

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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2015

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

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

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

(Address of principal executive offices)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value \$.001 per share	NYSE MKT
Securities registered pursuant to section 12(g) of the Act:	NONE

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

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

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

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

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

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

Large accelerated filer  Accelerated filer

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

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

As of June 30, 2015, the last business day of Milestone Scientific Inc.'s most recently completed second fiscal quarter, the aggregate market value of the common stock held by non – affiliates of the issuer was \$25,888,742. This amount is based on the closing price of \$3.40 per share of Milestone Scientific's common stock as of such date, as reported on the NYSE MKT.

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

DOCUMENTS INCORPORATED BY REFERENCE

None

---

MILESTONE SCIENTIFIC Inc.

Form 10-K Annual Report

TABLE OF CONTENTS

PART I

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

PART II

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

PART III

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

PART IV

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

SIGNATURES

38

EXHIBITS

## FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K are “forward-looking statements” (within the meaning of the Private Securities Litigation Reform Act of 1995) regarding the plans and objectives of management for future operations. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Milestone Scientific Inc. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Milestone Scientific Inc.’s plans and objectives are based, in part, on assumptions involving the continued expansion of business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific Inc. Although Milestone Scientific Inc. believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, particularly in view of Milestone Scientific’s early stage operations, the inclusion of such information should not be regarded as a representation by Milestone Scientific Inc. or any other person that the objectives and plans of Milestone Scientific Inc. will be achieved. Milestone Scientific Inc. undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

## PART I

### Item 1. Description of Business

All references in this report to “Milestone Scientific,” “us,” “our,” “we” or “Milestone” refer to Milestone Scientific Inc., and its consolidated subsidiaries (Wand Dental Inc. and Milestone Medical Inc.) unless the context otherwise indicates.

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

In July 2014, Milestone Scientific acquired all of the 750,000 outstanding shares of an inactive Florida corporation and changed its name to Wand Dental, Inc. (“Wand Dental”). In September 2014, that corporation was merged into a Delaware corporation, retaining the same name and capitalization. On July 1, 2014, Wand Dental was capitalized with cash and received Milestone Scientific’s dental business and related dental assets including the exclusive license of Milestone Scientific’s, patents, trademarks, and technology for use in the dental marketplace. Wand Dental is consolidated into Milestone Scientific.

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

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

## BUSINESS

### Background

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

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

In 1997, Milestone Scientific first introduced The Wand® (CompuDent® instrument) and the disposable Wand® handpiece. CompuDent® provides painless injections for all routine dental treatments, including implants, root canals, crowns, fillings and cleanings. Milestone Scientific’s Computer-Controlled Local Anesthetic Delivery (C-CLAD) instrument handpiece does not look or feel like a syringe. And, what’s more, it works better than a syringe, resulting in a more pleasant experience for the patient and practitioner.

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

In 2007, Milestone Scientific received FDA 510(k) Pre-market clearance for marketing and sale of the STA instruments, (dental instrument). Milestone Scientific introduced the instrument to the market in February 2007 and this instrument is currently being marketed throughout the world.

Central to Milestone Scientific's intellectual property platform and current product development strategy is its patented CompuFlo® technology for the precise delivery of medicaments. The CompuFlo® pressure/force Computer-Controlled Local Anesthetic Delivery (C-CLAD) technology is an advanced, patented and FDA-approved medical technology for the painless and accurate delivery of drugs, anesthetics and other medicaments into all tissue types, as well as for the aspiration of bodily fluids or previously injected substances. Its regulation and control of flow rate continues to provide the CompuDent® benefits of painless injections, while its Dynamic Pressure Sensing® capability provides visual and audible in-tissue pressure feedback, identifying tissue types to the healthcare provider. This pressure feedback extends the benefit of painlessness from anesthetics with known viscosities to a wide range of liquid drugs and other medicaments with varying viscosities and flow rates. Dynamic Pressure Sensing also allows the healthcare provider to know when certain types of tissues have been penetrated and permits the healthcare provider to inject medicaments precisely at the desired location. Thus, pressure feedback can prevent the suffusion of tissue outside the intended target area, a vitally important characteristic in the injection of chemotherapeutics and other toxic substances.

The CompuFlo® technology consists of two critical elements. One element is the ability to determine exit pressure In Situ (in the injection site tissue) at the tip of the needle. This minimizes tissue damage (and eliminates the pain of the injection) because the flow rate and pressure of the injection are controlled. The other critical element of the technology is an integrated injection database of algorithms that have been defined which allow for the measurement of the exit pressure. This database of algorithms contains the critical components of specific drugs, parameters of needles, tubing and syringes and all other pertinent components for the safe and efficacious delivery of medications for all procedures.

The CompuFlo® technology also consists of a disposable injection handpiece that provides for precise tactile control during the injection, an electromechanical (computer-controlled) fluid delivery instrument and the ability to record data from the injection event. As confirmed by numerous noted medical and dental experts within academia and the clinical practice arenas, CompuFlo® has the potential to greatly increase the safety and efficacy of many drug delivery procedures that currently rely upon the over 150-year-old hypodermic syringe technology and the tactile senses and delivery expertise of the administrator.

