

MILESTONE SCIENTIFIC INC.

Form 10-K

April 01, 2015

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, 2014

or

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

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

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

220 South Orange Avenue, Livingston, NJ 07039

(Address of principal executive offices)

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

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to section 12(g) of the Act: Common Stock, par value \$.001 per share

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, 2014, the last business day of Milestone's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non – affiliates of the issuer was \$40,263,722. This amount is based on the closing price of \$1.35 per share of Milestone's common stock as of such date, as reported on the OTCQB.

As of March 31, 2015 the registrant has a total of 21,371,161 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>	3
Item 1A.	<u>Risk Factors</u>	11
Item 1B.	<u>Unresolved Staff Comments</u>	13
Item 2.	<u>Description of Property</u>	13
Item 3.	<u>Legal Proceedings</u>	13
Item 4.	<u>Mine Safety Disclosure</u>	13

PART II

	<u>Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of</u>	
Item 5.	<u>Equity Securities</u>	14
Item 6.	<u>Selected Financial Data</u>	14
Item 7.	<u>Management's Discussion and Analysis or Plan of Operations</u>	14
Item 7A.	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	22
Item 8.	<u>Financial Statements</u>	22
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	22
Item 9A.	<u>Controls and Procedures</u>	22
Item 9B.	<u>Other Information</u>	22

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>	23
Item 11.	<u>Executive Compensation</u>	25
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	28
Item 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	30
Item 14.	<u>Principal Accounting Fees and Services</u>	30

PART IV

Item 15.	<u>Exhibits and Financial Statement Schedules</u>	32
----------	---	----

SIGNATURES

34

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 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'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. Although Milestone 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's early stage

operations, the inclusion of such information should not be regarded as a representation by Milestone or any other person that the objectives and plans of Milestone will be achieved. Milestone 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,” “us,” “our,” “we” or “Milestone Scientific” refer to Milestone Scientific Inc. Milestone Scientific Inc. and subsidiary unless the context otherwise indicates. Milestone has rights to the following trademarks: CompuDent®, CompuMed®, CompuFlo®, The Wand®, The Wand Plus®, The SafetyWand®, Dynamic Pressure Sensing Technology®, STA Single Tooth Anesthesia™ (STA Instrument, instruments and handpieces), Ionic White® (light emitting diode), and Ionic White™ (whitening toothpaste). Milestone was incorporated in the State of Delaware in 1989.

In July 2014 Milestone acquired all of the 750,000 outstanding shares of an inactive, previously established 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 the Milestone Scientific 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 Inc.

BUSINESS

Background

Milestone since its inception has engaged in pioneering proprietary, innovative, computer-controlled injection technologies and solutions for the medical and dental markets. Milestone 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 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 first introduced The Wand® (CompuDent® instrument) and the disposable Wand handpiece. CompuDent provides painless injections for all routine dental treatments, including root canals, crowns, fillings and cleanings. Milestone’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 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 received FDA 510(k) Pre-market clearance for marketing and sale of the STA instruments, (dental instrument). Milestone introduced the instrument to the market in February 2007 and this instrument is currently being marketed throughout the world.

Central to Milestone'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 and CompuMed 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 in real time. 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 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's continuing efforts to develop and commercialize this important technology. Milestone 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'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 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 introduced the instrument to market in February 2007 at the Chicago Dental Society's 143rd Midwinter Meeting. The patented STA Instrument incorporates the "pressure feedback" elements of Milestone'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 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 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 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 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 a blanket purchase order for 12,000 STA instruments and related handpieces to be delivered over 36 months, thereby marking Milestone's initial penetration into China's emerging dental market. The agreement was terminated in September 2014 and a new distributor, Milestone China Inc. owned forty (40) percent by Milestone Scientific Inc. became the distributor for the STA Instruments and handpieces in China.

In early October 2012, the State Food and Drug Administration (SFDA) of the People's Republic of China approved Milestone'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 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 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.

Beginning in the second and third quarter 2010, Milestone expanded its international and domestic sales force by hiring a Director of International Sales and Director of Domestic Sales. These additions have proven to be a valuable addition to our dental market business, as we expand our distribution in both markets.

In November 2012, Milestone 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.

In August 2013, Milestone appointed Henry Schein as its exclusive distributor in the USA and Canada for the CompuDent handpieces.

In May of 2014, Milestone completed a private placement, which raised gross proceeds in the total of \$10 million, for the sale of \$3 million in common stock (2 million shares at \$1.50 per share) and \$7 million in 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 anti-dilution adjustment .

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's 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.

Medical Instrument for Joint Venture

In July 2011, Milestone 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 held a 50% interest in the joint venture Milestone Medical Inc. (Milestone Medical), and shareholders of Beijing 3H, and a group of individual investors including a large shareholder in Milestone who is also a principal of a supplier to Milestone, also held a 50% interest in the joint venture.

The joint venture provided for Milestone'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 the joint venture to design and develop two commercial instruments using Milestone's CompuFlo® technology and disposables. Milestone will have distribution responsibility in the U.S., Canada. Milestone Medical will distribute for the rest of the world, while 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, shareholders of Beijing 3H sold their shares in Milestone Medical (shares individually owned by two shareholders of Beijing 3H to other founding investors) and the distribution agreement with Beijing 3H for the medical instruments was terminated. Milestone Medical entered into an agreement with Milestone China Inc. (Hong Kong Company), 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 this sale was to reduce Milestone's ownership percentage from 50% to 45.5% (post transaction).

In the fourth quarter of 2014, Milestone purchased 995,000 shares from a founding shareholder of Milestone Medical for \$447,750 (\$0.45 per share). As a result, Milestone increased its aggregate ownership of Milestone Medical to 10,995,000 shares, or 49.9% of its issued and outstanding shares, as of December 31, 2014.

On December 31, 2014 Milestone entered into a line of credit with Milestone Medical, to provide up to \$2 million of funding through April 15, 2016 for the further commercialization, and marketing of the two medical instruments. Interest will be charged at a rate of 3.25% per annum, the prime rate in the U.S. at the inception of the agreement.

Product Platform

Milestone has developed and brought to market a highly differentiated portfolio of industry innovations. Thus far, Milestone's proprietary solutions have succeeded in elevating the state of the art in the professional dental arena. The product portfolio includes:

STA Single Tooth Anesthesia Instrument™ (Wand STA 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'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 unique procedure 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 and waiting up to 18 minutes (or longer if the blocking injection needs to be re-administered) before proceeding to perform a procedure on the targeted tooth. An instrument which allows dentists to effectively anesthetize a single tooth will greatly enhance the productivity of dental practices and, when combined with the painless injection capabilities already present in the CompuDent instrument, such an instrument should provide a compelling value in the marketplace. The STA Instrument will generate recurring revenues from per-patient disposable handpieces.

Since its market introduction in the spring of 2007, the STA Instrument has received favorable reviews and awards from the dental industry. In July 2007, noted industry publication Dentistry Today featured the STA Instrument as one of the “Top 100 Products in 2007,” helping to promote much broader recognition of the instrument and validating STA’s value proposition for dentists and patients, alike. In early 2008, Medical Device & Diagnostic Industry magazine distinguished the STA Instrument as a 2008 Medical Design Excellence Award winner in the “Dental Instruments, Equipment and Supplies” product category. Of the 33 products to receive this coveted award, the STA was one of only two winning products that serve dental practitioners. In December 2008, Milestone 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’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’s 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 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 handpieces 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 is losing time and money.

Competition

Milestone'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.

Milestone's instruments compete on the basis of their performance characteristics and the benefits provided to both 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 believes that they can reduce practitioner stress levels, as well. Milestone'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 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 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 establish an effective distribution network with a strong marketing plan. Historically, Milestone 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 cannot assure you that it can compete successfully; that competitors will not develop technologies or products that render the products less marketable or obsolete; or, that Milestone will succeed in improving the existing products, effectively develop new products, or obtain required regulatory approval for those products.

Patents and Intellectual Property

Milestone 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
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 2014 and 2013 fiscal years, Milestone expensed \$88,243 and \$191,345, respectively, on research and development activities. The higher costs incurred in 2013 were primarily associated with the continued development of the Single Tooth Anesthetic (STA) delivery instrument and continuing efforts on developing medical products utilizing the CompuFlo technology.

Milestone 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 to protect the products, unauthorized parties may attempt to reverse engineer, copy, or obtain and use products and information that Milestone regarded as proprietary, or may design products serving similar purposes that do not infringe on Milestone's patents. Milestone'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.

In the event that the products infringe upon patent or proprietary rights of others, Milestone may be required to modify processes or to obtain a license. There can be no assurance that Milestone 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.

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 will have to submit additional 510(k) applications with the FDA. Milestone 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 device. 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.

Milestone 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 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 time.

In March 2012, Milestone received approval for the Wand STA Single Tooth Anesthesia Instrument from ANVISA in Brazil. In June 2007, Milestone received a CE mark for the marketing of the STA Instrument in Europe. In June 2003 Milestone received a CE mark for marketing of the Safety Wand and The Wand Handpieces with Needle in Europe. In July 2003, Milestone 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 to claims of liability. Milestone maintains liability insurance in an amount that Milestone believes is adequate. However, there can be no assurance that the insurance coverage will be sufficient to pay product liability claims brought against Milestone. A partially or completely uninsured claim, if successful and of significant magnitude, could have a material adverse effect on Milestone.

Employees

On December 31, 2014, Milestone had a total of 14 employees, consisting of two executive officers of Milestone and an executive officer of Wand Dental, a director of International and Professional Relations, a director of engineering, a director of marketing, two customer service representatives, three accountants, a quality care person, a personal assistant and an administrative manager. Milestone also has a consultant who serves as a Director of Clinical Affairs and a consultant for marketing strategy.

Item 1A. CERTAIN RISK FACTORS THAT MAY AFFECT GROWTH AND PROFITABILITY

The following factors may affect the growth and profitability of Milestone and should be considered by any prospective purchaser or current holder of Milestone's securities:

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

For the years ended December 31, 2014 and 2013, revenues were approximately \$10.3 million and \$10 million, respectively. Milestone has a net loss of approximately \$1,708,000 for year ended December 31, 2014 and a net profit of approximately \$1,465,000 for year ended December 31, 2013. In addition, Milestone has had losses for each year since the commencement of operations with the exception of 2013. Milestone has an accumulated deficit of approximately \$62 million. At December 31, 2014, Milestone had cash and cash equivalents, including Treasury Bills of \$10,367,993 and working capital of \$13,147,257. The working capital increased by \$9,223,234 from December 31, 2013. The positive change in working capital is primarily due to the cash proceed from the Private Placement in May 2014 (\$10 million). Milestone management continues to examine all areas of the business to manage our cash flow. Milestone 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, 2014, Milestone believes that it has sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. Milestone will continue to manage its cash position while taking strategic steps to expand its business in the medical and dental, business sectors.

Milestone cannot become successful unless it gains greater market acceptance for its 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 SafetyWand, 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 41,000 instruments of the STA Instrument and its predecessors have been sold worldwide since 1998. Since being introduced to market in February 2007, more than 13,000 instruments of the STA Instrument have been sold. Milestone 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.

Milestone's limited distribution channels must be expanded in order to become successful.

Future revenues depend on Milestone's ability to market and distribute its computer-controlled injection products successfully. In November 2012, Milestone signed on an exclusive distributor and marketing company to sell and distribute the STA instruments and handpieces in the USA and Canada. To be successful, Milestone will need to engage additional distributors, provide for their proper training and ensure adequate customer support. Milestone 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.

