the sale of \$3 million of common stock (2 million shares at \$1.50 per share) and \$7 million on the sale of Series A Convertible Preferred Stock, convertible into common stock at \$2.545 per share on May 14, 2019, or \$1.50 per share unless certain conditions are not met, both subject to an anti-dilution adjustment.

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, Project Management. The increase in staffing is to support the growth of the company's initiative in our CompuFlo® software for anticipated new medical and dental instruments.

CompuFlo® Advanced Injection Technology – Core Technology

The CompuFlo® technology is patented and embedded in the STA Instrument that is being sold worldwide in the dental market. CompuFlo® technology has been tried and proven in human and animal studies, as well as by dentists in most parts of the world who are using the STA Instrument in their practices.

CompuFlo® is a revolutionary new technology for injections. CompuFlo® enables health care practitioners to monitor and precisely control “pressure,” “rate” and “volume” during all injections and can be used to inject all liquid medicaments as well as anesthetics. CompuFlo® can also be used to aspirate body fluids.

Negative side effects from the use of traditional hypodermic drug delivery injection instruments are well documented in dental and medical literature and include risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications. The pain and tissue damage are a direct result of uncontrolled flow rates and pressures that are created during the administration of drug solutions into human tissue. While several technologies have been capable of controlling flow rate, the ability to accurately and precisely control pressure has been unobtainable until the development of CompuFlo®.

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.

CompuFlo® pressure sensing technology provides an objective tool that 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, who identify the epidural space by relying on the subjective perception of loss of resistance to saline.

In the absence of curative procedures, arthritis patients are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious, because the doctor using a syringe failed to locate the intra-articular space or did not inject the appropriate volume of hyaluronic acid or other medicament into that space. The CompuFlo® technology has been successful in administering viscous 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.

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,

diseases of the auto immune system and Rheumatoid Arthritis. 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.

7

Milestone Medical Inc.

In March 2011, Milestone Scientific entered into a joint venture agreement with Beijing 3H (Heart-Help-Health) Scientific Technology Co., Ltd. (“Beijing 3H”) for the development, commercialization, manufacture and marketing of an epidural and intra-articular injection instruments. Milestone Scientific, with the consent of the investors, organized a domestic research and development joint venture corporation, now known as Milestone Medical (“Milestone Medical”). Milestone Scientific held a 50% interest in Milestone Medical, and collectively, certain shareholders of Beijing 3H and a group of individual investors, including a large shareholder in Milestone Scientific, who is also a principal of a supplier to Milestone Scientific, also held a 50% interest in Milestone Medical.

The joint venture agreement provided for Milestone Scientific’s contribution of an exclusive worldwide royalty-free license to use its patents. Shareholders of Beijing 3H, and a group of individual investors contributed \$1.5 million to Milestone Medical to design and develop two commercial instruments using Milestone’s CompuFlo® technology and disposables. Milestone Scientific has distribution responsibility in the U.S. and Canada. Milestone Medical has distribution responsibility for the rest of the world, except that Beijing 3H had rights to distribute products exclusively in the People’s Republic of China, Macao, Hong Kong and other regions of Asia. In September 2014, the shareholders of Beijing 3H sold their shares in Milestone Medical (shares individually owned by two shareholders of Beijing 3H to other founding investors). Along with selling their shares, the joint venture agreement and their distribution responsibilities for the medical instruments was terminated. Subsequently, in 2015 Milestone Medical entered into an agreement with Milestone China Ltd. (Hong Kong Company) (“Milestone China”), forty (40) percent owned by Milestone Scientific, to distribute both medical instruments in the People’s Republic of China, Macao, Hong Kong and other regions of Asia.

In the fourth quarter of 2013, Milestone Medical sold 2 million shares of its common stock for \$1.50 per share in a private placement transaction in Poland. As a result of the sale Milestone Medical received net proceeds of \$2,363,000. The effect of the sale reduced Milestone Scientific’s ownership from 50% to 45.5% post transaction.

In the fourth quarter of 2014, Milestone Scientific purchased an additional 995,000 shares of Milestone Medical from another shareholder for \$447,750 (\$0.45 per share), which increased its percentage of ownership to 49.98% of Milestone Medical.

During the fourth quarter of 2015, Milestone Medical has been consolidated as a subsidiary of Milestone Scientific as they were determined to be the primary beneficiary of the variable interest entity. (See Note F to the Consolidated Financial Statements)

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 Instrument™

The STA Single Tooth Anesthesia Instrument™ (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.

8

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® (also known as The Wand Plus® internationally) 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 20th 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®

The Wand® handpiece is used in conjunction with the STA, CompuDent® and CompuMed® instruments. It is an ergonomically designed and patented handpiece that enables all traditional and newer injections, such as AMSA, P-ASA and Modified-PDL, to be more comfortable and easier to deliver. Moreover, the pen-like grasp of The Wand® allows bi-directional rotation during injection, which prevents needle deflection that occurs with a traditional syringe. A straighter path results in a more accurate injection, meaning fewer missed mandibular blocks, and more rapid onset of anesthesia. Missed blocks are reported in the literature to occur 30% of the time. This raises both patient anxiety and difficulties for the dentists in managing their business. While awaiting profound anesthesia, the dentist loses time and money.

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 the 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:

	U.S. PATENT	NUMBER	DATE OF ISSUE
COMPUTER CONTROLLED DRUG DELIVERY SYSTEMS			
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
Microprocessor-controlled Fluid Dispensing Apparatus		6,159,161	12/12/2000
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
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 2015 and 2014 fiscal years, Milestone Scientific expensed \$100,856 and \$88,243, 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 intellectual property rights. Despite the precautions taken by Milestone Scientific to protect the products, unauthorized parties may attempt to reverse engineer, copy, or obtain and use products and information that Milestone Scientific regarded 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 the operating results and financial condition of the Company.

In the event that the products infringe upon patent or proprietary rights of others, Milestone Scientific may be required to modify processes or to obtain a license. 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 would have a material adverse

effect on Milestone Scientific.

Government Regulation

The FDA cleared the CompuDent® instrument and its disposable handpieces for marketing in the U.S. for dental applications in July 1996; the CompuMed® instrument for marketing in the U.S. for medical applications in May 2001; and The Safety Wand® for marketing in the U.S. for dental applications in September 2003. For us to commercialize the other products in the U.S., Milestone Scientific would have to submit additional 510(k) applications with 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 U.S. 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 U.S. 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 us. 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 U.S. 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®, The 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 Milestone Scientific.

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® STA Single Tooth Anesthesia InstrumentTM 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 Milestone Scientific

Employees

On December 31, 2015, Milestone Scientific had a total of 15 employees, consisting of three executive officers of Milestone Scientific and an executive officer of Wand Dental, a director of International and Professional Relations, a director of engineering, a director of marketing, a senior brand manager, a senior project manager, two customer service representatives, two accountants, a quality care person, a personal assistant and an administrative manager. Milestone Scientific also has a consultant who serves as a Director of Clinical Affairs and a consultant for business development.

Item 1A. Certain Risk Factors that may affect Growth and Profitability.

The following factors may affect the growth and profitability of Milestone Scientific and should be considered by any prospective purchaser or current holder of Milestone Scientific's 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, 2015 and 2014, revenues were approximately \$9.4 million and \$10.3 million, respectively. Milestone Scientific has a net loss of approximately \$5.4 million for year ended December 31, 2015 and a net loss of approximately \$1.7 million for year ended December 31, 2014. In addition, Milestone Scientific has had losses for each year since the commencement of operations with the exception of 2013. Milestone Scientific has an accumulated deficit of approximately \$78.6 million. At December 31, 2015, Milestone Scientific had cash and cash equivalents approximately \$4.2 million, and working capital of approximately \$8.2 million. The working capital in 2015 decreased by

approximately \$4.9 million from December 31, 2014. The change in working capital is primarily due to the use of cash for operations and the consolidation of Milestone Medical liabilities. As of December 31, 2015 Milestone Scientific believes that with the new Dental Distributor Agreement with Henry Schein Inc. (effective January 1, 2016), the world's largest supplier of medical, dental and veterinary supplies and devices, that dental revenues are projected to improve in the upcoming 12 months. To further reduce our expenditures, Milestone Medical expenses related to USA 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 revenue through the new distribution agreement, management believes that Milestone Scientific will have sufficient cash reserves to meet all of its anticipated obligations over the next twelve months.

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 current negotiations 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 43,000 instruments of the STA Instrument and its predecessors have been sold worldwide since 1998. Since being introduced to market in February 2007, more than 15,000 of the STA Instrument have been sold. Milestone Scientific cannot assure that its current or proposed products will be accepted by 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. In November 2012, Milestone Scientific signed on an exclusive distributor and marketing company to sell and distribute the STA instruments and handpieces in the USA and Canada. This exclusive agreement was modified to a non-exclusive agreement in December 31, 2015 and will expire on March 31, 2016. Beginning January 1, 2016, Henry Schein, the leading distributor of dental products in the USA and Canada, will have a non-exclusive distribution agreement with Milestone Scientific. To be successful, Milestone Scientific will need to engage additional distributors, 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 or engage suitable distributors, or that the sales force or distributors will be able to successfully market and sell the products.

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® instruments and with one of the principal manufacturers of the handpieces, for those items, respectively. Pursuant to the informal arrangements, they manufacture these products under specific purchase orders without minimum purchase commitment. However, in November 2009, Milestone Scientific issued a purchase order to Tricor System Inc. to manufacture 12,000 STA Instruments, over the following three years. 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® 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 an adverse effect.

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 Milestone Scientific.

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

Milestone Scientific depends on the personal efforts and abilities of the Chief Executive Officer and the Director of Clinical Affairs. Milestone Scientific maintains a key man life insurance policy in the amount of \$1,000,000 on the life of the Chief Executive Officer. However, the loss of his services or 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 \$1.17. The market price of common shares 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 shareholders.