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

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

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

Given Milestone Scientific's experience and established brand awareness within the dental industry, it elected to focus its initial product development efforts on the integration of CompuFlo® into its legacy computer-controlled dental

injection instrument. As a result, Milestone Scientific developed the industry's first solution for painlessly administering a single-tooth injection as the only injection necessary for achieving anesthesia, foregoing the need to administer a traditional nerve branch block. This new instrument, which also provides for use of a disposable handpiece, was trademarked the "STA Single Tooth Anesthesia Instrument<sup>™</sup>" now more commonly known as The Wand<sup>®</sup> STA Instrument.

After receiving FDA 510(k) Pre-market Notification acceptance for the marketing and sale of the STA Instrument, Milestone Scientific introduced the instrument to market in February 2007 at the Chicago Dental Society's 143<sup>d</sup>

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

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

In the spring of 2009, Milestone Scientific signed an Exclusive Distribution and Marketing Agreement with China National Medicines Corporation, dba Sinopharm, which is China's largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and the country's largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone Scientific a blanket purchase order for 12,000 STA instruments and related handpieces to be delivered over 36 months, thereby marking Milestone Scientific's initial penetration into China's emerging dental market. The agreement was terminated in September 2014 and a new distributor, Milestone China Ltd. became the distributor for the STA Instruments and handpieces in China. Milestone China is owned forty (36) percent by Milestone Scientific.

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

According to a 2011 report published by the U.S. Department of Commerce, titled "China's Emerging Markets: Opportunities in the Dental and Dental Lab Industry," China's dental market lags behind other healthcare services and has largely been neglected in the past. In fact, CS Market Research reports that "of China's 1.3 billion plus population, 50% of the adults and 70% of the children are estimated to have decayed tooth problems, and over 90% have periodontal disease." However, with increasing affluence of the Chinese population, as well as increasing attention towards personal care, demand for dental services has been growing. Market research firm Freedonia agrees, noting that demand for dental products in China is expected to climb due primarily to escalating personal income levels and government programs promoting awareness of the benefits of good oral care.

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

In November 2012, Milestone Scientific signed an exclusive distributor and marketing agreement with a well-known US domestic manufacturer and distributor, for the sale and distribution of the STA instrument and handpieces in the United States and Canada. The marketing initiative will include participation in U.S. and Canadian dental shows, as well as pediatric dental shows; an active advertising initiative targeting major dental publications; and direct mailing campaigns to over 150,000 dentists across the U.S. and Canada. The exclusive distributor and marketing agreement was converted to a non-exclusive agreement on December 31, 2015. In addition, on January 1, 2016 Henry Schein was added as an additional non-exclusive distributor of the STA instruments and handpieces in the United States and Canada.

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

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

#### CompuFlo® Advanced Injection Technology – Core Technology

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

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

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

Precisely controlling in-tissue pressure increases patient safety by reducing the risk of tissue damage and post-treatment pain related to excessive pressure that may occur during certain injections. Identification of the tissue, in which the needle tip is imbedded, is believed to be highly important in epidural injections, intra-articular injections and numerous organ, subcutaneous and intramuscular injections.

CompuFlo® pressure sensing technology provides an objective tool that consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the extraligamentary tissue. In studies utilizing the CompuFlo® technology the epidural space has been correctly identified 100% of the time. Knowing the precise location of a needle during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes, who identify the epidural space by relying on the subjective perception of loss of resistance to saline.

In the absence of curative procedures, arthritis patients are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious, because the doctor using a syringe failed to locate the intra-articular space or did not inject the appropriate volume of hyaluronic acid or other medicament into that space. The CompuFlo® technology has been successful in administering viscous hyaluronic acid and other medicaments into the intra-articular space in both small and large joints using its computer-controlled pressure sensing capabilities in an independent animal study.

There are a number of injectable drugs routinely self-administered in a home or office setting using spring loaded automatic injection devices by people who suffer from long term chronic conditions such as Multiple Sclerosis,

diseases of the auto immune system and Rheumatoid Arthritis. The CompuFlo® technology, using pressure sensing capabilities, can serve as a painless subcutaneous injection method for these self-administered drugs. A significant reduction in pain during delivery should have a positive impact on compliance, which is a major consideration when physicians are treating patients.

7

---

Milestone Medical Inc.