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

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

Milestone 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 issued a purchase order to Tricor System Inc. to manufacture 12,000 STA Instruments, over the following three years. Milestone 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 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 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.

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

Milestone could be subject to claims for personal injury from the alleged malfunction or misuse of the dental and medical products. While Milestone carries liability insurance that is believed to be adequate, Milestone 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.

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

Milestone depends on the personal efforts and abilities of the Chief Executive Officer and the Director of Clinical Affairs. Milestone 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 maintains no insurance, could have a materially adverse effect on the business.

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

Milestone's stock price has been extremely volatile, fluctuating during the last two years between \$2.45 and \$1.00. 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's control.

Milestone is controlled by a limited number of shareholders.

Milestone's principal shareholders, Leonard Osser, Gian Domenico Trombetta and K. Tucker Andersen, beneficially own 44% of the issued and outstanding shares of common stock. As a result, they have the ability to exercise substantial control over Milestone'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's securities.

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

Sales of a substantial number of shares of Milestone'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, 2014, Milestone had outstanding options to purchase 1,488,796 shares of common stock at prices ranging from \$0.36 to \$2.23 per share with a weighted average exercise price of \$1.33. 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 would be able to obtain additional equity capital on more favorable terms. Thus, the terms upon which Milestone 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 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'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.

The Management of Milestone has assessed the effectiveness of internal control over financial reporting as of December 31, 2014. 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 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 hired an outside consultant to assist with the development and implementation of the necessary internal controls and reporting procedures. In 2014 and 2013, Milestone utilized the outside consultant on a quarterly basis to review compliance with the internal controls over financial reporting. This expense amounted to \$5,250 and \$9,500 in 2014 and 2013, respectively and the cost is expected to continue in 2015.

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Property

The headquarters for Milestone is located at 220 South Orange Avenue, Livingston, New Jersey which consists of approximately 5,893 square feet of office space. Milestone leases its headquarters at a monthly cost of \$9,085, 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 does not own or intend to invest in any real property. Milestone 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 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

Milestone's Common Stock trades on the OTC Market on the OTCQB market tier under the symbol "MLSS". The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

Common Stock

The following table sets forth the high and low sales prices of the Common Stock

	HIGH	LOW
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
2013		
First Quarter	\$ 1.65	\$ 1.00
Second Quarter	\$ 1.35	\$ 1.00
Third Quarter	\$ 1.40	\$ 1.10
Fourth Quarter	\$ 1.95	\$ 1.25

Holders

According to the records of the transfer agent, there were approximately 142 and 144 shareholders of record of Milestone's common stock as of December 31, 2014 and 2013, respectively. However, Milestone believes that there are approximately 1,800 beneficial owners of Milestone's common stock at December 31, 2014 and 2013, respectively.

Dividends

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

For information regarding securities authorized under the equity compensation plan, see Item 12.

Sales of Unregistered Securities

See NOTE K – STOCKHOLDERS' EQUITY, to the 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 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” on page 12-14 of this Form 10-K.

OVERVIEW

In 2014, Milestone continued to focus on advancing efforts to achieve our two primary objectives; those being:

- 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); and
- Enhancing our global reach by partnering with distribution companies in the medical sector for out epidural and intr-articular instruments.

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 55 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 August 2013, Milestone entered an exclusive distributor agreement (beginning October 1, 2013), with Henry Schein, for the sale and distribution of the CompuDent handpieces in the United States and Canada.

In July 2013, Milestone 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 with the FDA market, the exclusive rights to market, resell, label and distribute Milestone’s CompuFlo injection technology for use in epidural applications for childbirth and other pain management needs in the U.S. hospital sector.

In November 2012, Milestone 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.

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’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, Milestone added in the spring of 2010 an International Sales Director to focus on the growth of our products outside the USA and Canada.

In March 2011, we entered into a definitive joint venture agreement with shareholders of Beijing 3H (Heart-Help-Health) Scientific Technology Co., Ltd. (Beijing 3H) and a group of individual investors for the development, commercialization, manufacture and marketing of epidural and intra-articular injection medical instruments. At December 31, 2014 Milestone holds a 49.98% interest in the joint venture and other remaining founding shareholders holds a 40.93% interest in (the “Medical Joint Venture” or “Milestone Medical Inc.”).

Milestone contributed an exclusive worldwide royalty-free license to use its patents as they pertain to these two instruments and disposables only to the Medical Joint Venture. Shareholders Beijing 3H and a group of individual investors contributed \$1.5 million to the joint venture to enable the joint venture to design and develop two commercial instruments and related disposables using

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

Milestone's CompuFlo® technology. Milestone will have distribution responsibility in the U.S. and Canada while Beijing 3H would distribute products exclusively in the People's Republic of China, Macao, Hong Kong and other regions of Asia. In the third quarter of 2014, a shareholder of Beijing 3H sold his interest in Milestone Medical Inc. and its agreement to distribute said instruments in Asia terminated. Milestone China (40% owned by Milestone Scientific Inc.) signed distributor agreement with Milestone Scientific to distribute Milestone Medical Inc. instruments in Asia. As of December 31, 2014, the Medical Joint Venture and the development project is ongoing and nearing the completion of the two medical instruments. In fact, in September 2014 the Medical Joint Venture, Milestone Medical Inc. received CE clearance to distribute their instruments in European Community (EU). Milestone is actively pursuing Medical distributors for the instrument in the EU community. Milestone Medical Inc signed a distribution agreement in March 2015, with a Polish Medical distributor for the distribution of the epidural instrument starting in April 2015.

In November 2013, Milestone Medical Inc., issued 2 million shares of its common stock at \$1.50 per share, totaling (\$3.0 million) in a private placement in Poland. The consummation of the private placement provided for the admission of the Milestone Medical Inc. common stock for trading on a platform maintained by the Warsaw Stock Exchange. As a result of this transaction, Milestone owned approximately forty-five (45.5%) percent (post-transaction) of Milestone Medical Inc. and Milestone recorded a \$1,363,650 Gain on the Dilutive Effect of these additional shares issued by Milestone Medical Inc. In the fourth quarter of 2014, Milestone purchased an additional 995,000 shares from a founding shareholder. As a result, Milestone Scientific Inc. owns 49.98% of Milestone Medical Inc. at December 31, 2014.

In late June 2014, Milestone agreed to invest \$1 million for a 40% ownership in a Hong Kong organized medical and dental distribution company ("Milestone China"). Milestone's contribution to this entity will be 772 STA instruments. Handpieces will be purchased for cash as required. The new entity provides positive impact on dental and future medical business in China and other parts of Asia. Milestone China did not begin operations until July 2014 and the first shipment of 300 STA instruments occurred in July 2014. Milestone recorded this investment under the equity method of accounting. The remaining 472 STA instruments were delivered by Milestone to Milestone China in January 2015.

The following table shows a breakdown of Milestone'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,					
	2014		2013			
DOMESTIC						
Instruments	\$	1,037,956	22.3%	\$	1,221,589	23.1%
Handpieces		3,543,509	76.1%		3,958,548	74.7%
Other		74,182	1.6%		119,415	2.2%
Total Domestic	\$	4,655,647	100.0%	\$	5,299,552	100.0%
INTERNATIONAL						
Instruments	\$	1,531,146	27.0%	\$	1,450,436	30.8%
Handpieces		4,083,631	71.9%		3,336,262	70.8%
Other		62,666	1.1%		(74,830)	-1.6%
Total International	\$	5,677,443	100.0%	\$	4,711,868	100.0%

DOMESTIC/INTERNATIONAL ANALYSIS

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

Domestic	\$ 4,655,647	45.1%	\$ 5,299,552	52.9%
International	5,677,443	54.9%	4,711,868	47.1%
Total Product Sales	\$ 10,333,090	100.0%	\$ 10,011,420	100.0%

Milestone earned gross profit of 65% and 68% in the years ended December 31, 2014 and 2013, 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 anticipates expending funds for research and development in 2015, these amounts will vary based on the operating results for each quarter. Milestone has incurred annual operating losses and negative cash flows from operating activities since its inception, except for 2013. Milestone, at December 31, 2014, as a result of \$10 million capital raise (\$9.4 million net cash) in May 2014, has sufficient cash reserves to meet all of its anticipated obligations for at least the next twelve months.

Milestone 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 2015, Milestone 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 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.

Milestone announced the formation of a strategic alliance, whereby a third party distributor will serve as the exclusive distributor of Milestone's Single Tooth Anesthesia System® (STA System) and all related disposable items in the United States and Canada, beginning November 15, 2012. Additionally, the third party distributor will initiate a marketing campaign to drive sales in these territories.

In August 2013, Milestone appointed Henry Schein as its exclusive distributor in the USA and Canada for the CompuDent handpieces.

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. Milestone 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, then he will also receive the corresponding percentage of the consideration received by us for such sale or license.

Milestone provided the exclusive worldwide royalty-free license to Milestone Medical Inc. for the use of Milestone's patents for development of two medical instruments in 2011. In return for the license, Milestone originally received a 50% interest in Milestone Medical Inc. As of December 31, 2014, Milestone Scientific owns 49.98% of Milestone Medical Inc.

Summary of Critical Accounting Policies and Significant Judgments and Estimates

Milestone'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 evaluates its estimates, including those related to accounts receivable, inventories, stock-based compensation and contingencies. Milestone 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 believes that the following accounting policies and significant judgments and estimates are most critical in understanding and evaluating the reported financial results.

Treasury Bills

The fair values of Milestone marketable securities are determined in accordance with GAAP, with fair value being defined as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the Company utilizes the three-tier value hierarchy, as prescribed by GAAP.

Accounts Receivable

The realization of Accounts Receivable current and long-term will have a significant impact on Milestone. The criteria used by management to evaluate the adequacy of the allowance for doubtful accounts included, among others, credit worthiness of the customer, current trends, prior payment performance, the age of the receivables and Milestone'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.

Investment in Medical Joint Venture

Milestone entered into a Medical Joint Venture with a third party, shareholders of Beijing 3H, and a group of individual investor for the development and commercialization of two medical products. Milestone as of December 31, 2014 own 49.98% of the Medical Joint Venture and have recorded the investment on the equity basis of accounting. Milestone's proportionate share of expenses incurred by the Medical Joint Venture will be charged to the Statement of Operations on a periodic basis.

Investment in Milestone China

In July 2014, Milestone agreed to invest \$1.0 million (distributor price), 772 STA instruments for a forty percent ownership in a Hong Kong based medical and dental distribution company, ("Milestone China"). The instruments will be shipped to the distributor over one year period. The distributor will purchase STA handpieces on a cash basis as required. 300 STA instruments were shipped in July 2014 and were recorded at Milestone's cost in the investment account for Milestone China on the Balance Sheet in the third quarter 2014. Milestone China began operations in July 2014.