Milestone Scientific's principal shareholders, 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 shareholder 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 Milestone Scientific's 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 Milestone Scientific's 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, 2015, Milestone Scientific had outstanding options to purchase 1,427,769 shares of common stock at prices ranging from \$0.36 to \$3.89 per share with a weighted average exercise price of \$1.56. 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 shares has been volatile and may continue to fluctuate significantly because of various factors, some 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, 2015. 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 2015 and 2014, 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 \$10,000 and \$5,000 in 2015 and 2014, respectively and the cost is expected to continue in 2016.

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Property

The headquarters for Milestone Scientific is located at 220 South Orange Avenue, Livingston, New Jersey which consists of approximately 7,625 square feet of office space. Milestone Scientific leases its headquarters at a monthly cost of \$12,522 which it believes to be competitive and the lease term expires on January 30, 2020. The leased office space is in good condition. 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, Milestone Scientific's 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.

2015	HIGH	LOW
First Quarter	\$ 3.00	\$ 2.35
Second Quarter	\$ 4.00	\$ 2.42
Third Quarter	\$ 3.52	\$ 2.55
Fourth Quarter	\$ 3.20	\$ 2.16
2014		
First Quarter	\$ 1.84	\$ 1.17
Second Quarter	\$ 2.03	\$ 1.41
Third Quarter	\$ 2.08	\$ 1.80
Fourth Quarter	\$ 2.45	\$ 1.85

Holders

As of March 25, 2016, Milestone Scientific had approximately 130 shareholders of record of Milestone Scientific's common stock. Milestone Scientific believes that there are approximately 1,800 beneficial owners.

Dividends

The holders of Milestone Scientific's 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 financial statements for 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 "Certain Risk Factors That May Affect Growth and Profitability" on pages 12-14 of this Form 10-K.

OVERVIEW

- In 2015, Milestone Scientific continued to focus on advancing efforts to achieve our two primary objectives; those being;
- Enhancing our global reach by partnering with distribution companies in the medical sector for our epidural and intra-articular instruments.; 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, including the STA Single Tooth Anesthesia Instrument™ (STA Instrument).

STA Instrument Growth

Since its market introduction in early 2007, the STA Instrument and prior computerized controlled local anesthesia delivery products have been used to deliver over 65 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

In November 2012, Milestone Scientific entered an exclusive distribution and marketing agreement with a well-known U.S. domestic manufacturer and distributor, for the sale and distribution of the STA instruments and handpieces in United States and Canada. The exclusive distributor and marketing agreement was converted to a non-exclusive agreement as December 31, 2015. Henry Schein a global leader of distribution in the dental supplies was added as a non-exclusive distributor of the STA instruments and handpieces in the United State and Canada in January 2016.

In July 2014, Milestone Scientific entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare. Pursuant to the strategic partnership, the distributor will hold, for a period of three years beginning with the FDA approval, the exclusive rights to market, resell, label and distribute Milestone Scientific's CompuFlo® injection technology for use in epidural applications for childbirth and other pain management needs in the U.S. hospital sector. This relationship was terminated in 2015 due to delay in receiving 510k approval from the USA, FDA.

In August 2014, Milestone Scientific entered an exclusive distributor agreement (beginning October 1, 2014), with Henry Schein, for the sale and distribution of the CompuDent® handpieces in the United States and Canada.

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 early October 2012, the State Food and Drug Administration (SFDA) of the People's Republic of China approved Milestone Scientific's Single Tooth Anesthesia System® (STA System). In May 2014, the CFDA, (previously the SFDA), granted registration approval of the STA handpieces in China.

Shortly before the end of the second quarter 2009, we announced that we were refining our international marketing strategy to gain greater access to and penetration of the international dental markets for the STA Instrument, CompuDent® and related disposable handpieces. The new sales strategy provides for increasing hands-on oversight and support of our existing international distribution network, while also attracting new distributors throughout Europe, Asia and South America. To assist in this endeavor, in the spring of 2010, Milestone Scientific added an International Sales Director to focus on the growth of our products outside the USA and Canada.

In September 2014, Milestone Medical received CE clearance to distribute their 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 Polish Medical distributor for the distribution of the epidural instrument starting in April 2015.

In late June 2014, Milestone Scientific agreed to invest \$1 million in Milestone China by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone China will purchase handpieces for cash as required. Milestone Scientific believes that Milestone China has made a positive impact on the dental and future medical business in China and other parts of Asia. Milestone China began in July 2014 and the first shipment of 300 STA instruments occurred in July 2014. Milestone Scientific records this investment under the equity method of accounting. The remaining 472 STA instruments were delivered by Milestone Scientific to Milestone China in January 2015.

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,			
	2015		2014	
DOMESTIC				
Instruments	\$623,195	17.8 %	\$1,037,956	22.3 %
Handpieces	2,799,785	79.8 %	3,543,509	76.1 %
Other	83,362	2.4 %	74,182	1.6 %
Total Domestic	\$3,506,342	100.0%	\$4,655,647	100.0%
INTERNATIONAL				
Instruments	\$2,062,556	34.5 %	\$1,531,146	27.0 %
Handpieces	3,836,002	64.1 %	4,083,631	71.9 %
Other	86,669	1.4 %	62,666	1.1 %
Total International	\$5,985,227	100.0%	\$5,677,443	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	\$3,506,342	36.9 %	\$4,655,647	45.1 %
International	\$5,985,227	63.1 %	\$5,677,443	54.9 %
Total Product Sales	\$9,491,569	100.0%	\$10,333,090	100.0%

Milestone Scientific earned gross profit of 68% and 65% in the years ended December 31, 2015 and 2014, 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 2016, these amounts will vary based on the operating results for each quarter.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for 2013. At December 31, 2015, Milestone Scientific has sufficient cash reserves to meet all of its anticipated obligations for at least the next twelve months, including a limited amount of financing for the operation of Milestone Medical until additional financing is consummated in 2016. Milestone Scientific is actively pursuing the continued generation of positive cash flows from operating activities through increase in revenue, assessment of current contracts and current negotiations.

In 2016, Milestone Scientific plans to further 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 U.S. 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, and support and broaden our global distribution network.

Current Product Platform

See Item 1. Description of Business

Technology Rights

The technology underlying the SafetyWand and CompuFlo® technology 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, for 43,424 shares of restricted common stock and \$145,000 in cash, paid on April 1, 2005. In addition, the Director of Clinical Affairs will receive additional deferred contingent payments of 2.5% of the total sales of products using some of these technologies, and 5% of the total sales of products using some of the other technologies. If products produced by third parties use any of these technologies, under a license from Milestone Scientific, then he will also receive the corresponding percentage of the consideration received by us for such sale or license.

Milestone Scientific provided the exclusive worldwide royalty-free license to Milestone Medical for the use of Milestone Scientific's patents for development of two medical instruments in 2011. In return for the license, Milestone Scientific originally received a 50% interest in Milestone Medical. As of December 31, 2015, Milestone Scientific owns 49.98% of Milestone Medical (see Note F to the Consolidated Financial Statements).

Summary of Critical Accounting Policies and Significant Judgments and Estimates

Milestone Scientific's discussion and analysis of the financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. 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 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 Company's Ability to Continue as a Going Concern

The Company has made various estimates in assessing its ability to continue as a going concern at December 31, 2015. These estimates include a significant increase in the revenues generated by Wand Dental as a result of the new distribution agreement with Henry Schein. Management is also forecasting an increase in the revenues generated by Milestone China. Due to the nature of the distribution relationships with both Henry Schein and Milestone China, the Company expects a decline in their profit margins due to favorable pricing negotiated between the parties, but projects

favorability from reducing their selling, general and administrative costs for one-time expenses incurred during 2015.

Accounts Receivable

The realization of accounts receivable will have a significant impact on Milestone Scientific. The criteria used by management to evaluate the adequacy of the allowance for doubtful accounts included, among others, credit worthiness of

20

the customer, current trends, prior payment performance, the age of the receivables and Milestone Scientific's overall historical experience.

Inventories

Inventory costing, obsolescence and physical control are significant to the on-going operation of the business. 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.

Impairment of Long-Lived Assets

The long lived assets of Milestone Scientific, principally patents and trademarks are the base features of the business. Milestone Scientific reviews long-lived assets for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recoverable. The carrying value of the asset is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets.

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 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.

Results of Operations

The following table sets forth for the consolidated results of operations for the year ended December 31, 2015 compared to 2014 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	Years Ended December 31,			
	2015		2014	
Total revenue	\$9,491,569	100 %	\$10,333,090	100 %
Cost of products sold	3,048,260	32 %	3,630,765	35 %
Gross Profit	6,443,309	68 %	6,702,325	65 %
Selling, general and administrative				
expenses	9,399,201	99 %	7,404,258	72 %
Research and development expenses	100,856	1 %	88,243	1 %
Operating expenses	9,500,057	100 %	7,492,501	73 %
Loss from operations	(3,056,748)	-32 %	(790,176)	-8 %
Other expenses	(5,347)	0 %	-	0 %
Interest income	3,838	0 %	2,389	0 %
Loss before Provision for Income Tax	(3,058,257)	-32 %	(787,787)	-8 %
Provision for Income Tax	(36,157)	0 %	(9,509)	0 %
Loss before equity in net earnings of equity				
investments	(3,094,414)	-33 %	(797,296)	-8 %
Loss on earnings from Milestone Medical Inc.	(2,019,211)	-21 %	(891,500)	-9 %
Loss on earnings from Education Joint Venture	(7,846)	0 %	(17,890)	0 %
Loss on earnings from China Joint Venture	(418,432)	-4 %	(810)	0 %
Net loss in equity investments	(2,445,489)	-26 %	(910,200)	-9 %
Net loss	(5,539,903)	-58 %	(1,707,496)	-17 %
Less: Net loss attributable to the		1 %		0 %
noncontrolling interests	72,381		5,472	
Net loss attributable to Milestone				
Scientific Inc.	\$ (5,467,522)	-58 %	\$ (1,702,024)	-16 %

Year ended December 31, 2015 compared to year ended December 31, 2014

The following paragraphs will describe the results of 2015 compared to 2014.