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

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

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

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

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

#### Instruments Platform-Medical and Dental

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

#### STA Single Tooth Anesthesia Instrument™

The STA Single Tooth Anesthesia Instrument™ (STA Instrument) is a patented, computer-controlled local anesthesia delivery instrument that incorporates the “pressure feedback” elements of Milestone Scientific’s patented CompuFlo® technology, thereby allowing dentists to administer injections accurately into the periodontal ligament space, effectively anesthetizing a single tooth. While the periodontal ligament injection has been available for some time, there has been no effective technology that allows dentists to easily perform the procedure painlessly, safely and predictably until now. With this STA Instrument dentists can easily and predictably anesthetize a single tooth root in

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

8

---

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

### CompuDent®

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

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

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

### CompuMed®

CompuMed® is a patented computer-controlled injection instrument geared to the needs of the medical market and providing benefits similar to CompuDent®. CompuMed® allows many medical procedures, now requiring intravenous sedation, to be performed with only local anesthesia due to dramatic pain reduction. Also, dosages of local anesthetic can often be significantly reduced, thus reducing side effects, accelerating recovery times, lowering

costs and eliminating potential complications. CompuMed® has accumulated clinical evidence demonstrating benefits from use in colorectal surgery; podiatry; dermatology, including surgery for the removal of basal cell carcinomas and other oncological dermatologic procedures; nasal and sinus surgery, including rhinoplasty; hair transplantation and cosmetic

surgery, among others. The CompuMed® is being replaced by instruments that include CompuFlo® technology geared to specific medical disciplines.

#### The Wand®

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

#### Competition

Milestone Scientific's proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) instruments compete with disposable and reusable syringes that generally sell at lower prices and that use established and well-understood methodologies in both the dental and medical marketplaces. Upon commercial introduction and sale, Milestone Medical's epidural injection instrument will also compete with Apad, a computer controlled injection instrument which claims to be able to reliably identify the epidural space.

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

Milestone Scientific faces intense competition from many companies in the medical and dental device industry, possessing substantially greater financial, marketing, personnel, and other resources. Most competitors have established reputations, stemming from their success in the development, sale, and service of competing dental products. Further, rapid technological change and research may affect the products. Current or new competitors could, at any time, introduce new or enhanced products with features that render the products less marketable or even obsolete. Therefore, Milestone Scientific must devote substantial efforts and financial resources to improve existing products, bring products to market quickly, and develop new products for related markets. In addition, the ability to compete successfully requires that Milestone Scientific establish an effective distribution network with a strong marketing plan. Historically, Milestone Scientific has been unsuccessful in executing the marketing plans for the products, primarily due to resource constraints. New products must be approved by regulatory authorities before they may be marketed. Milestone Scientific cannot assure that it can compete successfully, that competitors will not develop technologies or products that render the products less marketable or obsolete, or, that Milestone Scientific will succeed in improving the existing products, effectively develop new products, or obtain required regulatory approval for those products.

## Patents and Intellectual Property

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

	U.S. PATENT	
COMPUTER CONTROLLED DRUG DELIVERY SYSTEMS	NUMBER	DATE OF ISSUE
Dental Anesthetic and Delivery Injection Unit	6,022,337	2/8/2000
Cartridge Holder for Injection Device	6,132,414	10/17/2000
Dental Anesthetic Delivery Injection Unit	6,152,734	11/28/2000
Microprocessor-controlled Fluid Dispensing Apparatus	6,159,161	12/12/2000
Pressure/Force Computer Controlled Drug Delivery System	6,200,289	3/13/2001
Dental Anesthetic and Delivery Injection Unit with Automated Rate Control	6,652,482	11/25/2003
Pressure/Force Computer Controlled Drug Delivery System with Exit Pressure	6,786,885	9/14/2004
Pressure/Force Computer Controlled Drug Delivery System with Automated Charging	6,887,216	5/3/2005
Drug Delivery System with Profiles	6,945,954	9/20/2005
Cartridge Holder for Anesthetic and Delivery Injection Device	D558,340	12/25/2007
Design for Drive Unit for Anesthetic	D566,265	4/8/2008
Design for Drive Unit for Anesthetic	D579,540	10/28/2008
Drug Infusion Device with Tissue Identification Using Pressure Sensing	7,449,008	11/11/2008
Computer Controlled Drug Delivery Systems with Pressure Sensing	7,618,409	11/17/2009
Hand Piece for Fluid Administration	7,625,354	12/1/2009
Self-Administration Injection System	7,740,612	6/22/2010
Computer controlled drug delivery system with dynamic pressure sensing	7,896,833	3/1/2011
Injection Device Adapter	D741,811	10/27/2015
Engineered Sharps Injury Protection Devices		
Handpiece for Injection Device with a Retractable and Rotating Needle	6,428,517	8/6/2002
Safety IV Catheter Device	6,726,658	4/27/2004
Safety IV Catheter Infusion Device	6,905,482	6/14/2005
Handpiece for Injection Device with a Retractable and Rotating Needle	6,966,899	11/22/2005

During the 2015 and 2014 fiscal years, Milestone Scientific expensed \$100,856 and \$88,243, respectively, on research and development activities.

Milestone Scientific relies on a combination of patent, copyright, trade secret, and trademark laws and employee and third party non-disclosure agreements to protect intellectual property rights. Despite the precautions taken by Milestone Scientific to protect the products, unauthorized parties may attempt to reverse engineer, copy, or obtain and use products and information that Milestone Scientific regarded as proprietary, or may design products serving similar purposes that do not infringe on Milestone Scientific's patents. Milestone Scientific's failure to protect its proprietary information and the expenses of doing so could have a material adverse effect on the operating results and financial condition of the Company.