Impairment of Long-Lived Assets

The long lived assets of Milestone, principally patents and trademarks are the base features of the business. Milestone 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 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 the warehouse and revenue is therefore recognized on shipment. In both cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone'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, 2014 compared to 2013 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	Years Ended			
	December 31, 2014		December 31, 2013	
Total revenue	\$ 10,333,090	100%	\$10,011,420	100%
Cost of products sold	3,630,765	35%	3,198,908	32%
Gross Profit	6,702,325	65%	6,812,512	68%
Selling, general and administrative expenses	7,404,258	72%	5,534,463	55%
Research and development expenses	88,243	1%	191,345	2%
Operating expenses	7,492,501	73%	5,725,808	57%
(Loss) income from operations	(790,176)	-8%	1,086,704	11%
Total other income (expense) before provision for income taxes	(907,811)	-9%	378,226	4%
(Loss) Income	(1,697,987)	-16%	1,464,930	15%
Provision for Income Tax	(9,509)	0%	-	0%
Net (loss) income	(1,707,496)	-16%	1,464,930	15%
Less: Net loss attributable to the noncontrolling interests	5,472	0%	-	0%
Net (loss) income attributable to Milestone Scientific Inc.	\$ (1,702,024)	-16%	\$ 1,464,930	15%

See Notes to Financial Statements

Year ended December 31, 2014 compared to year ended December 31, 2013

Total revenues for the twelve months ended December 31, 2014 and 2013 were \$10,333,090 and \$10,011,420, respectively. The total increase in product sales is \$321,670 or 3.2%. Overall instrument sales decreased by \$102,923 as Milestone strategically decided to reduce instrument prices in 2014 to increase future handpiece sales. This trend was not successful and will not continue in the future. Domestic revenue decreased by \$643,904 or 12.2%. Of the decrease, \$415,038 represented decreased handpiece revenues. This decrease does not appear to be a long term issue. In 2013, there was a large purchase of handpieces as the end of the year. This sale resulted in a decrease in 2014 handpiece revenue. Domestic instrument sales decreased by \$183,633, principally due to the reduction price of STA instrument.

Internationally, the overall revenue for this segment increased by \$965,574 or 20.5% over 2013. The principal driver for the increase was handpiece sales, which increased by \$747,368. The CompuDent handpieces continued to have a substantial market share of the total handpieces on an international basis, even though our CompuDent instrument sales have been curtailed. Internationally, our STA instruments revenue is growing steadily and our STA handpieces business is increasing at a faster rate than the instrument sales.

Cost of products sold for the years ended December 31, 2014 and 2013 were \$3,630,765 and \$3,198,908, respectively. The \$431,857, or 14% increase in cost of sales is primarily due to added cost related to improvements in the voice chips of the STA instruments and an increase in sales volume.

Milestone generated a gross profit of \$6,702,325 or 65% in 2014 as compared to a gross profit of \$6,812,512 or 68% in 2013. The total dollar increase in gross profit was \$110,187 in 2014 over 2013. The gross profit percentage

decrease of 3% is due to the added cost of the improved voice chips in the STA as noted above with the lower selling price of the instruments to increase market penetration, thus providing a larger base of instruments in the market and as additional future handpiece sales.

Selling, general and administrative expenses for the years ended December 31, 2014 and 2013 were \$7,404,258 and \$5,534,463, respectively. The increase of \$1,869,795 approximately 34%, was included in all areas of expense categories. Marketing expenses increased by \$32,666 as Milestone increased its individual corporate expense in trade shows marketing studies for the dental and medical markets. Selling expenses decreased by \$100,412, with a more limited exposure of corporate personnel and third party field hygienists focusing their attention on dental groups and dental schools. Payroll expenses increased by \$66,214 overall for this expense category principally due to the increase in personnel. Other expenses increased by \$1,873,510, principally due to the increase

in consulting services for international distributors for the STA instruments (Dental), corporate marketing, investor relations and capital market advisors of approximately \$708,935 as the Company prepares its strategic marketing growth plan. Additionally, there was an increase in stock based compensation of \$209,935 for officers of the Company, \$169,259 for the pension of the CEO and a reversal of \$308,349 in bad debt in 2013. The bad debt reserve was established in 2010 for the sale of STA instruments to a distributor in China. As of December 31, 2014, the entire accounts receivable has been collected and the reserve is fully reversed.

Research and development expenses for the years ended December 31, 2014 and 2013 were \$88,243 and \$191,345, respectively, a decrease of \$103,102.

The loss from operations for the year ended December 31, 2014 was \$790,176 and income from operations for the year ended December 31, 2013 was \$1,086,704, respectively. The \$1,876,880 or 173% decrease in income from operations, is mainly attributable to a decrease in gross profit of \$110,187 and increased operating expenses of \$1,761,221.

For the year ended December 31, 2013, interest expense was \$70,801. The majority of this amount relates to the \$450,000 long term note payable. This note was converted to common stock on August 8, 2013. This did not occur in 2014.

There is a loss on the Medical Joint Venture of \$891,500 and \$924,363 for the years December 31, 2014 and 2013, respectively. The loss is a non cash loss for Milestone since the Medical Joint Venture is funded independently of the cash requirement of Milestone. There was a loss on the Education Joint Venture of \$17,890 and \$7,918 for the years ended December 31, 2014 and 2013, respectively. There was a loss on China Joint Venture of \$810 for the year ended December 31, 2014. This did not occur in 2013.

In 2013, Milestone recognized a Gain on Dilutive Effect on its shares in the Medical Joint Venture. As a result of issuance of 2 million shares by Milestone Medical Inc., (joint venture), Milestone's overall ownership percentage was reduced to 45.5% from originally 50%. The dilution in ownership percentage in accordance with the equity method of accounting resulted in recognized gain, (treated as if the reduced ownership shares were sold). As a result of the accounting, Milestone recognized a gain of \$1,363,650. This significant gain was not replicated in 2014.

For the reasons explained above, the net loss for the year ended December 31, 2014 was \$1,707,496 as compared to the net income for the year ended December 31, 2013 of \$1,464,930.

Liquidity and Capital Resources

As of December 31, 2014, Milestone had cash and cash equivalents of \$10,367,993, treasury bills of \$5,500,044 and a working capital of \$13,147,257. Milestone had net loss of \$1,707,496 for the year ended December 31, 2014 and a net income of \$1,464,930 for the year ended December 31, 2013. The working capital as of December 31, 2014 is the result of a capital raises in May 2014. Milestone raised \$10 million (\$9.4 million net) on the sale of common and convertible preferred stock. Current liabilities decreased by \$45,355. The principal reduction was in accounts payable as Milestone continues to keep current with its suppliers.

Accounts receivable increased by \$8,623, due to a large billing month in December 2014 over 2013, inventories increased by \$1,175,447, particularly in handpieces, to provide a safety stock of these items to meet our end user needs. Also, cash increased by \$9,220,795 for operations. Current liabilities decreased by \$100,424, principally due to a decrease in accounts payable by \$566,460 and offset by an increase in accrued expenses and other payables of \$466,036.

Milestone has also decreased noncurrent advances to a contract manufacturer of \$1,587,155 due to the increase in STA instrument inventory that was received in 2014. Milestone continues to take positive steps to maintain adequate

inventory levels and advances to contract manufacturers to maintain available inventory to meet our domestic and international sales requirements. Milestone had net loss of \$1,707,496 for the year ended December 31, 2014 and incurred a net income of \$1,464,930 for the year ended 2013. Cash flows from operating activities for the years ended December 31, 2014 and 2013 was a positive \$376,943 and \$1,258,736, respectively.

Milestone entered a Medical Joint Venture agreement with a third party in 2011, for the development and commercialization of two medical instruments. Milestone invested an additional \$75,000 into this Medical Joint Venture in 2013. Additionally, based on the joint venture agreement, Milestone financed the development and legal fees for FDA regulations in the USA (\$270,562) in 2014. Milestone recorded a \$1,363,650 Gain on the Dilutive Effect of these additional shares issued by Milestone Medical Inc. This did not occur in 2014. (See Note G to the Financial Statements.)

Milestone borrowed \$450,000 from a shareholder in 2008 and issued a \$450,000 promissory note to the same shareholder. In December 2008 and again in June 2011, Milestone refinanced the \$450,000 note, extending the due date to January 3, 2014. The \$450,000 Note is classified as a Long Term Note Payable on the Balance Sheet at December 31, 2012. In 2013, Milestone issued

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

613,644 shares (\$1.40 per share) of common stock on conversion of \$860,081 of principal and interest outstanding on the debt. (See Note J to the Financial Statements.)

Milestone, at December 31, 2014, has agreed to accept the remaining 1,546 STA instruments by first quarter 2015, liquidating the noncurrent advances to the subcontractor. Milestone 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, 2014 and 2013 were a positive \$376,943 and \$1,258,736, respectively.

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

For the years ended December 31, 2014 and 2013, Milestone used \$1,304,528 and \$561,387, respectively, in investing activities, primarily attributable to the Loss on the Joint Venture in 2014.

In 2014, the Company finalized a Private Placement of \$10 million (net \$9.4 million). These funds had the effect of increasing our cash provided from financing activities and provided a substantial financial base for the Company in 2014 and future years.

Milestone has incurred annual operating losses and negative cash flows from operating activities since its inception, except year ended December 31, 2013 and a positive cash flow in 2014. Milestone 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. With the \$10 million Private Placement (net \$9.4 million) in May 2014, Milestone believes that it does have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months from December 31, 2014.

Off-Balance Sheet Arrangements

Milestone 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 contractual obligations at December 31, 2014, expected on the liquidity and cash flows in future periods, is as follows:

	Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years
Operating lease obligations \$	508,486	\$ 114,985	\$ 338,990	\$ 54,510
Purchase obligations (1)	1,215,063	1,031,089	183,974	-
Total	\$ 1,723,549	\$ 1,146,074	\$ 522,964	\$ 54,510

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

Loan Commitments

In December 2014, Milestone entered into a line of credit with Milestone Medical Inc. to provide up to \$2 million. The funds from the loan will be used to finalize the commercialization of the medical instruments (epidural and intra-articular instruments.) The loan provides for interest charge at a rate of 3.25% per annum, the prime rate in the United States at the inception of the line of credit. The agreement terminates at April 15, 2016. No funds have been issued against the agreement as December 31, 2014.

Recent Accounting Pronouncements

See “Note B - Summary of Significant Accounting Policies” to the financial statements for explanation of recent accounting pronouncements impacting Milestone.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Milestone 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 required by this Item are set forth beginning on page F-1.

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

None.

Item 9A. Controls and Procedures

Milestone’s Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of Milestone’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’s Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of December 31, 2014 are effective to ensure that information required to be disclosed in the reports Milestone 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’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 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 management assessed the effectiveness of its internal control over financial reporting as of December 31, 2014. 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”) in 2013. Based on the assessment and the criteria set forth by COSO, management believes that Milestone maintained effective internal control over financial reporting as of December 31, 2014.

There have been no changes in Milestone’s internal control over financial reporting identified in connection with the evaluation that occurred during Milestone’s last fiscal quarter ended December 31, 2014 that have materially affected, or that are reasonably likely to materially affect, Milestone’s internal controls over financial reporting.

Item 9B. Other Information

None.