Total revenues for the twelve months ended December 31, 2015 and 2014 were approximately \$9.4 and \$10.3 million, respectively. The total dental revenue decreased by \$911,303 or 8.8% which was primarily related to the decrease in handpiece sales in the United States. Domestic sales decreased by approximately \$1.1 million in 2015. The major reduction in handpieces was mainly in the sales of our legacy handpieces. This decrease is due to the special marketing incentives by our US distributors to upgrade dental users of the CompuDent® instruments to the new STA instruments. However, this strategy was not successful. There was a significant decrease in STA handpieces in 2015, primarily because customers purchased larger quantities in 2014 to avoid a price increase in 2015. International sales increased by approximately \$238,002. The increase in international sales was due to the increase in sales in China. In

the USA, Milestone Scientific has modified its exclusive distributor and marketing agreement with Aseptico Inc. This exclusive agreement was changed to a non-exclusive agreement in December 31, 2015. The term of this non-exclusive agreement expires on March 31, 2016. Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, the leading distributor of dental products in the USA and Canada.

The gross margin in 2015 increased to 68% versus 65% in 2014. This increase in gross profit margin is due to price increase in instruments and in handpiece sales in 2015. Although the gross margin percentage increased 3%, gross profit dollars in 2015 decreased to approximately \$6.4 million from approximately \$6.7 million in 2014 or, by approximately \$329,000 year over year.

Selling, general and administrative expenses in December 31, 2015 were approximately \$9.4 million compared to \$7.4 million in 2014. The increase of approximately \$2 million is predominantly due to Milestone Scientific's addition of

a President, a full time CEO for Wand Dental Inc., a Senior Business Brand Manager, and a Senior Manager of Project Management. This staffing was provided to support the growth of Milestone Scientific's initiative in the CompuFlo® software for anticipated new medical and dental instruments. This increase amounted to \$420,000 in 2015 over 2014. Professional fees increased by approximately \$1.5 million, primarily due to the increase in legal fees, the cost of consulting services for international distributors for the STA instruments (Wand Dental), costs related to achieving a Polish Government Grant (no grants have been obtained to date) and the cost of investor relations as we prepare to implement our strategic marketing growth plan worldwide.

Research and development expenses for the years ended December 31, 2015 and 2014 were \$100,856 and \$88,243, respectively.

The loss from operations for the years ended December 31, 2015 and 2014 was \$3,056,748 and \$790,176, respectively. The additional loss of \$2.2 million is primarily the result of a decrease in gross profit margin of approximately \$300,000 and an increase in selling, general and administrative expenses of \$2 million.

There was a loss on the Education Joint Venture of \$7,846 and \$17,890 for the years ended December 31, 2015 and 2014, respectively. There was a loss on the China Joint Venture of \$348,651 and \$810 for the years ended December 31, 2015 and 2014, respectively.

For the reasons explained above, the net loss for the year ended December 31, 2015 was \$5,467,522 as compared to the net loss for the year ended December 31, 2014 of \$1,702,024.

Liquidity and Capital Resources

Looking at the current balance sheet for Milestone Scientific and subsidiaries, current assets decreased by approximately \$3.8 million. The major reduction in current assets is the cash of \$6.2 million, inventories increased \$1.8 million and advances on contracts increased by approximately \$500,000. The cash reduction is primarily due to the loss from operations and the financial support of Milestone Medical for the year ended December 31, 2015.

Current liabilities increased by approximately \$1.2 million, from approximately \$2.4 million to approximately \$3.6 million. The increase is due to an increase in accounts payable and accrued expenses, as result of consolidating Milestone Medical at December 31, 2015.

Working Capital decreased by \$5 million, primarily due to the loss from operations for the year ended December 31, 2015. However, Milestone Scientific believes that its cash on hand and revenues from the dental business will be sufficient to operate the ongoing business for at least the next 12 months. As noted above, the funding for Milestone Medical will be limited during 2016.

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. Cash flows from operating activities for the year ended December 31, 2015 and 2014 were a negative \$2,946,339 and positive \$376,943, respectively.

In May of 2014, Milestone Scientific completed a private placement, which raised gross proceeds in the total of \$10 million, for the sale of \$3 million of common stock (2 million shares at \$1.50 per share) and \$7 million in Series A Convertible Preferred Stock (the "Series A Shares") (7,000 shares at \$1,000 per share). The Series A Shares are convertible into common stock at \$2.545 per share, or at \$1.50 per share on or after May 14, 2019 if certain conditions are not met, subject to various anti-dilution adjustments. The net proceeds of \$9.4 million had the effect of increasing Milestone Scientific's cash provided from financing activities and provided a substantial financial base for Milestone

Scientific in 2014.

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. The consolidation of Milestone Medical

23

in December 2015 and the lack of capital raising activities by Milestone Medical in 2015 has created a unique situation for Milestone Scientific advancing into 2016. However as noted previously, Milestone Scientific is not obligated to continue its financial support of Milestone Medical, but the timeline for Milestone Medical 510K FDA clearance is expected in 2016 (mid-year). Milestone Scientific expects that clearance to commercialize the epidural and intra articular instruments in 2016 will significantly improve the capital raising opportunities and financial picture. As of December 31, 2015, Milestone Scientific believes that with the new distribution agreement with Henry Schein Inc. (effective January 1, 2016), the world's largest supplier of medical, dental and veterinary supplies and devices, that dental revenues are projected to improve in the upcoming 12 months. To further reduce Milestone Scientific's expenditures, Milestone Medical expenses related to USA FDA clearance for the epidural and intra-articular instruments can be controlled as required to meet Milestone Scientific's budget. By limiting the FDA related expenses and increasing the dental instrument revenue through the new distribution agreement and performing a detailed cash flow projection of the consolidated Company and its Subsidiaries, management believes that Milestone Scientific will have sufficient cash reserves to meet all of its anticipated obligations over the next twelve months.

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, 2015, expected on the liquidity and cash flows in future periods, is as follows:

	Payments Due by Period			
	Total	1 Year	1-3 Years	3-5 Years
Operating lease obligations	\$837,308	\$160,056	\$510,323	\$326,986
Purchase obligations (1)	\$604,984	\$604,984	\$-	\$-
Total	\$1,442,292	\$765,040	\$510,323	\$326,986

(1)Purchase obligations include agreements for the purchase of instruments and handpieces. The agreements are referred to as purchase orders.

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.

24

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, 2015 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, 2015. 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, 2015.

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, 2015 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.

25

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 shareholders 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 29, 2016 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leslie Bernhard (1) (2) (3)	71	Chairman of the Board and Director	2003
Leonard Osser	68	Chief Executive Officer and Director	1991
Joseph D'Agostino	64	Chief Financial Officer and Chief Operating Officer	
Steven F. Robins	50	President	2015
Leonard Schiller (1) (2) (3)	75	Director	1997
Gian Domenico Trombetta	55	Director	2014
Edward J. Zelnick, M.D. (1) (2) (3)	70	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 29, 2016:

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	71	Director of Professional Relations
Mark Hochman, D.D.S.	57	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 September 2009. In addition, Ms. Bernhard has also been serving as an Independent Director (as defined below) of Milestone Scientific since May 2003. She co-founded AdStar, Inc. and since 1986 has served as its President, Chief Executive Officer and Executive Director. AdStar is an application service provider for the newspaper classified advertising industry. Ms. Bernhard serves on the Board of Directors of Universal Power Group, Inc. of Dallas, TX, a manufacturer and distributor of batteries and battery related products. 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

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.

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, Consumer Electronics Industry Association and Homeland Security Industry Association. He is a graduate of William Paterson University where he earned a Bachelor of Arts degree in Science.

Steven F. Robins, President

Steven Robins has been the President of Milestone Scientific and Milestone Medical since January 1, 2015. Mr. Robins has an extensive background in the healthcare industry and has been working with Milestone Scientific on a consulting basis since July 2014. Mr. Robins has held both general management and marketing positions at Bausch & Lomb, Johnson & Johnson and Pfizer. Prior to July 2014, Mr. Robins was employed at Bausch & Lomb Vision Care, in the positions of President North America from May 2009 to August 2011 and promoted to Global Chief Marketing Officer from September 2011 to August 2014. Prior to Bausch & Lomb, Mr. Robins was a Vice President and General Manager of Johnson & Johnson's Consumer Healthcare Business unit in Canada from November 2006 to April 2009. From April 1994 to October 2006, he was at Pfizer Consumer Healthcare, where he held a series of roles including Group Marketing Director Upper Respiratory. Mr. Robins holds a Bachelor of Arts degree in History from Bates College, Lewiston, Maine.

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 holds a faculty appointment as a 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. He has also lectured both nationally and internationally at over 35 dental schools and in over 22 countries on Computer-Controlled Local Anesthesia Delivery. Dr. Casagrande 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

and has served on the faculty of the University of Southern California, School of Dentistry

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, Klein & McElroy, and P.C. since 1977. He has also been President of The Dearborn Group, a residential property management and real estate acquisition company since 1980. Mr. Schiller became a Director of the Gravitass Cayman Corporation in February 2010. Gravitass Cayman Corporation is an Investment Fund.

27

Mr. Schiller's professional experience and background as an attorney and a partner of a law firm and with us, as one of our directors since 1997, have given him the expertise needed to serve as one of our directors.