In the event that the products infringe upon patent or proprietary rights of others, Milestone Scientific may be required to modify processes or to obtain a license. There can be no assurance that Milestone Scientific would be able to do so in a timely manner, upon acceptable terms and conditions, or at all. The failure to do so would have a material adverse

effect on Milestone Scientific.

#### Government Regulation

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

The manufacture and sale of medical devices and other medical products are subject to extensive regulation by the FDA pursuant to the FDC Act, and by other federal, state and foreign authorities. Under the FDC Act, medical devices

must receive FDA clearance before they can be marketed commercially in the U.S. Some medical products must undergo rigorous pre-clinical and clinical testing and an extensive FDA approval process before they can be marketed. These processes can take a number of years and require the expenditure of substantial resources. The time required for completing such testing and obtaining such approvals is uncertain, and FDA clearance may never be obtained. Delays or rejections may be encountered based upon changes in FDA policy during the period of product development and FDA regulatory review of each product submitted. Similar delays also may be encountered in other countries. Following the enactment of the Medical Device Amendments to the FDC Act in May 1976, the FDA classified medical devices in commercial distribution into one of three classes. This classification is based on the controls necessary to reasonably ensure the safety and effectiveness of the medical devices. Class I devices are those devices whose safety and effectiveness can reasonably be ensured through general controls, such as adequate labeling, pre-market notification, and adherence to the FDA's Quality Instrument Regulation ("QSR"), also referred to as "Good Manufacturing Practices" ("GMP") regulations. Some Class I devices are further exempted from some of the general controls. Class II devices are those devices whose safety and effectiveness reasonably can be ensured through the use of special controls, such as performance standards, post-market surveillance, patient registries, and FDA guidelines. Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and effectiveness. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices.

If a manufacturer or distributor can establish that a proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not required pre-market approval, the manufacturer or distributor may seek FDA marketing clearance for the device by filing a 510(k) Pre-market Notification. The 510(k) Pre-market Notification and the claim of substantial equivalence may have to be supported by various types of data and materials, including test results indicating that the device is as safe and effective for its intended use as a legally marketed predicate device. Following submission of the 510(k) Pre-market Notification, the manufacturer or distributor may not place the device into commercial distribution until an order is issued by the FDA. By regulation, the FDA has no specific time limit by which it must respond to a 510(k) Pre-market Notification. At this time, the FDA typically responds to the submission of a 510(k) Pre-market Notification within 180 days. The FDA response may declare that the device is substantially equivalent to another legally marketed device and allow the proposed device to be marketed in the U.S. However, the FDA may determine that the proposed device is not substantially equivalent or may require further information, such as additional test data, before the FDA is able to make a determination regarding substantial equivalence. Such determination or request for additional information could delay market introduction of products and could have a material adverse effect on us. If a device that has obtained 510(k) Pre-market Notification clearance is changed or modified in design, components, method of manufacture, or intended use, such that the safety or effectiveness of the device could be significantly affected, separate 510(k) Pre-market Notification clearance must be obtained before the modified device can be marketed in the U.S. If a manufacturer or distributor cannot establish that a proposed device is substantially equivalent to a legally marketed device, the manufacturer or distributor will have to seek pre-market approval of the proposed device, a more difficult procedure requiring extensive data, including pre-clinical and human clinical trial data, as well as extensive literature to prove the safety and efficacy of the device.

Though the STA Instrument, CompuDent®, The Safety Wand® and CompuMed® have received FDA marketing clearance, there can be no assurance that any of the other products under development will obtain the required regulatory clearance in a timely manner, or at all. If regulatory clearance of a product is granted, such clearance may entail limitations on the indicated uses for which the product may be marketed. In addition, modifications may be made to the products to incorporate and enhance their functionality and performance based upon new data and design review. There can be no assurance that the FDA will not request additional information relating to product improvements; that any such improvements would not require further regulatory review, thereby delaying the testing, approval and commercialization of product improvements; or, that ultimately any such improvements will receive FDA clearance.

Compliance with applicable regulatory requirements is subject to continual review and will be monitored through periodic inspections by the FDA. Later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on such product or manufacturer, including fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and criminal prosecution and could have a material adverse effect on Milestone Scientific.

Milestone Scientific is subject to pervasive and continuing regulation by the FDA, whose regulations require manufacturers of medical devices to adhere to certain QSR requirements as defined by the FDC Act. QSR compliance

requires testing, quality control and documentation procedures. Failure to comply with QSR requirements can result in the suspension or termination of production, product recall or fines and penalties. Products also must be manufactured in registered establishments. In addition, labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. The export of devices is also subject to regulation in certain instances.