PART III

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

Milestone'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 and their respective ages as of March 31, 2015 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leslie Bernhard (2)	71	Chairman of the Board and Director	2003
Leonard Osser	67	Chief Executive Officer and Director	1991
Joseph D'Agostino	63	Chief Executive Officer and Chief Operating Officer	
Steven F. Robins	49	President	
Pablo Felipe Serna Cardenas (1)	40	Director	2006
Leonard Schiller (1) (2)	74	Director	1997
Gian Domenico Trombetta	54	Director	2014
Edward J. Zelnick, M.D.	69	Director	2015

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

Key Personnel

The following are the names of individuals who are not executive officers of Milestone but are deemed key personnel of Milestone, their respective ages and positions as of March 30, 2015:

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	70	Director of Professional Relations
Mark Hochman, D.D.S.	56	Director of Clinical Affairs

Leslie Bernhard, Chairman of the Board

In October 2009, Leslie Bernhard assumed the position of Chairman of the Board, filling a position left vacant by Mr. Osser who assumed the position of Chief Executive Officer. Leslie Bernhard has been serving as an Independent Director (as defined below) of Milestone since May 2003 and was named Chairman of the Board in September of 2009. 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'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

Mr. Osser has been Milestone's Chief Executive Officer and a director since September 2009. Prior to that, he served as Milestone's Chairman from 1991 until September of 2009, and during that time, from 1991 until 2007, was also Chief Executive Officer of Milestone. In September 2009, he resigned as Chairman of Milestone, but remained a director, and assumed the position of Chief Executive Officer. From 1980 until the consummation of Milestone'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

Joining Milestone in January 2008 as Acting CFO, Joseph D'Agostino brings to Milestone a wealth of finance and accounting experience earned over 25 years serving both publicly and privately held companies. Following a nine month performance assessment by the Board of Directors, Mr. D'Agostino was officially named Milestone's Chief Financial Officer in October 2008. Mr. D'Agostino was given the additional position of Chief Operating Officer in September 2011. 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. Immediately prior to joining Milestone, 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

Mr. Robins has been the President of Milestone and Milestone Medical Inc since January 1, 2015. Mr. Robins has an extensive background in the healthcare industry and has been working with Milestone 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 2013. 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

Dr. Hochman has served as 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.

Dr. Eugene Casagrande, Director of International & Professional Relations

Since 1998, Dr. Casagrande 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. 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

Mr. Schiller has been a director of Milestone since April 1997. Mr. Schiller has been a partner in the Chicago law firm of Schiller, Klein & McElroy, 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 Gravitas Cayman Corporation in February 2010. Gravitas Cayman Corporation is an Investment Fund. 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.

Pablo Felipe Serna Cardenas, Director

Mr. Serna Cardenas has been a director of Milestone since June 2006. He is the founder of SPOT Investments, a European-based financial services firm. Previously, from 2001 to 2005, he was a director and Senior Manager at Dynamic Decisions Group Ltd, an equity research and valuation consulting firm. In that capacity, Mr. Serna Cardenas led the corporate finance team at Dynamic Decisions in investment banking and project valuation consulting. Prior to joining Dynamic Decisions, from 1999-2001, Mr. Serna Cardenas served as an associate with Real Options Group. Real Options Group is an international academic research center consulting to business entities. Before joining Real Options Group, Mr. Serna Cardenas was the general manager with Studio's, Consultorias y Asesorias Financieras, a Financial Consulting firm in Columbia. He has been a director of Pairstech Fund, a UK hedge Fund since 2008. Mr. Cardenas' professional experience and background as an entrepreneur and as a financial consultant and with us, as one of our directors since 2006, have given him the expertise needed to serve as one of directors.

Gian Domenico Trombetta, Director

Mr. Trombetta became a director of Milestone in May 2014 and the President and Chief Executive Officer of Milestone'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, 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's professional experience and background as a medical doctor and in clinical research, have given him the expertise needed to serve as one of our directors. Dr. Zelnick became a director in February 2015.

Milestone'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, reviews general policy matters relating to compensation and benefits of employees of Milestone, and administers the issuance of stock options to Milestone's officers, employees, directors and consultants. All compensation arrangements between Milestone and its directors, officers and affiliates are reviewed by the Compensation Committee. The Audit Committee meets with management and Milestone'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 Pablo Felipe Serna Cardenas qualifies as an Audit Committee Financial Expert pursuant to Item 407 (d) (5) of Regulation S-K. Mr. Cardenas 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 person who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten-percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. Based solely on review of the copies of such forms furnish to us, or written representations that no Forms 5 were required, we believe that all Section 16(a) filing requirements applicable to our officers and director were complied with during the fiscal year ended December 31, 2014, except that our CEO did not timely file a Form 4 and our CFO did not timely file three Form 4s.

Code of Ethics

Milestone 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's web site at www.milesci.com. Milestone will also provide a copy of the Code of Ethics to any person without charge, upon written request addressed to the Chief Financial Officer, Joseph D'Agostino at the principal executive office, located at 220 South Orange Avenue, Livingston, NJ, 07039.

Item 11. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2014 and 2013 by (I) Milestone's CEO, Wand Dental Inc. CEO and (ii) the CFO, who are the most highly compensated executive officers other than the CEO who was serving as an executive officer at the end of the 2014 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 OF COMPENSATION TABLE

NAME AND PRINCIPAL POSITION	YEAR	Bonuses	Other Compensation	Option Awards (2)	Total
Leonard A. Osser Chief Executive Officer	2014	\$ 300,000	\$ 400,000	\$ 34,310	\$ 1,134,310
	2013	\$ 300,000	\$ 400,000	\$ 42,149	\$ 1,142,149
Gian Domenico Trombetta Chief Executive Officer Wand Dental Inc	2014	\$ 120,000	\$ 80,000	-	\$ 200,000
Joseph D'Agostino Chief Financial Officer	2014	\$ 171,600	\$ 206,750	\$ 33,460	\$ 413,500
	2013	\$ 171,600	\$ 50,000	\$ 33,012	\$ 100,000

- (1) Payment of \$400,000 of bonuses for the years ended December 31, 2014 and 2013, respectively, of which \$200,000, in 2013, was deferred and will be paid in common stock upon the termination of his employment with Milestone in accordance with the terms of his employment agreement. Other compensation represents payments made for business use of corporate apartment in China, health insurance coverage 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, 2014 and 2013, 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, 2014."
- (3) Payment of the bonuses have been deferred and will be paid in common stock upon the termination of his employment with Milestone in accordance with the terms of his employment agreement. Other compensation represents payments made for health insurance coverage and car allowance.

Employment Contracts

As of September 1, 2009, Milestone 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 or within 30 days after the termination of his employment.

In accordance with the employment contract, 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 and 1,306,716 shares of common stock are to be paid out at the end of the contract in settlement of \$1,408,333 at December 31, 2013 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. Under the 2008 agreement Mr. Osser is employed as an executive, but not the CEO. In March 2013, the 2008 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. A further objective of the compensation program is to provide incentives and reward each manager for their contribution. In addition, Milestone strives to promote an ownership mentality among key leadership and the Board of Directors.

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

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 does not currently engage any consultant to advise on executive and/or director compensation matters.

Stock price performance has not been a factor in determining annual compensation because the price of Milestone's common stock is subject to a variety of factors outside of the control. Milestone 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 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/retaining executive managers.

Outstanding Equity Awards at December 31, 2014

The following table includes certain information with respect to the value of all unexercised options previously awarded to the Named Executive Officers.

Name	Options Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable(1)	Number of Securities Underlying Unexercised Options (#) UnExercisable(1)	Option Exercise Price (\$)	Option Expiration Date	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	61,728	123,457	\$2.38	11/20/2019	706,717	\$1,625,449
	137,972	110,476	\$1.65	12/31/2018		
	133,334	-	\$0.75	1/9/2017		
	73,333	-	\$1.49	11/1/2019		
Total	406,367	233,933				
Joseph D'Agostino	50,000	100,000	\$2.09	11/11/2019	99,631	\$229,151.00
	16,423	32,838	\$2.03	11/20/2019		

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

	44,444	22,222	\$1.50	12/31/2018
	78,126	-	\$1.28	12/31/2017
	277,778	-	\$0.36	12/31/2016
	100,000	-	\$1.00	12/20/2015
	100,000	-	\$1.00	12/20/2015
Total	666,771	155,060		

(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 in accordance with the terms of his employment agreement.

(3) Based on the closing price per share of \$2.30 as reported on the OTCQB on December 31, 2014.

27

Compensation of Directors

Director Compensation

Name	2014 Stock Award (1)	Fees Earned or Paid in Cash (\$)	Total (\$)
Leonard M. Schiller	\$ 18,400	\$ 36,000	\$ 54,400
Leslie Bernhard	\$ 18,400	\$ 86,000	\$ 104,400
Pablo Felipe Serna Cardenas	\$ 18,400	\$ 36,000	\$ 54,400

(1) Represents the aggregate grant-date fair value of the awards computed in accordance with the FASB ASC Topic 718. 10,000 Shares, valued at \$1.84 per share on January 16, 2014, were issued to each director.

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

The following table, together with the accompanying footnotes, sets forth information, as of March 31, 2015, regarding stock ownership of all persons known by Milestone to own beneficially more than 5% of Milestone's outstanding common stock, Named Executives, all directors, and all directors and officers of Milestone as a group:

March 31, 2015

Names of Beneficial Owner (1)	Shares of Common Stock Beneficially Owned (2)	Percentage of Ownership
Executive Officers and Directors		
Leonard Osser	3,198,456	(3) 14.32%
Joseph D'Agostino	1,332,738	(4) 7.75%
Leonard Schiller	169,533	*
Pablo Felipe Serna Cardenas	33,043	*
Leslie Bernhard	35,000	*
Gian Domenico Trombetta	4,750,491	(5) 18.87%
Edward J. Zelnick, M.D.	-	-
All directors & executive officers as group (7 persons)	9,519,261	(6) 37.82%
K. Tucker Andersen	3,125,744	13.94%
Tom Cheng	1,150,099	5.13%

* Less than 1%

(1) The addresses of the persons named in this table are as follows: Leonard Osser, Joseph D'Agostino 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; Pablo Felipe Serna Cardenas, Via Camillo Golgi 2 Opera, Italy 20090; 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, and Tom Cheng, c/o United Systems 18725 E. Gale Ave Suite 221, City of Industry, CA 91748.

- (2) A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 30, 2015, 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 21,371,161 outstanding shares on March 30, 2015, plus those shares underlying options exercisable within 60 days from the filing of this report held by the named individual or the group.

- (3) Includes 2,085,373 shares held by Mr. Osser or family, 706,716 shares to be issued at the termination of his employment agreement, and 406,367 shares subject to common stock options; 73,333 at \$1.49, 133,334 at \$0.75, 137,972 at \$1.65 and 61,728 at \$2.38.
- (4) Includes 99,631 shares to be issued at the termination of employment. Also 566,339 shares held by Mr. D'Agostino at March 30, 2015. Additionally, this includes 666,768 shares subject to common stock options as follows: 200,000 shares at \$1.00; 277,778 shares at \$0.36; 78,126 shares at \$1.28; and 44,444 shares at \$1.50; 50,000 shares at \$2.09; and 16,420 at \$2.03.
- (5) Includes 2 million shares purchased through Innovest, BP4 and conversion of \$7 million of preferred stock at \$2.545 per share.
- (6) Includes an aggregate of 1,048,689 shares of common stock underlying outstanding options and the conversion of \$7 million of preferred stock at \$2.545 per share (2,750,491 shares)

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes, as of December 31, 2014, the (i) options granted under the Milestone 2004 Stock Option Plan and (ii) options granted under the Milestone 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	Weighted-average	Number of securities
	to be issued upon	exercise price of	remaining available for
	exercise outstanding	outstanding options	future issuance under
	options and warrants	and warrants	equity compensation plan
Equity compensation plan approved by stockholders			
Grants under our 2004 Stock Option Plan (1)	299,999	\$1.17	86,042
Grants under our 2011 Stock Option Plan (2)	1,188,797	\$1.38	754,537
Total	1,488,796	\$1.33	840,579

- (1) The 2004 Stock Option Plan, as amended, provides for the grant of options to purchase up to 750,000 shares of Milestone's common stock and expires in July 2014. Options may be granted to employees, officers, directors and consultants of Milestone for the purchase of common stock of Milestone 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. For the year ended December 31, 2014, 312,293 shares were exercised.
- (2) The 2011 Stock Option Plan provides for the grant of options to purchase 2,000,000 shares of Milestone's common stock and expires in June 2021. Options may be granted to employees, directors and consultants of Milestone for the purchase of common stock of Milestone 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. 56,666 options were exercised in 2013.