Gian Domenico Trombetta, Director

Gian Domenico Trombetta became 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 private equity and special situation investment firm and has been its President and Chief Executive Officer since 1996. He serves as the Chief Executive Officer or a board member of numerous private commercial companies... 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-Fontainebleau-France.

Edward J. Zelnick, M.D., Director

Edward J. Zelnick, M.D. 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 assembles test subjects and clinicians for clinical research organizations. 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 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. Dr. Zelnick became a director in February 2015.

Milestone Scientific's Board of Directors has established a compensation, audit and nominating and corporate governance committees. 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 and corporate governance committee has dual responsibilities. The nominating and corporate governance 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, 2015, except that our CEO did not timely file a Form 4, our CFO did not timely file one Form 4 and our President did not timely

file his Form 3.

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

28

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, 2015 and 2014 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 2015 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	Other Compensation	Option Awards (2)	Total
Leonard A. Osser						
Chief Executive Officer	2015	\$ 300,000	\$ 300,000	(1) \$ 236,267	(2) \$ 400,000	\$ 1,236,267
	2014	\$ 300,000	\$ 400,000	(1) \$ 234,310	(2) \$ 200,000	\$ 1,134,310
Gian Domenico Trombetta						
Chief Executive Officer - Wand Dental Inc	2015	\$ 120,000	\$ 160,000	(3) \$ -	(2) \$ 320,000	\$ 600,000
	2014	\$ 120,000	\$ 80,000	(3) \$ -	(2) \$ -	\$ 200,000
Joseph D'Agostino						
Chief Financial Officer	2015	\$ 171,600	\$ 114,500	(3) \$ 44,983	(2) \$ 229,000	\$ 560,083
	2014	\$ 171,600	\$ 206,750	(3) \$ 33,460	(2) \$ 413,500	\$ 825,310

1. Payment of \$300,000 and 400,000 of bonuses for the years ended December 31, 2015 and 2014, respectively, of which \$200,000, in 2015 and \$100,000 in 2014, was deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. Fifty percent of the non-cash portion of Mr. Osser's 2015 bonus was approved by the Compensation Committee of the Board in each of third quarter of 2015 and first quarter of 2016, respectively. Other compensation represents payments made for business use of corporate apartment in China, health insurance coverage, pension payment, and car allowance.
2. The amounts in this column reflect the fair value of the options at 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, 2015 and 2014, which is located on pages F-7 through F-17 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, 2015."
3. Payment of the bonuses have been 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. The 2015 bonus was approved by the Board in 2016. Other compensation represents payments made for health insurance coverage

and car allowance.

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 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 of the Board of Directors. 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, \$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 and 706,716 shares of common stock are to be paid out at the end of the contract in settlement of \$630,985 at December 31, 2014 of accrued deferred compensation and, accordingly, such shares have been classified in stockholders' equity with the common shares classified as to be issued.

This 2009 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.

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 the Company. 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 chief executive officer compensation consists of a base salary component and periodic stock option grants. It is the Compensation Committee's intention to set totals for the chief executive officer 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 chief executive officer 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 chief executive officer'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, 2015

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, 2015.

Name	Options Awards		Stock Awards			
	Number of Securities	Number of Securities	Option Exercise Price	Option Expiration	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	102,880	82,305	\$ 2.38	11/20/2019	776,862	\$ 1,825,626
	194,576	53,872	\$ 1.65	12/31/2018	-	-
	133,334	-	\$ 0.75	1/9/2017	-	-
	73,333	-	\$ 1.49	11/1/2019	-	-
	19,102	38,205	\$ 3.89	6/23/2020	-	-
Total	523,225	174,382				
Joseph D'Agostino	83,333	66,667	\$ 2.09	11/11/2019	99,631	\$ 229,151
	27,367	21,894	\$ 2.03	11/20/2019	-	-
	51,852	14,814	\$ 1.50	12/31/2018	-	-
	78,126	-	\$ 1.28	12/31/2017	-	-
	277,778	-	\$ 0.36	12/31/2016	-	-
Total	518,456	103,375				

(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 employment agreement.

(3) Based on the closing price per share of \$2.35 as reported on the NYSEMKT on December 31, 2015.

Compensation of Directors

Director Compensation

NAME	Fees Earned	Total (\$)
------	-------------	------------

	or Paid in Cash (\$)	
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 29, 2016, 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	3,463,330	(3) 13.54 %
Joseph D'Agostino	1,495,511	(4) 5.85 %
Leonard Schiller	172,033	*
Gian Domenico Trombetta	4,861,881	(5) 19.01 %
Steven Robins	5,147	-
All directors & executive officers as		
group (8 persons)	9,997,162	(6) 39.09 %
K. Tucker Andersen	3,125,744	12.22 %
Tom Cheng	1,150,099	4.50 %
Robert Gintel	1,403,500	5.49 %
* Less than 1%		

- The addresses of the persons named in this table are as follows: Leonard Osser, Joseph D'Agostino, Steven Robins, Gian Domenico Trombetta, and Edward Zelnick 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; Leslie Bernhard, c/o AdStar, Inc., 4553 Glencoe Avenue, Suite 325, Marina del Rey, California 90292; 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 Robert Gintel, 5 Bay Ridge Road Key Largo FL 33037
- A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 29, 2016, 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 the filing of this report 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. All percentages are determined based on the number of all shares, including those underlying options exercisable and conversion of \$7 million of preferred stock within 60 days from the filing of this report held by the named individual, divided by 21,687,164 outstanding shares on March 29, 2016, plus those shares underlying options exercisable within 60 days from the filing of this report held by the named individual or the group.
- Includes 2,110,373 shares held by Mr. Osser or his family, 776,862 shares to be issued at the termination of his employment agreement, and 576,095 shares subject to common stock options as follows 73,333 at \$1.49, 133,334 at

\$0.75, 211,640 at \$1.65 and 102,880 at \$2.38, 19,102 at \$3.49, and 35,806 at \$2.65.

4. Includes 766,339 shares held by Mr. D'Agostino, 166,201 shares to be issued at the termination of his employment, and 562,971 shares subject to common stock options as follows: 277,778 shares at \$0.36; 78,126 shares at \$1.28; and 51,987 shares at \$1.50; 83,333 shares at \$2.09; 27,367 at \$2.03, and 44,380 at \$1.72.
5. Includes 66,390 shares to be issued at the termination of his employment, 44,260 shares subject to common stock options at \$2.65 per share, and 4,750,491 shares held directly by BP4 S.r.l. of which 2,750,491 shares are issuable upon the conversion of \$7 million of preferred stock at \$2.545 per share. Innovest S.p.A. is the controlling shareholder of BP4 S.r.l. and Mr. Trombetta is a shareholder and director of each of BP4 S.r.l. and Innovest S.p.A., and may be deemed to have voting and investment power over the securities held by BP4 S.r.l. Mr. Trombetta disclaims beneficial ownership of all securities held by BP4 S.r.l.
6. Includes an aggregate of 1,183,326 shares of common stock underlying outstanding options and 2,750,491 shares issuable upon the conversion of \$7 million of preferred stock at \$2.545 per share.

32

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes, as of December 31, 2015, the (i) options granted under the Milestone Scientific 2004 Stock Option Plan and (ii) options granted under the Milestone Scientific 2011 Stock Option 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.

	Number of Securities to be issued upon exercise of outstanding options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance under equity compensation plan
Equity compensation plan approved by stockholders			
Grants under our 2004			
Stock Option Plan (1)	73,333	\$ 1.49	86,042
Grants under our 2011			
Stock Option Plan (2)	1,354,436	\$ 1.57	582,874
Total	1,427,769		668,916

- (1) The 2004 Stock Option 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 Stock Option Plan became 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, 2015, 216,666 shares were exercised.
- (2) The 2011 Stock Option Plan provides for awards of options to purchase up to a maximum 2,000,000 shares of Milestone Scientific's common stock and expires in June 2021. Options may be granted to employees, 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 grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. No options were exercised in 2015.

Stock Plan

In December 2007, the Board of Directors authorized Milestone Scientific to issue up to \$1 million of its common stock to vendors or employees, and to grant them piggy back registration rights in the usual form, at a value of not less than 90% of the market value on the date of the agreement for the vendor or employee to accept said shares. Such future shares are not included in the above noted shares reserved for future issuance. At December 31, 2015 and 2014 there were \$11,316, respectively, available to be issued under this plan.

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

In 2013, Milestone Scientific entered a three year consulting agreement with K. Tucker Anderson to provide business and strategic services to the CEO of Milestone Scientific. The fee for these services are \$100,000 annually or shares of common stock valued at \$1.40 a share.

Tom Cheng, a beneficial owner of over 5% of Milestone Scientific's common stock, is also a shareholder of a major supplier of handpieces to Milestone Scientific. Milestone Scientific purchased \$2,698,522 and \$2,698,042 from this supplier for the years ended December 31, 2015 and 2014, respectively. In addition, Mr. Cheng is also an investor in Milestone Medical.

In the first quarter of 2013, the CEO of Milestone Scientific loaned Milestone Scientific \$50,000 for use in capitalizing a fifty percent equity portion in the joint venture with Milestone Education LLC. This balance is included in the accrued expenses on the Milestone Scientific balance sheets as of December 31, 2015 and 2014. The loan bore no interest and was repaid in 2014.

Director Independence

The Board has determined that Leonard M. Schiller, Leslie Bernhard, and Edward J. Zelnick (the “Independent Directors”) are independent as that term is defined in the listing standards of the NYSE MKT. As disclosed above, Leslie Bernhard, Edward Zelnick and Leonard M. Schiller members of the Audit Committee and are independent for such purposes. Leonard M. Schiller, Edward Zelnick 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, 2015, 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.