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

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

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

#### Product Liability

Failure to use any of the products in accordance with recommended operating procedures could potentially result in health hazards or injury. Failures of the products to function properly could subject Milestone Scientific to claims of liability. Milestone Scientific maintains liability insurance in an amount that Milestone Scientific believes is adequate. However, there can be no assurance that the insurance coverage will be sufficient to pay product liability claims brought against Milestone Scientific. A partially or completely uninsured claim, if successful and of significant magnitude, could have a material adverse effect on Milestone Scientific

#### Employees

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

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

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

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

For the years ended December 31, 2015 and 2014, revenues were approximately \$9.4 million and \$10.3 million, respectively. Milestone Scientific has a net loss of approximately \$5.4 million for year ended December 31, 2015 and a net loss of approximately \$1.7 million for year ended December 31, 2014. In addition, Milestone Scientific has had losses for each year since the commencement of operations with the exception of 2013. Milestone Scientific has an accumulated deficit of approximately \$78.6 million. At December 31, 2015, Milestone Scientific had cash and cash equivalents approximately \$4.2 million, and working capital of approximately \$8.2 million. The working capital in 2015 decreased by

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

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

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

As with any new technology, there is substantial risk that the marketplace will not accept the potential benefits of this technology or be unwilling to pay for any cost differential with the existing technologies. Market acceptance of CompuDent®, STA Instrument, The Safety Wand®, CompuMed® and CompuFlo® depends, in large part, upon the ability to educate potential customers of the product's distinctive characteristics and benefits and will require substantial marketing efforts and expense. More than 43,000 instruments of the STA Instrument and its predecessors have been sold worldwide since 1998. Since being introduced to market in February 2007, more than 15,000 of the STA Instrument have been sold. Milestone Scientific cannot assure that its current or proposed products will be accepted by practitioners or that any of the current or proposed products will be able to compete effectively against current and alternative products.

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

Future revenues depend on Milestone Scientific's ability to market and distribute its computer-controlled injection products successfully. In November 2012, Milestone Scientific signed on an exclusive distributor and marketing company to sell and distribute the STA instruments and handpieces in the USA and Canada. This exclusive agreement was modified to a non-exclusive agreement in December 31, 2015 and will expire on March 31, 2016. Beginning January 1, 2016, Henry Schein, the leading distributor of dental products in the USA and Canada, will have a non-exclusive distribution agreement with Milestone Scientific. To be successful, Milestone Scientific will need to engage additional distributors, provide for their proper training and ensure adequate customer support. Milestone Scientific cannot assure that it will be able to hire and retain an adequate sales force or engage suitable distributors, or that the sales force or distributors will be able to successfully market and sell the products.

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

Milestone Scientific and its subsidiary has informal arrangements with the manufacturer of the STA Instrument, CompuDent® and CompuMed® instruments and with one of the principal manufacturers of the handpieces, for those items, respectively. Pursuant to the informal arrangements, they manufacture these products under specific purchase orders without minimum purchase commitment. However, in November 2009, Milestone Scientific issued a purchase order to Tricor System Inc. to manufacture 12,000 STA Instruments, over the following three years. Milestone Scientific has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum

purchase commitments. Milestone Scientific has been supplied by the manufacturer of the STA Instrument, CompuDent® and CompuMed® since the commencement of production in 1998, the manufacturer of its handpieces since 2003. However, termination of the manufacturing relationship with any of these manufacturers could significantly and adversely affect the ability to produce and sell the products. Though other alternate sources of supply for handpieces exist, Milestone Scientific would need to recover its existing tools or have new tools produced to establish relationships with new suppliers. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of the supply, whether or not as a result or termination of the relationship, would have an adverse effect.

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

Milestone Scientific could be subject to claims for personal injury from the alleged malfunction or misuse of the dental and medical products. While Milestone Scientific carries liability insurance that is believed to be adequate, Milestone Scientific cannot assure that the insurance coverage will be sufficient to pay such claims should they be successful. A partially or completely uninsured claim, if successful and of significant magnitude, could have a material adverse effect on Milestone Scientific.

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

Milestone Scientific depends on the personal efforts and abilities of the Chief Executive Officer and the Director of Clinical Affairs. Milestone Scientific maintains a key man life insurance policy in the amount of \$1,000,000 on the life of the Chief Executive Officer. However, the loss of his services or Director of Clinical Affairs, on whom Milestone Scientific maintains no insurance, could have a materially adverse effect on the business.

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

Milestone Scientific's stock price has been extremely volatile, fluctuating during the last two years between \$4.00 and \$1.17. The market price of common shares could continue to fluctuate significantly in response to a variety of factors, some of which may be beyond Milestone Scientific's control.

Milestone Scientific is controlled by a limited number of shareholders.