Stock Plan

In 2006 Milestone adopted an equity compensation plan for the issuance of up to 300,000 shares of the common stock in lieu of cash compensation for services performed by employees, officers, directors and consultants (the “2006 Stock Plan”). The purpose of the 2006 Stock Plan is to conserve cash while allowing Milestone to adequately compensate existing employees, officers, directors and consultants, or new employees, officers, directors and consultants, whose performance will contribute to the long-term success and growth. Milestone believe that the availability of these shares will also strengthen the ability to attract and retain employees, officers, directors and consultants of high competence, increase the identity of interests of such people with those of the stockholders and help maintain loyalty to us through recognition and the opportunity for stock ownership. All shares granted under this plan will be at fair market value, or at a premium to that value, on the date of grant. As of December 31, 2014 there are no shares remaining for grants under the 2006 Stock Plan.

In December 2007, the Board of Directors authorized Milestone 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. At December 31, 2014 and 2013 there were \$11,316, respectively, available to be issued under this plan.

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

In 2008, Milestone borrowed \$450,000 from K. Tucker Andersen, the beneficial owner of over 13% of Milestone's common stock. The borrowing was originally a short term loan with a maturity date of January 19, 2009. In December 2008 and again on June 30, 2011, this borrowing was refinanced with the shareholder and the due date was extended to January 3, 2014. The note issued on this borrowing included a twelve percent interest rate, interest compounded quarterly, with interest and principle due at the maturity. Further, the note provided for the issuance of warrants to the stockholder that is exercisable for five years at the price of \$0.32 per share for 45,000 shares of common stock. The warrants were valued using the Black-Scholes model and are reflected as a discount against the debt. These warrants expired in June 2012. In 2013, Milestone issued 614,344 shares (\$1.40 per share) of common stock on conversion of \$830,081, all of principal and interest on the outstanding note.

In 2013, Milestone entered a three year consulting agreement with K. Tucker Anderson to provide business and strategic services to the CEO of Milestone. The fee for these services are \$100,000 annually.

Tom Cheng, a beneficial owner of over 5% of Milestone's common stock, is also a shareholder of a major supplier of handpieces to the Milestone. Milestone purchased \$2,698,042 and \$3,026,041 from this supplier for the years ended December 31, 2014 and 2013, respectively. In addition, Mr. Cheng is also a shareholder of Beijing 3H and an investor in the Medical Joint Venture.

In the first quarter of 2013, the CEO of Milestone loaned Milestone \$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 condensed balance sheets. There is no interest to this agreement. The loan was paid in 2014 without interest.

Director Independence

The Board has determined that Leonard M. Schiller, Leslie Bernhard, Pablo Felipe Serna Cardenas 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, Pablo Felipe Serna Cardenas and Leonard M. Schiller members of the Audit Committee and are independent for such purposes, and Leonard M. Schiller and Leslie Bernhard are members of the Compensation Committee and are independent for such purposes.

In determining director independence, the Board considered the stock awards to the Independent Directors for the year ended December 31, 2014, 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 incurred audit and financial statement review fees totaling \$127,450 and \$143,166, respectively from Baker Tilly Virchow Krause, LLP, its principal accountant for 2014 and 2013.

Audit Related Fees

There were no audit related fees to the principal accountant Baker Tilly Virchow Krause, LLP in 2014 and 2013.

Tax Fees

There were no fees for services related to tax compliance, tax advice and tax planning billed by the principal accountant in 2014 and 2013.

All Other Fees

There were no other fees billed during 2014 and 2013 by Milestone'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 2014.

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 financial statements and the reports of Milestone's independent auditor thereon, are filed herewith.

- Report of Independent Registered Public Accounting Firm
- Balance Sheets at December 31, 2014 and 2013
- Statements of Operations for the years ended December 31, 2014 and 2013
- Statement of Changes in Stockholders' Equity for the years ended December 31, 2014 and 2013
- Statements of Cash Flows for the years ended December 31, 2014 and 2013
- Notes to 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 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 September 6, 2013 (14)
3.2	By-laws of Milestone (1)
4.1	Speciman 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	Employment Agreement with Leonard Osser, dated December 20, 2003 (4)
10.3	Agreement with Mark Hochman, dated January 1, 2005 (5)
10.4	Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (5)
10.5	Employment Agreement with Leonard Osser, dated September 1, 2009 (7)
10.6	Amendment to the loan agreement of \$1.3 million from K. Tucker Andersen, dated April 18, 2008 (8)
10.7	2004 Stock Option Plan (9)
10.8	2011 Stock Option Plan (10)
10.9	Amendment to the Employment Agreement with Leonard Osser, dated March 6, 2013 (11)
10.10	Master Supply and Distribution Agreement, dated July 3, 2013, between Milestone Scientific Inc and Tri-anim Health Services, Inc (12)
10.11	Amendment to the Employment Agreement with Leonard Osser, effective March 17, 2014 (13)
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	

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

32.2 Section 1350 Certifications-Chief Financial Officer***
101.INS XBRL Instance Document*
101.SCH XBRL Taxonomy Extension Schema Document*
101.CAL XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB XBRL Taxonomy Extension Label Linkbase Document*
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF XBRL Taxonomy Extension Definition Linkbase Document*

*Filed herewith.

**Indicates management contract or compensatory plan or arrangement.

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

- (1) Incorporated by reference to Milestone's Registration Statement on Form SB-2 No. 333-92324.
- (2) Incorporated by reference to Amendment No. 1 to Milestone's Registration Statement on Form SB-2 No. 333-92324.
- (3) Incorporated by reference to Milestone's Form 10-KSB for the year ended December 31, 1996.
- (4) Incorporated by reference to Milestone's Registration Statement on Form S-2 No. 333-110376, Amendment No. 2.
- (5) Incorporated by reference to Milestone's Form 10-KSB for the year ended December 31, 2004.
- (6) Incorporated by reference to Milestone's Registration Statement on Form S-2 No. 333-110367, Amendment No. 5.
- (7) Incorporated by reference to Milestone's Form 10-K for the year ended December 31, 2009.
- (8) Incorporated by reference to Milestone's Form 10-K for the year ended December 31, 2010.
- (9) Filed as Appendix C to Milestone's Proxy Statement filed with the SEC on June 28, 2004 and incorporated herein by reference.
- (10) Filed as Appendix A to Milestone's Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.
- (11) Incorporated by reference to Milestone's 10-K for the year ended December 31, 2013.
- (12) Incorporated by reference to Milestone's Form 8-K filed with the SEC on July 9, 2013.
- (13) Incorporated by reference to Milestone's Form 10-Q filed with the SEC on May 13, 2014.
- (14) Incorporated by reference to Milestone's Form 10-K for the year ended December 31, 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: March 31, 2015

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

Signature	Date	Title
/s/ Leonard Osser Leonard Osser	March 31, 2015	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Joseph D'Agostino Joseph D'Agostino	March 31, 2015	Chief Financial Officer (Principal Financial Officer)
/s/ Leonard Schiller Leonard Schiller	March 31, 2015	Director
/s/ Leslie Bernhard Leslie Bernhard	March 31, 2015	Chairman and Director
/s/ Pablo Felipe Sema Cardenas Pablo Felipe Sema Cardenas	March 31, 2015	Director
/s/ Gian Domenico Trombetta Gian Domenico Trombetta	March 31, 2015	Director
/s/ Edward J. Zelnick, M.D. Edward J. Zelnick, M.D.	March 31, 2015	Director

INDEX TO FINANCIAL STATEMENTS

	Page
<u>Consolidated Report of Independent Registered Public Accounting Firm</u>	F- 2
<u>Consolidated Balance Sheets as of December 31, 2014 and 2013</u>	F- 3
<u>Consolidated Statements of Operations for the years ended December 31, 2014 and 2013</u>	F- 4
<u>Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2014 and 2013</u>	F- 5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013</u>	F- 6
<u>Notes to Consolidated Financial Statements</u>	F- 7

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Milestone Scientific Inc.

We have audited the accompanying consolidated balance sheets of Milestone Scientific Inc. as of December 31, 2014 and 2013 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 standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, 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, 2014 and 2013 and the results of its operations and its 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

March 31, 2015

MILESTONE SCIENTIFIC INC.

BALANCE SHEETS

December 31, 2014 and 2013

	December 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 10,367,993	\$ 1,147,198
Accounts receivable, net of allowance for doubtful accounts of \$5,000 in 2014	1,541,478	1,532,856
Inventories	2,497,099	1,321,652
Advances on contracts	721,197	727,478
Prepaid expenses and other current assets	454,567	150,451
Total current assets	15,582,334	4,879,635
Advances on contracts	-	1,580,874
Investment in Milestone Medical Inc.	888,720	924,115
Investment in Milestone Education LLC	24,192	42,082
Investment in Milestone China	348,651	-
Furniture, Fixtures & Equipment net of accumulated depreciation of \$416,210 as of December 31, 2014 and \$476,884 as of December 31, 2013	88,818	23,988
Patents, net of accumulated amortization of \$576,960 as of December 31, 2014 and \$498,502 as of December 31, 2013	530,029	591,735
Other assets	14,685	12,917
Total assets	\$ 17,477,428	\$ 8,055,346
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,453,908	\$ 2,020,368
Accrued expenses and other payables	981,168	515,132
Total current liabilities	2,435,076	2,535,500
Total liabilities	2,490,146	2,535,500
Commitments and Contingencies		
Stockholders' Equity		
Series A Convertible Preferred Stock, par value \$.001, authorized 5,000,000 shares, 7,000 and zero shares issued and outstanding, respectively	\$ 7	\$ -
Common stock, par value \$.001; authorized 50,000,000 shares; 21,404,494 shares issued 974,953 shares to be issued and 21,371,161 shares outstanding as of December 31, 2014; 17,759,540 shares issued 1,839,930 shares to be issued and 17,726,207 shares outstanding as of December 31, 2013	22,380	19,599
Additional paid-in capital	77,504,415	66,677,200
Accumulated deficit	(61,967,462)	(60,265,438)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total stockholders' equity	14,647,824	5,519,846
Noncontrolling interest	394,528	-
Total Equity	15,042,352	5,519,846
Total liabilities and stockholders' equity	\$ 17,477,428	\$ 8,055,346
See Notes to Financial Statements		

F-3

MILESTONE SCIENTIFIC INC.

STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2014 AND 2013

	2014	2013
Product sales, net	\$10,333,090	\$10,011,420
Cost of products sold	3,630,765	3,198,908
Gross profit	6,702,325	6,812,512
Selling, general and administrative expenses	7,404,258	5,534,463
Research and development expenses	88,243	191,345
Total operating expenses	7,492,501	5,725,808
(Loss) income from operations	(790,176)	1,086,704
Other income (expense)		
Other income	-	17,543
Interest income	5,057	115
Interest expense	(2,668)	(70,801)
Loss on Earnings from Medical Joint Venture	(891,500)	(924,363)
Loss on Earnings from Education Joint Venture	(17,890)	(7,918)
Loss on Earnings from China Joint Venture	(810)	-
Gain on Dilutive Effect on Medical Joint Venture stock issuance	-	1,363,650
Total other expense, net	(907,811)	378,226
(Loss) income before provision for income taxes	(1,697,987)	1,464,930
Provision for Income Tax	9,509	-
Net (loss) income	(1,707,496)	1,464,930
Less: Net loss attributable to the noncontrolling interest	5,472	-
Net (loss) income attributable to Milestone Scientific Inc.	\$(1,702,024)	\$ 1,464,930
Net (loss) income per share applicable to common stockholders -		
Basic	\$(0.08)	\$0.09
Diluted	\$(0.08)	\$0.08
Weighted average shares outstanding and to be issued -		
Basic	20,063,513	17,127,468
Diluted	20,063,513	17,483,638

See Notes to Financial Statements

MILESTONE SCIENTIFIC INC.

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2014 AND 2013

	Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interest	Treasury Stock	Total
Balance, January 1, 2013	-	\$-	18,199,015	\$18,199	\$64,560,224	\$(61,730,368)	-	\$(911,516)	\$1,936,539
Options issued to employees and consultants			-	-	219,196	-	-	-	219,196
Common stock to be issued to employee for bonuses			204,222	204	311,796	-	-	-	312,000
Common stock issued for directors compensation			39,129	39	44,961	-	-	-	45,000
Common stock issued for payment of consulting services to settle accounts payable			312,956	313	399,687	-	-	-	400,000
Common stock issued for conversion of notes payable and accrued interest			614,344	614	859,466	-	-	-	860,080
Common stock issued for payment of employee compensation			37,425	37	47,463	-	-	-	47,500
Exercise of stock options			56,666	57	34,543	-	-	-	34,600
Issuance of common stock for cash			135,714	136	199,864	-	-	-	200,000
Net income			-	-	-	1,464,930	-	-	1,464,930
Balance, December 31,	-	-	19,599,470	19,599	66,677,200	(60,265,438)	-	\$(911,516)	5,519,846

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

2013										
Options to employees and consultants										
Capital Contribution from noncontrolling interest										
Common stock to be issued to employee for bonuses										
Common stock issued for directors compensation										
Common stock issued for payment of consulting services										
Common stock issued for payment of employee compensation										
Exercise of stock options for employees and consultants										
Exercise of stock options for directors										
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	\$(61,972,462)	\$394,528	(911,516)		\$15,042,352
See Notes to Financial Statements										

F-5

MILESTONE SCIENTIFIC INC.

STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2014 AND 2013

	2014	2013
Cash flows from operating activities:		
Net income (loss)	\$ (1,702,024)	\$ 1,464,930
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Net loss contributed from noncontrolling interest	(5,472)	-
Depreciation expense	17,380	18,176
Amortization of patents	78,458	77,947
Common stock and options issued for compensation, consulting, and vendor services	1,031,623	1,077,213
Bad debt reversal		(308,350)
Loss on Earnings from Medical Joint Venture	891,500	924,363
Loss on Earnings from Education Joint Venture	17,890	7,918
Loss on China Joint Venture	810	-
Gain on Dilutive Effect on Medical Joint Venture	-	(1,363,650)
Changes in operating assets and liabilities:		
(Increase) Decrease in accounts receivable	(8,623)	(126,323)
(Increase) Decrease in inventories	(1,175,447)	(683,091)
Decrease to advances on contracts	1,587,155	519,094
Decrease to prepaid expenses and other current assets	(304,114)	88,610
(Increase) in other assets	(1,768)	(5,600)
(Decrease) in accounts payable	(516,460)	(316,226)
Increase (Decrease) in accrued expenses	466,035	(116,275)
Net cash provided by (used in) operating activities	376,943	1,258,736
Cash flows from investing activities:		
Investment in Education Joint Venture	-	(50,000)
Investment in Medical Joint Venture	(856,105)	(484,828)
Investment in China Joint Venture	(349,461)	-
Purchases of property and equipment	(82,210)	(5,539)
Payments for patent rights	(16,752)	(21,020)
Net cash used in investing activities	(1,304,528)	(561,387)
Cash flows from financing activities:		
Proceeds from exercise of stock options	348,697	34,600
Proceeds from the sale of common stock	-	200,000
Capital Contribution from noncontrolling interest	400,000	-
Net proceeds on Private Placement Offering	9,449,683	-
Proceeds from related party loan	-	50,000
Net cash provided by financing activities	10,148,380	284,600
NET INCREASE IN CASH AND CASH EQUIVALENTS	9,220,795	981,949
Cash and cash equivalents at beginning of year	1,147,198	165,249
Cash and cash equivalents at end of year	\$ 10,367,993	\$ 1,147,198
Supplemental disclosure of non cash investing and financing activities:		
Shares issued to directors for the exercise of stock options	\$ 41,250	\$ 34,600
Shares issued to directors for compensation	\$ 55,200	\$ 45,000

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

Shares issued for conversion of notes payable and accrued interest	\$ -	\$860,081
Shares issued to employees for exercise of stock options	\$ 250,531	-
Shares issued to employees in lieu of cash compensation	\$ 69,041	\$47,500
Shares issued to consultants for services	\$ 274,500	\$400,000
Shares issued to consultants for exercise of stock options	\$ 56,916	\$-
Capital Contribution-Fixed Asset, net for Medical Joint Venture	\$ 21,584	\$-
Gain on Dilutive Effect on Medical Joint Venture	\$ -	\$1,363,650
See Notes to Financial Statements		

F-6

MILESTONE SCIENTIFIC INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE A — ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Milestone Scientific Inc and subsidiary, (collectively “Milestone”, “our”, “us” or “we”) was incorporated in the State of Delaware in August 1989. Milestone 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’s products are manufactured by a third-party contract manufacturer.

Beginning July 1, 2014, Milestone Scientific Inc acquired 100 percent of an inactive, previously established company and merged the Milestone dental business into this company. As part of this merger, Milestone now owns 100 percent of this new subsidiary Wand Dental Inc. The subsidiary, Wand Dental Inc, has an exclusive distributor and licensing agreement for Milestone dental instruments and handpieces for the worldwide. All current Milestone distributors will be assigned to Wand Dental Inc.

Milestone has incurred operating losses and negative cash flows from operating activities since its inception, except for 2013 and the first quarter of 2014. Milestone is actively pursuing the generation of revenue, positive operating income and net income. The capital raised in May 2014, provides Milestone with the opportunity to continue to develop and commercialize additional medical instruments and aggressively market on dental instruments throughout the world. Milestone 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, 2014, Milestone has sufficient cash reserves to meet all of its anticipated obligations for the next twelve months.

NOTE B — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1. Principles of Consolidation

The accompanying consolidated financial statement have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and include the account of Milestone and its wholly owned subsidiary Wand Dental Inc. . Additionally, the consolidated financial statement include the account of Milestone Scientific Advanced Cosmetic System, Inc. (“ACS”), a company that is seventy (70) percent owned by Milestone. The minority interest (thirty percent) in ACS is recorded in the equity section of the consolidated financial statements as noncontrolling interest. All significant intercompany transactions and balances have been eliminated in the consolidation.

2. Cash and Cash Equivalents

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

3. Accounts Receivable

Milestone records accounts receivable at estimated net realizable value. The realization of accounts receivable current and long-term will have a significant impact on Milestone. Consequently, Milestone estimates losses resulting from the inability of its customers to make payments for amounts billed. The collectability of outstanding amounts is continually assessed (historical trend and credit worthiness of the customers).

4. Marketable Securities - Treasury Bills

Milestone invests excess cash in Treasury Bills with varying maturities, which are classified as available-for-sale securities and are re-measured to fair value on a recurring basis and are valued using Level 1 inputs, which are quoted prices (unadjusted) for identical assets in active markets:

F-7

5. Product Return and Warranty

Milestone 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 all evaluated and the customer is charged for the repair. Warranty expense was \$79,017 and \$97,234 for 2014 and 2013, respectively. Non-Warranty repairs are collected from the customers. Non-Warranty repair income was \$60,473 and \$118,344 for 2014 and 2013, 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. Investment in Unconsolidated Subsidiaries

Milestone Medical Inc.

Milestone has entered into a joint venture with a third party to form Milestone Medical Inc. ("Medical"), for the purpose of developing and commercializing two medical instruments. At inception, Milestone owned fifty percent of the joint venture and is recording its investment on the equity method of accounting. Milestone's proportionate share of losses incurred by Medical is charged to the Statement of Operations and adjusted against the Investment in Joint Venture. In the fourth quarter of 2013, Medical issued 2 million shares of its common stock in a private placement transaction. As a result of the shares being issued, Milestone's ownership in the Joint Venture was reduced to 45.5% and Milestone recorded a gain of \$1,363,650 as a result of the dilutive effect of these additional shares issued by Medical.

In the fourth quarter of 2014, Milestone Scientific purchased 995,000 shares, which increased its ownership to 49.9%, from a founding shareholder for \$447,750 (\$0.45 per share).

Milestone China Inc.

In June 2014, Milestone agreed to invest \$1.0 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 Inc. ("Milestone China"), a Hong Kong based medical and dental distribution company. The instruments will be shipped to the distributors over a period of two years and Milestone China will purchase future STA handpieces on a cash basis as required. 300 STA instruments were shipped in July 2014 and were recorded at Milestone's cost in the investment in Milestone China on the Balance Sheet in the third quarter of 2014. Milestone China did not begin operations until July 2014, and incurred a loss of \$2,025 for the year ending December 31, 2014. Forty percent of the loss, (\$810), was recorded in the consolidated statement of operations for the year ended December 31, 2014. Accordingly, the investment is recorded as \$348,651 as of December 31, 2014.

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 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. Milestone 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.

F-8

10. Impairment of Long-Lived Assets

Milestone 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 adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. Milestone has reviewed long-lived assets for impairment and concluded no impairment exist as of December 31, 2014 and 2013.

11. Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to the domestic distributor on the date of shipment of the goods, for essentially all shipments, since the terms are FOB warehouse. Milestone recognizes revenue on date of arrival where shipments are FOB destination. Shipments to the international distributors are FOB warehouse and revenue is therefore recognized on shipment. In both cases, the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone has no obligation on these sales for any post sale installation, set-up or maintenance, these being the responsibility of the buyer. Customer acceptance is considered made at delivery. The 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 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.

13. Research and Development

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

14. Advertising Expenses

Milestone expenses advertising costs as they are incurred. For the years ended December 31, 2014 and 2013, Milestone recorded advertising expenses of \$26,569 and \$30,104, respectively.

15. Income Taxes

Milestone 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 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 had net losses for 2014, the assumed effects of the exercise of 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 1,488,796 at December 31, 2014.

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

F-9

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 valuation allowances on deferred tax assets. Actual results could differ from those estimates.