Item 14. Principal Accounting Fees and Services

Audit Fees

Milestone Scientific incurred audit and financial statement review fees totaling \$277,000 and \$127,450, respectively from Baker Tilly Virchow Krause, LLP, its principal accountant for 2015 and 2014. These fees include fees for professional services rendered for the audit of our annual financial statements and the review of financial statements included in our report on Form 10-Qs or services that are normally provided in connection with statutory and regulatory filings.

Audit Related Fees

There were no audit related fees to the principal accountant Baker Tilly Virchow Krause, LLP in 2015 and 2014.

Tax Fees

There were no fees for services related to tax compliance, tax advice and tax planning billed by the principal accountant in 2015 and 2014.

All Other Fees

There were no other fees billed during 2015 and 2014 by Milestone Scientific’s principal accountants.

Audit Committee Administration of the Engagement

The engagement with Baker Tilly Virchow Krause, LLP, the principal accountants, was approved in advance by the Board of Directors and the Audit Committee. No non-audit or non-audit related services were approved by the Audit Committee in 2015.

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

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

1. Financial Statements. The following consolidated financial statements and the reports of Milestone Scientific's independent auditor thereon, are filed herewith.

· Report of Independent Registered Public Accounting Firm

· Consolidated Balance Sheets at December 31, 2015 and 2014

· Consolidated Statements of Operations for the years ended December 31, 2015 and 2014

· Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014

· Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014

· Notes to Consolidated Financial Statements

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 (14)
3.2	Form of Certificate of Designation filed on May 7, 2014 (15)
3.3	Certificate of Correction to the Certificate of Designation filed on May 12, 2014*
3.4	By-laws of Milestone (1)
4.1	Specimen stock certificate (2)
4.2	Form of warrant agreement, including form of warrant (6)
10.1	Lease dated November 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (3)
10.2	Agreement with Mark Hochman, dated January 1, 2005 (5)
10.3	Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (5)
10.4	Employment Agreement with Leonard Osser, dated September 1, 2009 (7)
10.5	Amendment to the loan agreement of \$1.3 million from K. Tucker Andersen, dated April 18, 2008 (8)
10.6	2004 Stock Option Plan (9)
10.7	2011 Stock Option Plan (10)
10.8	Amendment to the Employment Agreement with Leonard Osser, dated March 6, 2013 (11)
10.9	Master Supply and Distribution Agreement, dated July 3, 2013, between Milestone Scientific Inc and Tri-anim Health Services, Inc (12)
10.10	Amendment to the Employment Agreement with Leonard Osser, effective March 17, 2014 (13)
10.11	Agreement with Mark Hochman, dated July 2015*
21.1	List of Subsidiaries*
23.1	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.

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-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) Intentionally omitted...
- (5) Incorporated by reference to Milestone Scientific's Form 10-KSB for the year ended December 31, 2004.
- (6) Incorporated by reference to Milestone Scientific's Registration Statement on Form S-2 No. 333-110367, Amendment No. 5.
- (7) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2009.
- (8) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2010.
- (9) Filed as Appendix C to Milestone Scientific's Proxy Statement filed with the SEC on June 28, 2004 and incorporated herein by reference.
- (10) Filed as Appendix A to Milestone Scientific's Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.

36

- (11) Incorporated by reference to Milestone Scientific's 10-K for the year ended December 31, 2014.
- (12) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on July 9, 2014.
- (13) Incorporated by reference to Milestone Scientific's Form 10-Q filed with the SEC on May 13, 2014.
- (14) Incorporated by reference to Milestone Scientific's Form 10-K for the year ended December 31, 2015.
- (15) Incorporated by reference to Milestone Scientific's Form 8-K filed with the SEC on April 18, 2014.

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: April 6, 2016

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	April 6, 2016	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Joseph D'Agostino Joseph D'Agostino	April 6, 2016	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)
/s/ Leonard Schiller Leonard Schiller	April 6, 2016	Director
/s/ Leslie Bernhard Leslie Bernhard	April 6, 2016	Chairman and Director
/s/ Gian Domenico Trombetta Gian Domenico Trombetta	April 6, 2016	Director
/s/ Edward J. Zelnick, M.D. Edward J. Zelnick, M.D.	April 6, 2016	Director

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	F- 2
<u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	F- 3
<u>Consolidated Statements of Operations for the years ended December 31, 2015 and 2014</u>	F- 4
<u>Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014</u>	F- 5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014</u>	F- 6
<u>Notes to Consolidated Financial Statements</u>	F- 7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders, Audit Committee and Board of Directors

Milestone Scientific Inc. Livingston, New Jersey

We have audited the accompanying consolidated balance sheets of Milestone Scientific Inc. (the “Company”) as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity and cash flows for the years 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 audits.

We conducted our audits 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 audits 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 audits 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 2014 and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Baker Tilly Virchow Krause, LLP

New York, New York

April 6, 2016

F-2

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2015 and 2014

	December 31, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	\$4,194,384	\$10,367,993
Accounts receivable, net of allowance for doubtful accounts of \$5,000 as of December 31, 2015 and December 31, 2014	1,793,801	1,541,478
Other receivable	58,140	-
Inventories	4,258,094	2,497,099
Advances on contracts	1,215,128	721,197
Prepaid expenses and other current assets	304,604	454,566
Total current assets	11,824,151	15,582,333
Investment in Milestone Medical Inc	-	888,720
Investment in Milestone Education LLC	16,346	24,192
Investment in Milestone China	-	348,651
Furniture, fixtures & equipment net of accumulated depreciation of \$566,477 as of December 31, 2015 and \$416,210 as of December 31, 2014	235,935	88,818
Patents, net of accumulated amortization of \$646,388 as of December 31, 2015 and \$576,960 as of December 31, 2014	715,540	530,029
Other assets	17,355	14,685
Total assets	\$12,809,327	\$17,477,428
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$2,088,268	\$1,453,908
Accrued expenses and other payables	1,555,567	981,168
Total current liabilities	3,643,835	2,435,076
Commitments and Contingencies		
Stockholders' Equity		
Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, 7,000 shares issued and outstanding, respectively		
	7	7
Common stock, par value \$.001; authorized 50,000,000 shares; 21,720,497 shares issued, 963,451 shares to be issued and 21,687,164 shares outstanding as of December 31, 2015; 21,404,494 shares issued, 974,953 shares to be issued and 21,371,161 shares outstanding as of December 31, 2014		
	22,685	22,380

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-K

Additional paid-in capital	78,632,383	77,504,415
Accumulated deficit	(67,434,984)	(61,967,462)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	10,308,575	14,647,824
Noncontrolling interest	(1,143,083)	394,528
Total Equity	9,165,492	15,042,352
Total liabilities and stockholders' equity	\$12,809,327	\$17,477,428

The following table includes assets to settle liabilities of the consolidated variable interest. These assets and liabilities are included in the consolidated balance sheet above.

Assets:	
Cash and cash equivalents	\$1,222
Accounts receivable	45,075
Inventories	885,961
Advances on contracts	43,524
Furniture, fixtures & equipment net of accumulated depreciation	119,007
Liabilities:	
Accounts payable	\$461,292
Accrued expenses and other payables	354,361
See Notes to Consolidated Financial Statements	

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2015 AND 2014

	2015	2014
Product sales, net	\$9,491,569	\$10,333,090
Cost of products sold	3,048,260	3,630,765
Gross profit	6,443,309	6,702,325
Selling, general and administrative expenses	9,399,201	7,404,258
Research and development expenses	100,856	88,243
Total operating expenses	9,500,057	7,492,501
Loss from operations	(3,056,748)	(790,176)
Other (expenses)	(5,347)	-
Interest income	3,838	2,389
Total other expenses, net	(1,509)	2,389
Loss before provision for income tax and equity in net earnings of equity investments	(3,058,257)	(787,787)
Provision for income tax	(36,157)	(9,509)
Loss before equity in net earnings of equity investments	(3,094,414)	(797,296)
Loss on earnings from Milestone Medical Inc.	(2,019,211)	(891,500)
Loss on earnings from Education Joint Venture	(7,846)	(17,890)
Loss on earnings from China Joint Venture	(418,432)	(810)
Net loss in equity investments	(2,445,489)	(910,200)
Net Loss	(5,539,903)	(1,707,496)
Net loss attributable to noncontrolling interests	72,381	5,472
Net loss attributable to Milestone Scientific Inc.	\$(5,467,522)	\$(1,702,024)
Net loss per share applicable to common stockholders—		
Basic	\$(0.26)	\$(0.08)
Diluted	\$(0.26)	\$(0.08)
Weighted average shares outstanding and to be issued—		
Basic	21,429,993	20,063,513
Diluted	21,429,993	20,063,513

See Notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2015 AND 2014

	Preferred Stock		Common Stock		Additional Paid-in Capital		Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
	Shares	Amount	Shares	Amount	Capital	Deficit	interest	Stock		
Balance, January 1, 2014	-	\$-	19,599,470	\$19,599	\$66,677,200	\$(60,265,438)	\$-		\$(911,516)	\$5,519,845.00
Options to employees and consultants	-	-	-	-	429,131	-	-	-	-	429,131
Capital Contribution from noncontrolling interest	-	-	-	-	-	-	400,000	-	-	400,000
Common stock to be issued to employee for bonuses	-	-	112,131	112	226,638	-	-	-	-	226,750
Common stock issued for directors compensation	-	-	30,000	30	55,170	-	-	-	-	55,200
Common stock issued for payment of consulting services	-	-	147,731	148	274,353	-	-	-	-	274,500
Common stock issued for payment of	-	-	26,156	27	46,014	-	-	-	-	46,041

employee compensation									
Exercise of stock options for employees									
and consultants	-	-	388,959	389	307,058	-	-	-	307,447
Exercise of stock options for directors	-	-	75,000	75	41,175	-	-	-	41,250
Sale of Common Stock - Innovest and Series A									
Convertible Preferred Shares	7,000	7	2,000,000	2,000	9,447,676	-	-	-	9,449,683
Net loss						(1,702,024)	(5,472)		(1,707,496)
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 Inc.	-	-	-	-	-	-	(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