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

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

Sales of a substantial number of shares of Milestone Scientific's common stock in the public markets, or the perception that these sales may occur, could cause the market price of the stock to decline and could materially impair its ability to raise capital through the sale of additional equity securities. At December 31, 2015, Milestone Scientific had outstanding options to purchase 1,427,769 shares of common stock at prices ranging from \$0.36 to \$3.89 per share with a weighted average exercise price of \$1.56. Holders of these options are given the opportunity to profit from a rise in the market price of the common stock and are likely to exercise their securities at a time when Milestone Scientific would be able to obtain additional equity capital on more favorable terms. Thus, the terms upon which Milestone Scientific will be able to obtain additional equity capital may be adversely affected, since the holders of outstanding options and warrants can be expected to exercise them at a time when Milestone Scientific would, in all likelihood, be able to obtain any needed capital on terms more favorable than the exercise terms provided by such outstanding securities. The market price of the common shares has been volatile and may continue to fluctuate significantly because of various factors, some of which are beyond Milestone Scientific's control.

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

The Management of Milestone Scientific has assessed the effectiveness of internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Milestone Scientific complied with Sarbanes-Oxley requirements to include in the annual report a management report on

the effectiveness of the internal control over financial reporting. In 2005, Milestone Scientific hired an outside consultant to assist with the development and implementation of the necessary internal controls and reporting procedures. In 2015 and 2014, Milestone Scientific utilized the outside consultant on a quarterly basis to review compliance with the internal controls over financial reporting. This expense amounted to approximately \$10,000 and \$5,000 in 2015 and 2014, respectively and the cost is expected to continue in 2016.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Description of Property

The headquarters for Milestone Scientific is located at 220 South Orange Avenue, Livingston, New Jersey which consists of approximately 7,625 square feet of office space. Milestone Scientific leases its headquarters at a monthly cost of \$12,522 which it believes to be competitive and the lease term expires on January 30, 2020. The leased office space is in good condition. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

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

#### Item 3. Legal Proceedings

At the present time, Milestone Scientific is not involved in any material litigation.

#### Item 4. Mine Safety Disclosure

Not applicable.



## PART II

## Item 5. Market for Common Equity, and Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

## Market Information

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

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

## Holders

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

## Dividends

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

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

## Sales of Unregistered Securities

See NOTE J – STOCKHOLDERS' EQUITY, to the financial statements for the issuance of unregistered securities.

These issuances were exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act") and a legend restricting the sale, transfer, or other disposition of these shares other than in compliance with the Act was imprinted on stock certificates evidencing the shares.

ITEM 6. Selected Financial Data

Milestone Scientific is a “smaller reporting company” as defined by Regulations S-K and as such, is not required to provide the information contained in this item pursuant to Regulation S-K.

## ITEM 7. Management's Discussion and Analysis of Financial condition and Results of Operations

The following discussions of the financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this annual report. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Exchange Act, that involve risks and uncertainties. The actual results may differ materially from those anticipated in these forward-looking statements. See "Certain Risk Factors That May Affect Growth and Profitability" on pages 12-14 of this Form 10-K.

### OVERVIEW

- In 2015, Milestone Scientific continued to focus on advancing efforts to achieve our two primary objectives; those being;
- Enhancing our global reach by partnering with distribution companies in the medical sector for our epidural and intra-articular instruments.; and
- Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, including the STA Single Tooth Anesthesia Instrument™ (STA Instrument).

#### STA Instrument Growth

Since its market introduction in early 2007, the STA Instrument and prior computerized controlled local anesthesia delivery products have been used to deliver over 65 million safe, effective and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

#### Global Distribution Network

##### United States and Canadian Market

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

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

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

##### International Market

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

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

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

In September 2014, Milestone Medical received CE clearance to distribute their instruments in European Community (EU). Milestone Medical is actively pursuing distributors for the instrument in the EU community. Milestone Medical signed a distribution agreement in March 2015, with a Polish Medical distributor for the distribution of the epidural instrument starting in April 2015.

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

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

	Years Ended December 31,			
	2015		2014	
<b>DOMESTIC</b>				
Instruments	\$623,195	17.8 %	\$1,037,956	22.3 %
Handpieces	2,799,785	79.8 %	3,543,509	76.1 %
Other	83,362	2.4 %	74,182	1.6 %
<b>Total Domestic</b>	<b>\$3,506,342</b>	<b>100.0%</b>	<b>\$4,655,647</b>	<b>100.0%</b>
<b>INTERNATIONAL</b>				
Instruments	\$2,062,556	34.5 %	\$1,531,146	27.0 %
Handpieces	3,836,002	64.1 %	4,083,631	71.9 %
Other	86,669	1.4 %	62,666	1.1 %
<b>Total International</b>	<b>\$5,985,227</b>	<b>100.0%</b>	<b>\$5,677,443</b>	<b>100.0%</b>
<b>DOMESTIC/INTERNATIONAL ANALYSIS</b>				
Domestic	\$3,506,342	36.9 %	\$4,655,647	45.1 %
International	\$5,985,227	63.1 %	\$5,677,443	54.9 %
<b>Total Product Sales</b>	<b>\$9,491,569</b>	<b>100.0%</b>	<b>\$10,333,090</b>	<b>100.0%</b>

Milestone Scientific earned gross profit of 68% and 65% in the years ended December 31, 2015 and 2014, respectively. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses. Although Milestone Scientific anticipates expending funds for research and development in 2016, these amounts will vary based on the operating results for each quarter.