18. Fair Value of Financial Instruments

Fair Value Measurements: We follow the provisions of ASC 820, Fair Value Measurements and Disclosures related to financial assets and liabilities that are being measured and reported on a fair value basis. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). We are required to classify fair value measurements in one of the following categories:

Level 1 inputs which are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs which are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

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

19. Stock-Based Compensation

Milestone 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 2014 and 2013 was estimated as \$2.18 and \$1.62, respectively, on the date of grant. The fair value for 2014 and 2013 was determined using the Black-Scholes option-pricing model with the following weighted average assumptions:

	December 31,			
	2014		2013	
Volatility	149	%	168	%
Risk-free interest rate	1.62	%	1.37	%
Expected life	5 years		5 years	
Dividend yield	0	%	0	%
Forfeiture Rate	6	%	6	%

20. Recent Accounting Pronouncements

On May 28, 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-10, Revenue from Contracts with Customers. The objective of this update is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. This standard update contains principles that the Company will apply to determine the measurement of revenue and timing of when it is recognized. The Company will adopt this guidance

effective January 1, 2017, and is currently assessing the impact it may have on the Company's consolidated financial statements.

In August 2014, the FASB issued authoritative guidance requiring management to evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. This guidance is effective for the annual reporting period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and disclosures.

In November, 2014, the FASB issued Accounting Standards Board Update No. 2014-17: Business Combinations - Pushdown Accounting ("ASU 2014-17"). ASU 2014-17 provides an acquired entity with an option to apply pushdown accounting in its separate financial statements upon occurrence of an event in which an acquirer obtains control of the acquired entity. This new guidance became effective on November 18, 2014. The requirements of ASU 2014-17 did not have any impact on the Company's financial statements.

NOTE C — ACCOUNTS RECEIVABLE

Milestone sells a significant amount of its product on credit terms to its major distributors. Milestone estimates losses from the inability of its customers to make payments on amounts billed. A majority of credit sales are due within sixty days from invoicing.

NOTE D — INVENTORIES

	December 31	
	2014	2013
Inventories consist of the following:		
Finished Goods	\$2,466,829	\$1,186,376
Component parts and other materials	30,270	135,276
	\$2,497,099	\$1,321,652

NOTE E — ADVANCES ON CONTRACTS

Milestone has entered into fixed arrangements with a contract manufacturer to manufacture STA, CompuDent and Wand Plus. The contract manufacturer bills Milestone as the work progresses and it is Milestone'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. The balance of the advances as of December 31, 2014 and 2013 totaled \$721,197 and \$2,308,352, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory. Milestone also has an outstanding accounts payable of approximately \$113,873 and \$37,000 at December 31, 2014 and 2013, respectively to the contract manufacturer related to the progress billings received. Milestone charged to operations approximately \$60,000 in 2013 for STA parts that had expired shelf lives.

NOTE F – INVESTMENT IN JOINT VENTURES

Milestone Medical Inc

In March 2011, Milestone entered into an agreement with shareholders of Beijing 3H Scientific Technology Co., Ltd (Beijing 3H), a People's Republic of China, ("PRC") Company and a group of other investors, to establish a medical joint venture entity in the PRC to develop intra-articular and epidural drug delivery instruments utilizing Milestone's patented CompuFlo technology. Shareholders of Beijing 3H and other investors agreed to contribute up to \$1.5 million to this medical joint venture entity. Milestone contributed an exclusive worldwide royalty-free license to use CompuFlo technology to the joint venture. The initial cash investment of \$1.5 million was subject to refund if the instruments were not developed because of technological problems within 30 months of the inception date. Milestone evaluated the technological feasibility of the products to be developed using the CompuFlo technology periodically and at every reporting date to establish if circumstances indicate if the technology continued to be feasible. Based on the available evidence Milestone concluded that the contingency associated with the return of capital to shareholders of Beijing 3H and a group of investors no longer existed as of December 31, 2013, since the instruments have advanced beyond the development stage and accordingly no amounts have been accrued in the accompanying financial statements relating to this contingency. Milestone, with the consent of Beijing 3H, organized a domestic research and development corporation now known as Milestone Medical Inc. ("Milestone Medical") to which the principal shareholders of Beijing 3H and other shareholders completed a capital contribution of \$1,500,000 and Milestone Medical was initially owned fifty percent by shareholders of Beijing 3H and fifty percent by Milestone. Milestone Medical had a remaining net book value of approximately \$349,000 at December 31, 2014. Milestone has accounted for its investment in Milestone Medical using the equity method of accounting. Further, Milestone was authorized by the Milestone Medical to manage and oversee the development of the epidural and intra-articular instruments. In connection with this authorization, Milestone also entered into an agreement with a significant vendor to develop these two instruments.

Milestone has distribution responsibility in the U.S. and Canada. Beijing 3H will distribute in Macao, Hong Kong and other regions of Asia. Milestone Medical will distribute the epidural instruments in the PRC. In the rest of the world, responsibilities are shared by Milestone and Beijing 3H.

In July 2013, Milestone entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare in the United States. During the three year strategic partnership, the distributor will hold the exclusive rights to market,

resell, label and distribute Milestone's CompuFlo injection technology for use in epidural applications for childbirth and other pain management needs in hospitals in the U.S. This agreement will begin after FDA approval.

In the fourth quarter of 2013, Milestone Medical issued 2 million shares of its common stock in a private placement offering at \$1.50 per share (\$3.0 million) in Poland. As a result of this sale, Milestone Medical received net proceeds of \$2,363,000. The effect of this sale of new shares was to reduce Milestone's ownership percentage from 50% to 45.5% (post transaction). Consistent with the equity method of account, the ownership percentage is treated as if the decreased percentage of ownership was the result of the sale of these shares. As a result, Milestone recorded in the fourth quarter of 2013, a \$1,363,650 gain on dilutive effect of the sale of equity in Milestone Medical.

In the fourth quarter of 2014, the Company purchased an additional 995,000 shares from a former shareholder in Milestone Medical Inc for \$447,750 (\$0.45 per share). After this purchase, the Company owned 49.98% of Milestone Medical. At the same time, Milestone Medical Inc terminated its distribution agreement with Beijing 3H. Milestone Medical Inc contracted with Milestone China to become the new distributor in Asia for both the epidural and intra-articular instruments. The Company owns forty percent of Milestone China Ltd.

Milestone recorded a loss on its investment in Milestone Medical of \$891,500 and \$924,363 for the years ended December 31, 2014 and 2013, respectively. The losses described represent 49.98% and 50% of the applicable losses reported by the Medical Joint Venture during the years ended December 31, 2014 and 2013, respectively. Milestone utilizes the equity method of accounting to recognize its financial results of the joint venture.

Milestone expensed \$249,966 and \$225,979 on behalf of the Milestone Medical for the years ended December 31, 2014 and 2013, respectively, for legal expenses related to seeking U.S. Food and Drug Administration marketing clearance for the epidural and intra-articular devices under section 510k. As part of the joint venture agreement, Milestone is to pay all fees related to the FDA clearance process.

Milestone had an investment in Milestone Medical of \$888,720 as of December 31, 2014 and there are no remaining suspended losses.

On July 1, 2013, Milestone and Milestone Medical signed an agreement for the reimbursement of specific expenses incurred by Milestone specifically for the benefit of Milestone Medical. The expenses related to the agreement that have not been paid are \$125,144 as of December 31, 2014 and are included in accounts receivable, net.

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

The following condensed financial information of Milestone Medical Inc., Medical Joint Venture, and 49.98% ownership of Milestone at December 31, 2014 and 2013, respectively is as follows:

Milestone Medical Inc Financial Information

	December 31,	
	2014	2013
Current Assets	\$1,582,415	\$2,258,809
Non Current Assets	1,593,737	1,561,130
Total Assets	\$3,176,152	\$3,819,939
Current Liability	\$962,655	\$125,962
Equity	2,213,497	3,693,977
Total Liability and Equity	\$3,176,152	\$3,819,939

	December 31,	
	2014	2013
Revenue	\$-	\$-
Operation expenses	1,896,784	1,019,606
Net Loss	\$(1,896,784)	\$(1,019,606)

Milestone Medical Inc. is a Development Stage Company and does not have revenues at this time. Milestone has recorded its share of the losses \$891,500 and \$509,803 for December 31, 2014 and 2013, respectively.

Milestone Education Inc.

In the first quarter of 2013, the CEO of Milestone loaned Milestone \$50,000 for use in capitalizing a fifty percent equity portion in the joint venture with Milestone Education LLC (the “Education Joint Venture”). This balance is included in the accrued expenses and other payables on the condensed balance sheet at December 31, 2013. This loan bore no interest and was paid off in April 2014.

The Education Joint Venture is expected to provide training and education to our dentists throughout the world. Milestone accounted for its investment in the Education Joint Venture using the equity method of accounting. Milestone Education LLC began operations in 2013. The Education Joint Venture incurred a loss of \$35,779 and \$15,836 for the years ended December 31, 2014 and 2013, respectively. Fifty percent of these losses were recorded in the consolidated statements of operations for the years ended December 31, 2014 and 2013, respectively

Milestone China Inc

In June 2014, Milestone agreed to invest \$1.0 million through the contribution of 772 STA instruments (at a distributor price of approximately \$1,295 per instrument) for a forty percent ownership in a Hong Kong based medical and dental distribution company, (“Milestone China”). The instruments will be shipped to the distributors over a period of two years. Milestone China will purchase STA handpieces on a cash basis as required. 300 STA instruments were shipped in July 2014 and are recorded at Milestone’s cost in the investment account for Milestone China on the Balance Sheet in the third quarter of 2014. Milestone China did not begin operations until July 2014. The Milestone China Joint Venture incurred a loss of \$810, which is forty (40) percent of the \$2,025 net loss, for the year ended December 31, 2014, respectively. Forty percent of the loss were recorded in the condensed statement of operations for the year ended December 31, 2014. Accordingly, the investment was recorded as \$348,651 as of December 31, 2014.

NOTE G — FURNITURE, FIXTURES AND EQUIPMENT

	December 31	
	2014	2013
Furniture, Fixtures and Equipment consist of the following:		
Leasehold improvements	\$24,734	\$22,317
Office furniture and equipment	122,198	96,703
Molds	7,200	7,200
Trade show displays	89,395	89,395
Computers and software	166,272	190,027
Tooling equipment-STA & Wand	31,477	31,477
STA Trials Instruments	63,752	63,752
Total	505,027	500,871
Less accumulated depreciation	(416,210)	(476,884)

\$88,818 \$23,988

Depreciation expense was \$17,380 and \$18,176 for the years ended December 31, 2014 and 2013, respectively.

NOTE H — 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 \$78,458 in 2014 and \$77,947 in 2013. Estimated amortization expense of existing patents for each of the next five fiscal years amounts to approximately \$79,000 per year.

NOTE I— LINE OF CREDIT AND NOTES PAYABLE

Milestone borrowed \$450,000 from a shareholder in 2008. The loan was originally a short term loan with a maturity date of January 19, 2009. In December 2008, May 30, 2012 and again on March 29, 2013, this loan was extended with the shareholder and the due date was been extended to January 5, 2015. The loan accrued interest at 12% per annum, interest compounded quarterly, and interest and principal was due at maturity. The loan (\$450,000) and related interest (\$410,081) was converted to 614,344 shares of common stock on August 8, 2013.

NOTE J — STOCKHOLDERS' EQUITY

ISSUANCES OF PREFERRED AND COMMON STOCK

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

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 237,293 shares valued at \$250,531 for exercise of stock options to employees.

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

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

During 2014, Milestone's to be issued shares are 112,131 valued at \$226,750 for employees for bonus compensation.

During 2013, Milestone issued 39,129 shares valued at \$45,000 for the director's compensation.