See Notes to Consolidated Financial Statements

F-5

MILESTONE SCIENTIFIC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2015 AND 2014

	2015	2014
Cash flows from operating activities:		
Net loss	\$(5,539,903)	\$(1,707,496)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation expense	27,947	17,380
Amortization of patents	69,428	78,458
Common stock and options for compensation, consulting and vendor services	1,128,274	1,031,623
Equity loss on Milestone Medical Inc.	2,019,211	891,500
Equity loss on Education joint venture	7,846	17,890
Equity loss on China joint venture	348,651	810
Changes in operating assets and liabilities:		
Increase in accounts receivable	(207,248)	(8,623)
Increase in other receivable	(58,140)	-
Increase in inventories	(875,034)	(1,175,447)
(Increase) decrease to advances on contracts	(450,407)	1,587,155
(Increase) decrease to prepaid expenses and other current assets	192,601	(304,114)
Increase in other assets	(2,670)	(1,768)
Increase (decrease) in accounts payable	173,068	(516,460)
Increase in accrued expenses and other payables	220,038	466,035
Net cash (used in) provided by operating activities	(2,946,338)	376,943
Cash flows from investing activities:		
Investment in Milestone Medical Inc.	-	(856,105)
Investment in China Joint Venture	-	(349,461)
Purchases of intangible assets	(9,939)	(16,752)
Purchases of property and equipment	(67,581)	(82,210)
Investment in Milestone Medical prior to consolidation (Note F)	(3,649,751)	-
Net cash used in investing activities	(3,727,271)	(1,304,528)
Cash flows from financing activities:		
Proceeds from exercise of stock options	-	348,697
Net proceeds on Private Placement Offering	-	9,449,683
Repayment of related party loan	-	(50,000)
Capital contribution from noncontrolling interest	500,000	400,000
Net cash provided by investing activities	500,000	10,148,380
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(6,173,609)	9,220,795
Cash and cash equivalents at beginning of year	10,367,993	1,147,198
Cash and cash equivalents at end of year	\$4,194,384	\$10,367,993
Supplemental disclosure of cash flow information:		
Net Assets Acquired from Variable Interest Entity	566,775	-

See Notes to Consolidated Financial Statements

MILESTONE SCIENTIFIC INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE A — ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Milestone Scientific Inc. and Subsidiaries, (collectively “Milestone Scientific”, “our”, “us” or “we”) 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®, Wand Plus® and STA (Single Tooth Anesthesia)™ and in medicine under the trademark CompuMed®. CompuDent® is suitable for all dental procedures that require local anesthetic. CompuMed® and Wand Plus are 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 instruments are sold in the United States and in over 47 countries abroad. Milestone Scientific’s products are manufactured by a third-party contract manufacturer.

In July 2014, Milestone Scientific acquired all of the 750,000 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 received Milestone Scientific’s dental business and related dental assets including the exclusive license of Milestone Scientific’s, patents, trademarks, and technology for use in the dental marketplace. Wand Dental is consolidated into Milestone Scientific.

On June 1, 2015, Milestone Scientific listed its common stock on the NYSE MKT LLC (NYSE MKT) under the ticker symbol MLSS.

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 revenue, positive operating income and net income. The capital raised in May 2014, provided Milestone Scientific with the opportunity to continue to develop and commercialize additional medical instruments and aggressively market the dental instruments throughout the world. 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 current negotiations and reductions in operating expenses. As of December 31, 2015, Milestone Scientific believes that with the new distribution agreement with Henry Schein Inc. (effective January 1, 2016), the world’s largest supplier of medical, dental and veterinary supplies and devices, that dental revenue is projected to improve in the upcoming 12 months. To further reduce our expenditures, Milestone Medical’s expenses related to USA FDA clearance for the epidural and intra-articular instruments can be controlled as required to meet Milestone Scientific’s budget. The Company has completed a detailed cash flow projection for the upcoming 12 months and has concluded that by limiting the FDA related expenses and increasing the dental instrument revenue through the new distribution agreement, management believes that Milestone Scientific will have sufficient cash reserves to meet all of its anticipated obligations over the next twelve months.

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, as well as Milestone Medical, Inc., a variable interest entity for which Milestone Scientific is the primary beneficiary. All significant intra-entity transactions and balances have been eliminated in consolidation.

Milestone Advanced Cosmetic Systems, Inc. (“ACS”) was organized in July 2014, and is owned fifty percent by Milestone China and fifty percent by Milestone Scientific. Milestone China is 40% owned by Milestone Scientific, as a result, through attribution Milestone Scientific owns seventy percent of ACS. Milestone China has provided \$900,000 of cash and Milestone Scientific provided a royalty-free license to utilize its technology to develop a Botox instrument. Milestone Scientific will also provide the resources to design and commercialize the instrument at cost.

F-7

2. 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 the Company determines that it has operating power and the obligation to absorb losses or receive benefits, the Company consolidates the VIE as the primary beneficiary, and if not, does not consolidate. The Company'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.

Assets recognized as a result of consolidating VIEs do not represent additional assets that could be used to satisfy claims against the Company's general assets. Conversely, liabilities recognized as a result of consolidating these VIEs do not represent additional claims on the Company's general assets; rather, they represent claims against the specific assets of the consolidated VIEs.

The Company is the primary beneficiary of Milestone Medical Inc. and Milestone Scientific Education Inc., as variable interest entities. Accordingly, the assets and liabilities of Milestone Medical Inc. are included in the accompanying consolidated balance sheet. Please refer to footnote F for further details regarding the treatment of the variable interest entity. However, the assets and liabilities of Milestone Scientific Education Inc. have not been consolidated as the impact on the financial statements is not considered material. Please refer to footnote G for further details regarding the treatment.

3. 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.

4. 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 reported by the Company.

5. Product Return and Warranty

Milestone Scientific 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. Warranty expense was \$73,539 and \$79,017 for 2015 and 2014, respectively. Non-Warranty repairs are collected from the customers. Non-Warranty repair income was \$39,264 and \$60,473 for 2015 and 2014, respectively.

6. 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.

7. Equity Method Investments

Investments in which we have 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 Sheet. Under

F-8

this method of accounting, our share of the net earnings or losses of the investee is presented below the income tax line on the Consolidated Statement of Operations since the activities of the investee are not closely aligned with the operations of the Company. We evaluate our 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.

8. 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.

9. Intangible Assets - Patents

Patents are recorded at cost to prepare and file the applicable documents with the United States Patent Office, or internationally with the applicable governmental office in the respective country. 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 a notice of such rejection. 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 the 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.

10. Impairment of Long-Lived Assets

Milestone Scientific reviews long-lived assets for impairment whenever events or circumstances 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. Milestone Scientific has reviewed long-lived assets for impairment and concluded no impairment exist as of December 31, 2015 and 2014.

11. 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 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.

12. 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.

13. Research and Development

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

F-9

14. Advertising Expenses

Milestone Scientific expenses advertising costs as they are incurred. For the years ended December 31, 2015 and 2014, Milestone Scientific recorded advertising expenses of \$33,570 and \$26,569, respectively.

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. The income tax provision or credit is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

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 2015 and 2014, 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 1,427,769 and 1,488,796 at December 31, 2015 and 2014, 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.

F-10

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 2015 and 2014 was estimated as \$3.01 and \$2.18, respectively, on the date of grant. The fair value for 2014 and 2014 was determined using the Black-Scholes option-pricing model with the following weighted average assumptions:

	December 31	
	2015	2014
Volatility	167%	149%
Risk-free interest	1.73%	1.62%
Expected Life	5 years	5 years
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. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

In June 2014, the FASB issued guidance for stock compensation which requires that a performance target that affects vesting of share-based payments and that could be achieved after the requisite service period be treated as a performance condition that affects vesting and as such, should not be reflected in estimating the grant-date fair value of the award. The guidance is effective for annual and interim periods beginning after December 15, 2015. This standard is not expected to have a material effect on the Company’s financial position, results of operations or cash flows.

In February 2015, the Financial Accounting Standards Board issued a new standard ASU No.2015-02, “Consolidation (Topic 810): Amendments to the Consolidation Analysis.” The new standard affects reporting entities that are required to evaluate whether they should consolidate certain legal entities. All legal entities are subject to reevaluation under the revised consolidation model, including limited partnerships and similar legal entity. The guidance is effective for public business entities for fiscal years, and for interim periods within those fiscal years beginning after December 15, 2015. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using

F-11

LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The guidance is effective for reporting periods beginning after December 15, 2016. The guidance should be applied prospectively, with earlier application permitted. We will adopt the guidance as of January 1, 2016, on a prospective basis. The adoption of this new guidance is not expected to have a material impact on our financial statements.

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. As of December 31, 2015 and 2014 there are no deferred tax assets or liabilities recorded.

In February 2016, the Financial Accounting Standards Board 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, 2019 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 Financial Accounting Standards Board 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 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.

NOTE C — 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.

NOTE D — INVENTORIES

	December 31	
	2015	2014
Inventories consist of the following:		
Finished goods	\$4,252,612	\$2,466,829
Component parts and other materials	5,482	30,270
	\$4,258,094	\$2,497,099

NOTE E — ADVANCES ON CONTRACTS

Milestone Scientific has entered into fixed arrangements with a contract manufacturer to manufacture STA, CompuDent® and Wand Plus®. The contract manufacturer bills Milestone Scientific as the work progresses and it is Milestone Scientific's policy is 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, 2015 and December 31, 2014 are \$1,215,128 and \$721,197, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE F – CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Medical

Milestone Medical, Inc. is 49.98% owned by Milestone Scientific Inc. The Company has been 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 our initial ownership in Milestone Medical.