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

In 2016, Milestone Scientific plans to further support increased sales and marketing activity through our current distributors and through newly appointed distributors of the STA instruments and handpieces in the international market. In the U.S. and Canada, Milestone Scientific will continue the utilization of independent hygienists for training individual practitioners and group practices domestically, refined and directed advertising to dental professionals, and support and broaden our global distribution network.

#### Current Product Platform

See Item 1. Description of Business

#### Technology Rights

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

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

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

Milestone Scientific's discussion and analysis of the financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, Milestone Scientific evaluates its estimates, including those related to accounts receivable, inventories, stock-based compensation and contingencies. Milestone Scientific bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

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

#### Assessment of Company's Ability to Continue as a Going Concern

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

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

#### Accounts Receivable

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

20

---

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

#### Inventories

Inventory costing, obsolescence and physical control are significant to the on-going operation of the business. Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded if required based on past and expected future sales.

#### Impairment of Long-Lived Assets

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

#### Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to domestic distributors on the date of shipment for essentially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific will recognize revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. Shipments to international distributors are FOB warehouse, therefore revenue is recognized on shipment of the goods. In all cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone Scientific has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

## Results of Operations

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

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

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

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

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

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

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

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

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

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

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

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

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

#### Liquidity and Capital Resources

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

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

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

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. Cash flows from operating activities for the year ended December 31, 2015 and 2014 were a negative \$2,946,339 and positive \$376,943, respectively.

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

Scientific in 2014.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for the year ended December 31, 2013. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through increases in revenues based upon management's assessment of present contracts, and current negotiations and reductions in operating expenses. The consolidation of Milestone Medical

23

---

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

#### Off-Balance Sheet Arrangements

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

#### Contractual Obligations

The impact of the consolidated contractual obligations at December 31, 2015, expected on the liquidity and cash flows in future periods, is as follows:

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

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

#### Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Milestone Scientific is a “smaller reporting company” as defined by Regulation S-K and, as such, is not required to provide the information required by this item.

Item 8. Financial Statements

The financial statements of Milestone Scientific required by this Item are set forth beginning on page F-1.

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

None.

24

---

#### Item 9A. Controls and Procedures

Milestone Scientific's Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of Milestone Scientific's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based upon that evaluation, Milestone Scientific's Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of December 31, 2015 are effective to ensure that information required to be disclosed in the reports Milestone Scientific files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Milestone Scientific's management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles in the United States, and that the receipts and expenditures are being made only in accordance with authorizations of the management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the assets that could have a material effect on the financial statements.

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

Milestone Scientific management assessed the effectiveness of its internal control over financial reporting as of December 31, 2015. In making this assessment, management used the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") adopted in 2013. Based on the assessment and the criteria set forth by COSO, management believes that Milestone Scientific maintained effective internal control over financial reporting as of December 31, 2015.

There have been no changes in Milestone Scientific's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone Scientific's last fiscal quarter ended December 31, 2015 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

Item 9B. Other Information

None.

25

---

## PART III

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

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

The current executive officers and directors of Milestone Scientific and their respective ages as of March 29, 2016 are as follows:

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

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

The following are the names of individuals who are not executive officers of Milestone Scientific but are deemed key personnel of Milestone Scientific, their respective ages and positions as of March 29, 2016:

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	71	Director of Professional Relations
Mark Hochman, D.D.S.	57	Director of Clinical Affairs

#### Leslie Bernhard, Chairman of the Board

Leslie Bernhard has been serving as Milestone Scientific's non-executive Chairman of the Board since September 2009. In addition, Ms. Bernhard has also been serving as an Independent Director (as defined below) of Milestone Scientific since May 2003. She co-founded AdStar, Inc. and since 1986 has served as its President, Chief Executive Officer and Executive Director. AdStar is an application service provider for the newspaper classified advertising industry. Ms. Bernhard serves on the Board of Directors of Universal Power Group, Inc. of Dallas, TX, a manufacturer and distributor of batteries and battery related products. Ms. Bernhard's professional experience and background with AdStar and with us, as one of our directors since 2003, have given her the expertise needed to serve as Chairman of the Board.

Leonard Osser, Chief Executive Officer

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

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

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

Steven F. Robins, President

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

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

Mark Hochman, D.D.S. has served as Milestone Scientific's Director of Clinical Affairs and Director of Research and Development since 1999. He has a Doctorate of Dental Surgery with advanced training in the specialties of Periodontics and Orthodontics from New York University of Dentistry and has been practicing dentistry since 1984. He holds a faculty appointment as a clinical associate professor at NYU School of Dental Surgery. Recognized as a world authority on Advanced Drug Delivery Instruments, Dr. Hochman has published numerous articles in this area, and shares in the responsibility for inventing much of the technology currently available from Milestone Scientific