During 2013, Milestone issued 312,956 shares valued at \$400,000 for payment of consulting services.

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

During 2013, Milestone issued 614,344 shares valued at \$860,080 for the conversion of notes payable and accrued interest.

During 2013, Milestone issued 37,425 shares valued at \$47,500 for payment of employee compensation.

During 2013, Milestone issued 56,666 shares valued at \$34,600 for exercise of stock options to two independent directors.

During 2013, Milestone sold 135,714 shares valued at \$200,000.

During 2013, Milestone's to be issued shares are 204,222 valued at \$312,000 for employee for bonus compensation.

SHARES TO BE ISSUED

As of December 31, 2014 and 2013, there were 954,953 and 1,839,930 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. 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.

SHARES RESERVED FOR FUTURE ISSUANCE

At December 31, 2014 and 2013 there were 2,443,749 and 3,497,761 shares reserved for future issuance; 1,488,796 and 1,657,831 shares underlying other stock options and warrants that were outstanding at December 31, 2014 and 2013, respectively: 974,953 shares in 2014 and 1,839,930 shares in 2013 to be issued in settlement of deferred compensation to Officers of Milestone.

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's common stock. Options may be granted to employees, officers, directors and consultants of Milestone for the purchase of common stock of Milestone 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 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

F-14

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 November 2009, the Board of Directors authorized 666,667 options be reserved for a special bonus to the Chief Executive Officer of Milestone, for obtaining a three year purchase order for the sale of 12,000 STA Instruments and related handpieces over a four year period. These options were reserved and 73,333 were granted but not vested in 2010. The full performance requirements, for the 73,333 options, were met in 2013. Such options are fully vested as of December 31, 2013. The 593,334 options were cancelled in December 2013 due to expiration of the contract that gave rise to the granting of the options.

In June 2011, the Shareholders of Milestone 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.

A summary of option activity for employees under the plans as of December 31, 2014 and 2013, and changes during the year then ended is presented below:

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Outstanding, January 1, 2013	1,283,741	0.79	3.07	-
Granted	309,090	1.62	5.00	-
Exercised	(56,666)	-	-	-
Forfeited or expired	(51,666)	0.99	-	-
Outstanding, December 31, 2013	1,484,499	1.03	2.88	-
Exercisable, December 31, 2013	1,115,006	0.99	2.41	-
Granted	390,470	2.25	4.87	-
Exercised during 2014	(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

	Number of Options	Weighted Averaged Exercise Price \$
VESTED OPTIONS		
Outstanding, January 1, 2013	849,066	0.81
Exercised	(56,666)	-
Vested Options	369,272	1.19
Forfeited	(46,666)	0.96
Outstanding, December 31, 2013	1,115,006	0.97
Exercised	(312,293)	0.93
Vested Options	324,018	1.45
Forfeited	(90,546)	1.30

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

Outstanding, December 31, 2014	1,036,185	1.11
NONVESTED OPTIONS		
Nonvested, January 1, 2013	434,675	0.91
Granted	309,090	1.62
Vested	(369,272)	1.19
Forfeited	(5,000)	1.00
Nonvested, December 31, 2013	369,493	1.22
Granted	390,470	2.18
Vested	(324,018)	1.45
Forfeited	-	-
Nonvested, December 31, 2014	435,945	1.87

Milestone recognizes compensation expense on a straight line basis over the requisite service period and in case of performance based options over the period of the expected performance. During the years ended December 31, 2014 and 2013 Milestone recognized \$429,131, and \$219,196 of total employee compensation cost related to options that vested each year,

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

respectively. As of December 31, 2014 and 2013, there was \$569,641 and \$400,212 of total unrecognized compensation cost related to non-vested options which Milestone expects to recognize over a weighted average period of 3.23 years and 1.60 years for December 31, 2014 and December 31, 2013, respectively.

A summary of option activity for non-employees under the plans as of December 31, 2014 and 2013, and changes during the year ended is presented below:

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contracted Life (years)	Aggregate Intrinsic Options Value \$
Outstanding, January 1, 2013	239,999	1.56	1.32	-
Exercisable, December 31, 2013	234,442	1.57	-	-
Forfeited	(66,667)	2.50	-	-
Outstanding, December 31, 2013	173,332	0.48	0.59	210,833
Exercisable, December 31, 2013	173,332	0.48	0.59	201,833
Forfeited	5,000	1.15	-	-
Outstanding, December 31, 2014	16,666	1.27	0.62	17,166
Exercisable, December 31, 2014	1,666	1.24	0.62	1,716

	Number of Options	Weighted Averaged Exercise Price \$
VESTED OPTIONS		
Outstanding, January 1, 2013	234,442	1.57
Vested	5,557	1.27
Forfeited	667	2.50
Outstanding, December 31, 2013	173,332	0.48
Exercised	15,166	0.38
Forfeited	5,000	-
Outstanding, December 31, 2014	16,666	1.27
NONVESTED OPTIONS		
Nonvested January 1, 2013	5,557	1.27
Vested during 2013	(5,557)	1.27
Outstanding, December 31, 2014	-	-

The fair value of the options was estimated on the date of grant using the Black Scholes option-pricing model. There were no non-employee options granted for the years ending December 31, 2014 and 2013. During the years ended December 31, 2014 and 2013, Milestone recognized no expense related to non-employee options that vested.

NOTE L — EMPLOYMENT CONTRACT AND DEFERRED COMPENSATION

Employment Contracts

As of September 1, 2009 Milestone 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 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, 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 and 1,306,716 shares of common stock are to be paid out at the end of the contract in

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

settlement of \$1,408,333 at December 31, 2013 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 amended the previous 2008 employment with 40-months remaining in its term. Under the 2008 agreement Mr. Osser is employed as an executive, but not the CEO. In March 2013, the 2008 agreement was amended to extend its remaining term to 120-months.

NOTE M — INCOME TAXES

Due to Milestone's history of past operating losses, which required a full valuation allowances for all of Milestone's deferred tax assets at December 31, 2014 and 2013, 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, 2014 and 2013 are as follows:

	2014	2013
Current Assets		
Allowance for doubtful accounts-short term	\$2,000	\$2,000
Inventory allowance	-	-
Warranty reserve	12,000	10,000
Impairment of Germany Investment	-	31,000
Deferred officers compensation	392,000	725,000
Subtotal	406,000	768,000
Valuation allowance	(406,000)	(768,000)
Current deferred tax asset	\$-	\$-
Non-current assets		
Allowance for doubtful accounts-long term	\$-	\$-
Net operating loss carryforward	15,686,000	14,855,000
Subtotal	15,686,000	14,855,000
Valuation allowance	(15,686,000)	(14,855,000)
Non-current deferred tax asset	\$-	\$-

As of December 31, 2014 and 2013, Milestone has federal net operating loss carryforwards of approximately \$ 46,379,000 and \$43,596,000, respectively that will be available to offset future taxable income, if any, through December 2032. Milestone has state net operating losses of \$ 2,968,000 and \$515,000 in 2014 and 2013, respectively, expiring through December 2030. The utilization of Milestone'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 has established a 100% valuation allowance for all of its deferred tax assets due to uncertainty as to their future realization.

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

	2014	2013
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 %

Accounting for Uncertain Tax Positions:

Milestone 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, 2014, no significant income tax uncertainties have been included in Milestone's Balance Sheets. Milestone'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 2011, 2012, and 2013 years are subject to audit by federal and state jurisdictions.

NOTE N — PRODUCT SALES AND SIGNIFICANT CUSTOMERS AND VENDORS

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

	Year End December 31,	
	2014	2013
Instruments	\$2,569,102	\$2,672,026
Handpieces	7,627,140	7,294,810
Other	136,848	44,584
	\$10,333,090	\$10,011,420
United States	\$4,655,648	\$5,299,552
Canada	100,321	553,984
Other foreign	5,577,121	4,157,884
	\$10,333,090	\$10,011,420

Milestone 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 \$948,024 (26%) and \$457,600 (13%) in 2014 and 2013, respectively. Milestone 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 \$2,698,043 (74%) and \$3,026,041 (87%) in 2014 and 2013, respectively. As further described in Note B, a five percent shareholder of Milestone is also a shareholder of this vendor. All other purchases from other suppliers were not significant in either 2014 or 2013.

For the year ended December 31, 2014, Milestone had two customers (distributors) that 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. For the year ended December 31, 2013, Milestone had two customers (distributors) that had approximately 42%, (21% and 21%) of its net product sales. Accounts receivable for the one major customer amounted to approximately \$732,762, or 48% of gross accounts receivable.

NOTE O — COMMITMENTS AND OTHER

(1) Lease Commitments

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

The headquarters for Milestone is located at 220 South Orange Ave, Livingston, New Jersey. Milestone leases approximately 5,893 square feet of office space. The lease term expires June 30, 2019 at a monthly cost of \$9,085. Additionally, Milestone has other smaller insignificant leases ending through 2017. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

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

	Year Ending December 31,
2015	\$ 114,985
2016	114,985
2017	114,985
2018	109,020
2019	54,510
	\$ 508,485

For the years ended December 31, 2014 and 2013, respectively, rent expense amounted to \$42,785 and \$41,653 respectively.

(2) Contract Manufacturing Arrangement

Milestone has informal arrangements with the manufacturer of its products. STA, single tooth anesthesia, CompuDent and CompuMed instruments are manufactured for Milestone by Tricor Systems, Inc. pursuant to specific purchase orders. The STA and The Wand Handpiece with Needle are supplied to Milestone by a contractor in the United States, which arranges for its manufacture in China. These contractors provide an informal long term financing basis for Milestone.

The termination of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone's ability to produce and sell its products. Although alternate sources of supply exist and new manufacturing relationships could be established, Milestone 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.

(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 purchased this technology pursuant to an agreement dated January 1, 2005, for 43,424 shares of restricted common stock and \$145,000 in cash, payable on April 1, 2005. In addition, 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, he 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 he will receive the corresponding percentage of the consideration received by Milestone for such sale or license. Milestone expensed the Director's royalty fees of \$404,828 and \$357,972 in 2014 and 2013, respectively. Additionally, Milestone expensed consulting fee to the Director \$43,290 and \$99,450 for year ended 2014 and 2013, respectively.

In January 2010, Milestone issued a purchase order to Tricor Instruments for the purchase of 12,000 STA Instruments to be delivered over the next three years. The purchase order is for \$5,261,640. As of December 31, 2013, Milestone's production and sales of instruments to this commitment has been delayed. The remaining instruments until this purchase order will be delivered in the first quarter 2015.

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

In November 2012, Milestone signed an exclusive distributor and marketing agreement with a well-known US domestic 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.

In August 2013, Milestone appointed Henry Schein as its exclusive distributor in the USA and Canada for the CompuDent handpieces.

Subsequent Events

The Company has evaluated subsequent events through March 30, 2015 and have determined that there are no events to be disclosed.

(4) Loan Commitments

In December 2014 Milestone entered in line of credit agreement with Milestone Medical Inc. (a 49.98% owned of the company) for \$2 million dollars. The loan is to be used to finalize the commercialization of the medical instruments (epidural and intra-articular instruments.) The loan provides for interest charge at a rate of 3.25% per annual, the prime rate at the inception of the line of credit. The agreement terminates at April 15, 2016. No funds have been issued against the agreement as December 31, 2014. \$200,000, was borrowed by Milestone Medical in February 2015.

NOTE P — PENSION PLAN

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