Since our initial investment in Milestone Medical, Inc., we have 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 the Polish Market. In December 2015, the Company suspended their capital raise efforts meriting re-consideration of the initial accounting for the investment as an equity method investment.

As a result of the change in circumstances around the proposed offering in December 2015 by Milestone Medical, we reevaluated the relationship between the two entities and the status of Milestone Medical as a VIE. We have concluded that Milestone Medical does not have sufficient capital at risk to support its activities without additional financial support from Milestone Scientific. As a result of these factors, we have concluded that the line of credit extended to Milestone Medical constitutes a variable interest in Milestone Medical and we should consolidate Milestone Medical as of December 31, 2015.

Since the factors giving rise to concluding that Milestone Medical is a VIE happened so close to the end of fiscal year 2015, the acquisition date for measuring the consolidation of Milestone Medical has been deemed to be December 31, 2015. As such the statement of operations do not include any adjustment for the consolidation and the portion of our loss from Milestone Medical for the year ended December 31, 2015 is included in "loss from earnings of Milestone Medical."

The assets and liabilities of Milestone Medical Inc. are included in the accompanying consolidated Balance Sheet as of December 31, 2015.

Pro Forma Financial Information (Unaudited).

The financial information in the table below summarizes the combined results of operations of Milestone Scientific and subsidiaries and Milestone Medical Inc. (a variable interest entity) 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 each of the period presented.

	2015	
	Pro Forma	2014 Pro Forma
	Consolidated	Consolidated
Revenue	\$9,542,544	\$ 10,333,089
Cost of sales	3,061,299	3,630,765
Gross profit	6,481,245	6,702,324
Selling, general and administrative expenses	12,645,445	8,899,447
Research and development expenses	892,255	489,551
Total operating expenses	13,537,700	9,388,998
Loss income from operations	(7,056,455)	(2,686,674)
Other Expenses	(5,347)	-
Interest Expense	(40,331)	(2,955)
Interest Income	3,838	5,057
Loss before provision for income taxes	(7,098,295)	(2,684,572)
Provision for income tax	(36,157)	(9,509)
Loss before equity in net earnings of equity investments	(7,134,452)	(2,694,081)
Loss on earnings from Education Joint Venture	(7,846)	(17,890)
Loss on earnings from China Joint Venture	(418,432)	(810)
Net loss in equity investments	(426,278)	(18,700)
Net loss	(7,560,730)	(2,712,781)
Net loss attributable to the noncontrolling interests	2,093,208	954,423
Net loss attributable to Milestone Scientific Inc.	\$(5,467,522)	\$(1,758,358)

The financial performance of Milestone Medical reported in the consolidated income statement for the years ended December 31, 2015 and 2014, respectively; includes revenues of approximately \$51,000 and \$0, operating expenses of approximately \$3,990,000 and \$1,900,000, and interest expense of approximately \$40,000 and \$280.

NOTE G – INVESTMENT IN JOINT VENTURES

Milestone Education LLC.

Milestone Education LLC (“Education”) began operations in 2013 to provide training and education to our dentists throughout the world. Milestone Scientific accounts for its investment in Education using the equity method of accounting. Approximately 80% of the revenue earned by Education is from services performed for Milestone Scientific. As a result of this relationship, we concluded that we have the power to direct the activities that most significantly impact Education’s economic performance, and that it is a variable interest entity and should be consolidated in the financials of Milestone Scientific. However the impact of the consolidation was deemed not to be material to the consolidated financial statements, and as such Education was not consolidated at December 31, 2015 and 2014. We recorded losses on earnings from Education of \$7,846 and \$17,889 for the years ended December 31, 2015 and 2014 respectively, which represents 50% of the reported losses of Education for each period respectively. Milestone Scientific’s had an investment in Milestone Education was \$16,346 as December 31, 2015 and \$24,192 as of December 31, 2014.

F-14

Advance Ocular Science SA

Advanced Ocular Sciences Inc. is an entity organized to develop an instrument that delivers injections into the eye. The company is a shell company as of December 31, 2015. Milestone Scientific owns 25% of this entity. As of the balance sheet date, no equity has been contributed to the Company by Milestone Scientific. During 2015, Milestone Scientific advanced \$78,798 for marketing and strategy planning to Advanced Ocular Sciences SA. Advanced Ocular Sciences SA., or their organizers are obligated to repay this advance once the public offering is approved and funded in Poland during 2016. Advance Ocular Science was not included in the consolidated financial statements at December 31, 2015 as no investment has been made by Milestone Scientific.

Milestone China Ltd.

In June 2014, Milestone Scientific agreed to invest \$1 Million through the contribution of 772 STA instruments (at a distributor price of approximately \$1,295 per instrument) for a forty percent ownership in Milestone China Ltd. (“Milestone China”). In 2014, the instruments were shipped and were recorded as an investment in Milestone China at the cost of the inventory contributed. Milestone Scientific recorded a loss on its investment in Milestone China of \$348,651 and \$810 in 2015 and 2014 respectively. As of December 31, 2015 and 2014, Milestone Scientific’s investment in Milestone China was \$0 and \$348,651, respectively. Milestone Scientific had suspended losses on its investment in Milestone China of \$215,347 as of December 2015.

Milestone Scientific sold \$507,000 in handpieces and \$938,200 in instruments during year ended December 31, 2015 to Milestone China Ltd. Milestone China Ltd. owes \$357,200 to Milestone Scientific for handpieces shipped in 2015, which is included in accounts receivable at December 31, 2015. Subsequent to the balance sheet, the full amount of the receivable was collected from Milestone China Ltd. .

Milestone Scientific recognizes the total revenue and costs of goods sold at the time the shipment of instruments and handpieces. 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 Accounting Standard Codification (“ASC”) 323 – Equity Method and Joint Ventures, the Company has deferred the gross profit associated with inventory shipped to Milestone China that has not been sold to third parties. The deferred profit of \$69,781 is included in the loss from the Milestone China within the Statement of Operations and presented as a reduction of the accounts receivable in the Consolidated Balance Sheet.

In January 2016, Milestone Scientific contributed 308 STA instruments (valued at \$308,000 (\$1,000 per instrument)) to Milestone China Inc. as an increase in our investment in this subsidiary.

NOTE H — FURNITURE, FIXTURES AND EQUIPMENT

	December 31	
	2015	2014
Furniture, Fixtures and Equipment consist of the following:		
Leasehold improvements	\$24,734	\$24,734
Office furniture and equipment	134,948	122,198
Molds	7,200	7,200
Trade show displays	136,029	89,395

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-K

Computers and software	217,265	166,272
Tooling Safety Wand	20,377	20,377
Tooling equipment-STA, Wand and Medical	115,745	11,100
STA Trials Instruments	63,752	63,752
EPI and IA instruments	82,362	-
Total	802,412	505,028
Less accumulated depreciation	(566,477)	(416,210)
	\$235,935	\$88,818

Depreciation expense was \$27,947 and \$17,380 for the years ended December 31, 2015 and 2014, respectively.

NOTE I — PATENTS

Patents are being amortized by 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 \$69,428 in 2015 and \$78,458 in 2014. Estimated amortization expense of existing patents for each of the next five fiscal years amounts to approximately \$79,000 per year.

NOTE J — STOCKHOLDERS' EQUITY

ISSUANCES OF PREFERRED AND COMMON STOCK

During 2015, Milestone Scientific provided shares to be issued 29,865 shares valued at \$100,000 for payment of employee bonus.

During 2015, Milestone Scientific issued 41,365 shares valued at \$120,000 for payment of consulting services.

During 2015, Milestone Scientific issued 17,817 shares valued at \$50,000 for payment of employee compensation.

During 2015, Milestone Scientific issued 16,666 shares valued at \$21,165 for exercise of stock options to a consultant.

During 2015, Milestone Scientific issued 200,000 shares valued at \$200,000 for exercise of stock options to an employee.

During 2014, Milestone Scientific issued 237,293 shares valued at \$250,531 for exercise of stock options to employees.

During 2014, Milestone Scientific issued 151,666 shares valued at \$56,916 for exercise of stock options to a consultant.

During 2014, Milestone issued 30,000 shares valued at \$55,200 for the director's compensation.

During 2014, Milestone issued 112,131 shares valued at \$226,750 to a consultant.

During 2014, Milestone issued 147,731 shares valued at \$274,500 for payment of consulting services.

During 2014, Milestone issued 26,156 shares valued at \$46,041 for payment of employee compensation.

During 2014, Milestone issued 75,000 shares valued at \$41,250 for exercise of stock options to three independent directors.

During 2014, Milestone issued 2,000,000 shares of common stock and 7,000 shares of Series A shares of preferred stock valued at \$10,000,000 to an investor, minus professional fees of \$500,000.

SHARES TO BE ISSUED

As of December 31, 2015 and 2014, there were 963,451 and 954,953 shares, respectively, that have been deferred from being issued, subject to employment agreements with the Chief Executive Officer, Chief Financial Officer and employees of Milestone Scientific. Such shares will be issued to each party upon termination of their employment. The number of shares were fixed at date of grant and there are no conditions other than continued employment by the officers. The grants were fully vested upon grant date.

F-16

SHARES RESERVED FOR FUTURE ISSUANCE

At December 31, 2015 and 2014 there were 2,391,220 and 2,443,749 shares reserved for future issuance and 1,427,769 and 1,488,796 shares underlying other stock options and warrants outstanding, respectively. There were 963,451 shares in 2015 and 974,953 shares in 2014 to be issued in settlement of deferred compensation to officers of Milestone Scientific.

NOTE K — STOCK OPTION PLANS

In July 2004, the Board of Directors approved the adoption of the 2004 Stock Option Plan. The 2004 Stock Option Plan provides 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 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 become exercisable over a three-year period from the grant date and expire five years after the date of grant.