Dr. Eugene Casagrande, Director of International & Professional Relations

Since 1998, Eugene Casagrande, D.D.S. has served as Director of International and Professional Relations, charged with pursuing a broad range of clinical and industry-related strategic business opportunities for Milestone Scientific. He has also lectured both nationally and internationally at over 35 dental schools and in over 22 countries on Computer-Controlled Local Anesthesia Delivery. Dr. Casagrande is past president of the California State Board of Dentistry and the Los Angeles Dental Society and is a Fellow of the American and International Colleges of Dentists

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

Leonard M. Schiller, Director

Leonard Schiller has been a director of Milestone Scientific since April 1997. Mr. Schiller has been a partner in the Chicago law firm of Schiller, Klein & McElroy, and P.C. since 1977. He has also been President of The Dearborn Group, a residential property management and real estate acquisition company since 1980. Mr. Schiller became a Director of the Gravitass Cayman Corporation in February 2010. Gravitass Cayman Corporation is an Investment Fund.

27

---

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

Gian Domenico Trombetta, Director

Gian Domenico Trombetta became a director of Milestone Scientific in May 2014 and the President and Chief Executive Officer of Milestone Scientific's Dental Division (Wand Dental Inc.) since October 2014. He founded Innovest S.p.A in 1993, a private equity and special situation investment firm and has been its President and Chief Executive Officer since 1996. He serves as the Chief Executive Officer or a board member of numerous private commercial companies... Mr. Trombetta was Project Manager for Booz Allen & Hamilton Inc., a management consulting firm from 1988 to 1992. Mr. Trombetta holds a degree in business administration from the Luiss University in Rome, Italy and a MBA degree from INSEAD-Fontainebleau-France.

Edward J. Zelnick, M.D., Director

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

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

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

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

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten-percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. Based solely on review of the copies of such forms furnished to us, or written representations that no Forms 5 were required, we believe that all Section 16(a) filing requirements applicable to our officers and director were complied with during the fiscal year ended December 31, 2015, except that our CEO did not timely file a Form 4, our CFO did not timely file one Form 4 and our President did not timely

file his Form 3.

#### Code of Ethics

Milestone Scientific has adopted a code of ethics that applies to its directors, principal executive officer, principal financial officer and other persons performing similar functions. This code of ethics is filed herewith as an exhibit to this annual report and is posted on Milestone Scientific's web site at [www.milestonescientific.com](http://www.milestonescientific.com). Milestone Scientific will also provide a copy of the Code of Ethics to any person without charge, upon written request addressed to the Chief

28

---

Financial Officer, Joseph D'Agostino at the principal executive office, located at 220 South Orange Avenue, Livingston, NJ 07039.

#### Item 11. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2015 and 2014 by Milestone Scientific's (i) CEO and (ii) two most highly compensated executive officers other than the CEO who was serving as an executive officer at the end of the 2015 fiscal year and whose salary as determined by Regulation S-K, Item 402, exceeded \$100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the "Named Executive Officers").

#### SUMMARY COMPENSATION TABLE

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

1. Payment of \$300,000 and 400,000 of bonuses for the years ended December 31, 2015 and 2014, respectively, of which \$200,000, in 2015 and \$100,000 in 2014, was deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. Fifty percent of the non-cash portion of Mr. Osser's 2015 bonus was approved by the Compensation Committee of the Board in each of third quarter of 2015 and first quarter of 2016, respectively. Other compensation represents payments made for business use of corporate apartment in China, health insurance coverage, pension payment, and car allowance.
2. The amounts in this column reflect the fair value of the options at date of grant. For details used in the assumption calculating the fair value of the option reward, see Note B to the Financial Statements for the year ended December 31, 2015 and 2014, which is located on pages F-7 through F-17 of this Report. Compensation cost is generally recognized over the vesting period of the award. See the table below entitled "Outstanding Equity Awards at December 31, 2015."
3. Payment of the bonuses have been deferred and will be paid in common stock upon the termination of his employment with Milestone Scientific in accordance with the terms of his employment agreement. The 2015 bonus was approved by the Board in 2016. Other compensation represents payments made for health insurance coverage

and car allowance.

#### Employment Contracts

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

the first three years following the date of grant, but shall only be exercisable while the CEO is employed by Milestone Scientific or within 30 days after the termination of his employment.

In accordance with the employment contract, \$776,862 shares of common stock are to be paid out at the end of the contract in settlement of \$830,985 at December 31, 2015 and 706,716 shares of common stock are to be paid out at the end of the contract in settlement of \$630,985 at December 31, 2014 of accrued deferred compensation and, accordingly, such shares have been classified in stockholders' equity with the common shares classified as to be issued.

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

#### Objective of Executive Compensation Program

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

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

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

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

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

Outstanding Equity Awards at December 31, 2015

The following table includes certain information with respect to all unexercised stock options and unvested shares of common stock of Milestone Scientific outstanding owned by the Named Executive Officers at December 31, 2015.

Name (1)	Options Awards Number of Securities Underlying Unexercised Options (#) (#) Exercisable	Unexercised Options (#) Unexercisable (1)	Option Exercise Price (\$)	Stock Awards