In December 2007, the Board of Directors authorized Milestone Scientific to issue up to \$2 million of its common stock to vendors or employees, and to grant them piggy back registration rights in the usual form, at a value of not less than 90% of the market value on the date of the agreement for the vendor or employee to accept said shares. Such future shares are not included in the above noted shares reserved for future issuance.

In June 2011, the Shareholders of Milestone Scientific approved the 2011 Stock Option Plan (the "2011 Plan") that provides 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 shares are included in the above noted shares reserved for future issuances.

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. During the years ended December 31, 2015 and 2014 Milestone Scientific recognized \$637,108, and \$429,131 of total employee compensation cost related to options that vested each year, respectively. As of December 31, 2015 and 2014, there was \$1,167,865 and \$569,641 of total unrecognized compensation cost related to non-vested options which Milestone Scientific expects to recognize over a weighted average period of 2.78 years and 3.23 years for December 31, 2015 and December 31, 2014, respectively.

A summary of option activity for employees under the plans as of December 31, 2015 and 2014, and changes during the year then ended is presented below:

Weighted Average

Remaining

	Number of Options	Exercise Price \$	Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Outstanding, January 1, 2014	1,484,499	1.03	2.88	-
Granted	390,470	2.25	4.87	-
Exercised	(312,293)	0.93	-	-
Forfeited or expired	(90,546)	1.30	-	-
Outstanding, December 31, 2014	1,472,130	0.79	3.23	1,430,231
Exercisable, December 31, 2014	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	2.78	1,220,338
Exercisable, December 31, 2015	1,041,680	1.29	2.41	1,135,819

Weighted Averaged

	Number of Options	Exercise Price \$
VESTED OPTIONS		
Outstanding, January 1, 2014	1,115,006	0.97
Exercised	(312,293)	0.93
Vested Options	324,018	1.45
Forfeited	(90,546)	1.30
Outstanding, December 31, 2014	1,036,185	1.11
Exercised	(200,000)	1.00
Vested Options	215,495	1.92
Forfeited	(10,000)	1.00
Outstanding, December 31, 2015	1,041,680	1.29
NONVESTED OPTIONS		
Nonvested, January 1, 2014	369,493	1.22
Granted	390,470	2.18
Vested	(324,018)	1.45
Forfeited	-	-
Nonvested, December 31, 2014	435,945	1.87
Granted	157,306	3.01
Vested	(215,495)	1.92
Forfeited	-	-
Nonvested, December 31, 2015	377,756	2.32

A summary of option activity for non-employees under the plans as of December 31, 2015 and 2014, and changes during the year ended is presented below:

			Weighted Average	
			Remaining	
		Weighted Averaged	Contractual Life	Aggregate Intrinsic
	Number of Options	Exercise Price \$	(Years)	Options Value \$
Outstanding, January 1, 2014	173,332	0.48	0.59	210,833
Exercisable, December 31, 2014	173,332	0.48	0.59	210,833
Exercised	(151,666)	0.38	-	-
Forfeited	(5,000)	1.15	-	-
Outstanding, December 31, 2014	16,666	1.27	0.62	17,166
Exercisable, December 31, 2014	16,666	1.27	0.62	17,166
Granted	8,333	2.70	4.83	22,499
Exercised	(16,666)	-	-	-
Outstanding, December 31, 2015	8,333	2.70	4.83	-
Exercisable, December 31, 2015	2,777	2.70	4.83	-

	Number of Options	Exercise Price \$
VESTED OPTIONS		
Outstanding, January 1, 2014	173,332	0.48
Exercised	151,666	0.38
Forfeited	5,000	1.15
Outstanding, December 31, 2014	16,666	1.27
Vested	5,556	2.70
Exercised	166,666	1.27
Forfeited	-	-
Outstanding, December 31, 2015	2,777	2.70
NONVESTED OPTIONS		
Nonvested January 1, 2014	-	-
Granted	8,333	2.70
Vested during 2015	2,777	3.70
Outstanding, December 31, 2015	5,556	2.70

The fair value of the options was estimated on the date of grant using the Black Scholes option-pricing model. There were 8,333 non-employee options granted for the years ending December 31, 2015 and none granted during 2014. During the years ended December 31, 2015 and 2014, Milestone Scientific recognized \$7,050 expense related to non-employee options that vested. At December 31, 2015 there was \$15,000 of total unrecognized compensation cost related to non-vested options which Milestone Scientific expects to recognize over weighted average of 4.83 years.

NOTE L — 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 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 of the Board of Directors. 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

F-19

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 employment contract, 735,369 shares of common stock are to be paid out at the end of the contract in settlement of 730,985 at December 31, 2015 and 706,716 shares of common stock are to be paid out at the end of the contract in settlement of \$630,985 at December 31, 2014 of accrued deferred compensation and, accordingly, such shares have been classified in stockholders' equity with the common shares classified as to be issued.

NOTE M — 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, 2015 and 2014, 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, 2015 and 2014 are as follows:

	2015	2014
Current Assets		
Allowance for doubtful accounts-short term	\$2,000	\$2,000
Warranty reserve	43,000	12,000
Deferred officers compensation	643,000	392,000
Subtotal	688,000	406,000
Valuation allowance	(688,000)	(406,000)
Non-current assets		
Depreciation and Amortization	\$149,000	\$-
Net operating loss carryforward	16,160,000	15,686,000
Federal tax effect of state deferred tax assets	(117,000)	
Subtotal	16,192,000	15,686,000
Valuation allowance	(16,192,000)	(15,686,000)

As of December 31, 2015 and 2014, Milestone Scientific has federal net operating loss carryforwards of approximately \$46,875,000 and \$44,478,000, respectively that will be available to offset future taxable income, if any, through December 2032. Milestone Scientific has state net operating losses of \$3,771,000 and \$1,374,000 in 2015 and 2014, respectively, expiring through December 2035. 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.

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-K

For the year ended December 31, 2015 and 2014, state tax liability was approximately \$62,000 and \$27,000. Such expense was recognized in the accompanying consolidated financial statements as of December 31, 2015. Due to Milestone Scientific's history of past operating losses, which required a full valuation allowances for all of Milestone Scientific's deferred tax assets at December 31, 2015 and 2014, no recognition was given to the utilization of the remaining Federal and State net operating loss carryforwards

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

	2015	2014
Statutory rate	34 %	34 %
State income tax - all states	6 %	6 %
	40 %	40 %
Current year valuation allowance	(40 %)	(40 %)
Benefit for income taxes	0 %	0 %

F-20

Accounting for Uncertain Tax Positions:

Milestone Scientific follows the Income Taxes Topic of the FASB Accounting Standards Codification, which provides clarification on accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The guidance 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, 2015, and 2014, 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 2012, 2013, and 2014 years are subject to audit by federal and state jurisdictions.

NOTE N — PRODUCT SALES AND SIGNIFICANT CUSTOMERS AND VENDORS

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

	Year Ending December	
	31	
	2015	2014
Instruments	\$2,911,614	\$2,569,102
Handpieces	6,409,924	7,627,140
Other	170,031	136,848
	\$9,491,569	\$10,333,090
United States	\$3,295,307	\$4,655,648
Canada	211,035	100,321
Other Foreign	5,985,227	5,577,121
	\$9,491,569	\$10,333,090

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. Purchases from this supplier were \$1,745,619 (28%) and \$948,024 (26%) in 2015 and 2014, respectively. 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. Purchases of handpieces from this vendor in China were \$2,698,522 (72%) and \$2,698,043 (74%) in 2015 and 2014, respectively. A five percent shareholder of Milestone Scientific is also a shareholder of this vendor. All other purchases from other suppliers were not significant in either 2015 or 2014. Milestone Scientific owed \$716,520 and \$455,573 to this supplier as of September 30, 2015 and December 31, 2014, respectively.

For the year ended December 31, 2015, Milestone Scientific had two customers (distributors) at December 31, 2015, that had approximately 33% (15% and 18%), of its net product sales. Accounts receivable for the two major customers amounted to approximately \$784,690 or 45% of gross accounts receivable. For the year ended December 31, 2014 Milestone had two customers (distributors) had approximately 45% (17% and 28%), of its net product sales. Accounts receivable for the two major customers amounted to approximately \$1,100,000 or 69% of gross accounts receivable.

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.

F-21

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

	Year Ending December 31,
2016	170,108
2017	170,108
2018	170,108
2019	170,108
2020	156,879
	\$ 837,311

For the years ended December 31, 2015 and 2014, respectively, rent expense amounted to \$121,866 and \$86,348 respectively.

(2) Contract Manufacturing Arrangement

Milestone Scientific has informal arrangements for the manufacture of its products. STA, single tooth anesthesia, and CompuDent® instruments are 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 adversely affect Milestone Scientific.

(3) Other Commitments and Subsequent Events

Other Commitments

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 us. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director 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. In addition, the Director is granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant, 8,333 shares of the 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 will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license. Milestone Scientific expensed the Director's royalty fee of \$313,751 and \$404,828 the years ended December 31, 2015 and 2014, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of \$260,000 and \$200,000 the years ended December 31, 2015 and 2014, respectively.

In January 2010, Milestone Scientific issued a purchase order to Tricor Systems Inc. for the purchase of 12,000 STA Instruments to be delivered over the next three years. The purchase order is for \$5,261,640. Wand Dental Inc, a wholly-owned subsidiary of Milestone Scientific was assigned this commitment on October 1, 2014. As of September 30, 2015, this commitment was completed. In the second quarter of 2015, Wand Dental Inc. entered into a new purchase commitment for 3,000 STA instruments, (\$1,785,750) for the delivery of these instruments beginning October 2015 and into 2016. The balance of the advances at December 31, 2015 and December 31, 2014 is \$1,215,127 and \$721,197, respectively.

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

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.

F-23