MILESTONE SCIENTIFIC INC.
Form 10-K
March 13, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2012

or

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

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

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

220 South Orange Avenue, Livingston, NJ 07039

(Address of principal executive offices)

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

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

None

Securities registered pursuant to section 12(g) of the Act:

Common Stock, par value $.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes x 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 x 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. x 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). þ 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 x

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

As of June 29, 2012, the last business day of the Company s most recently completed second fiscal quarter, the aggregate market value of the common stock held by non affiliates of the issuer was $3,913,458. This amount is based on the closing price of $0.37 per share of the Company s common stock as of such date, as reported on the OTCQB.

As of March 13, 2013 the registrant has a total of 16,781,726 shares of Common Stock, $0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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MILESTONE SCIENTIFIC INC.

Form 10-K Annual Report

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FORWARD-LOOKING STATEMENTS

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

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PART I

Item 1. Description of Business

All references in this report to Milestone, us, the Company , or Milestone Scientific refer to Milestone Scientific Inc. unless the context otherwis indicates. Milestone has rights to the following trademarks: *CompuDent*®, *CompuMed*®, *CompuFlo*®, *The Wand*®, *The Wand Plus*®, *The SafetyWand*®, *Cool Blue Wand*®, *Cool Blue Tooth Whitening Instrument , Dynamic Pressure Sensing Technology*®, *STA Single Tooth Anesthesia*™, (STA Instrument, instruments and handpieces), *Ionic White*® (light emitting diode), and *Ionic White* (whitening toothpaste). Milestone was incorporated in the State of Delaware in 1989.

BUSINESS

Background

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

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

In 1997, Milestone first introduced *The Wand*® (*CompuDent*® instrument) and the disposable *Wand* handpiece. *CompuDent* provides painless injections for all routine dental treatments, including root canals, crowns, fillings and cleanings. Milestone s Computer-Controlled Local Anesthetic Delivery (C-CLAD) instrument handpiece does not look or feel like a syringe. And, what s more, it works better than a syringe, resulting in a more pleasant experience for the patient and practitioner. With more than 18,000 *CompuDent* instruments sold within four months of its market introduction, this represented the most successful launch in the history of small equipment sales in U.S. dentistry.

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

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

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

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

tactile senses and delivery expertise of the administrator.

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

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

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

Given the Company s experience and established brand awareness within the dental industry, it elected to focus its initial product development efforts on the integration of *CompuFlo* into its legacy computer-controlled dental injection instrument. As a result, Milestone developed the industry s first solution for painlessly administering a single-tooth injection as the only injection necessary for achieving anesthesia, foregoing the need to administer a traditional nerve branch block. This new instrument, which also provides for use of a disposable handpiece, was trademarked the *STA Single Tooth Anesthesia Instrument* , now more commonly known as the *STA Instrument*.

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

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

In the spring of 2009, Milestone signed an Exclusive Distribution and Marketing Agreement with China National Medicines Corporation, dba Sinopharm, which is China s largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and the country s largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone a blanket purchase order for 12,000 *STA* instruments and related handpieces to be delivered over 36 months, thereby marking the Company s initial penetration into China s emerging dental market.

In early October 2012, the State Food and Drug Administration (SFDA) of the People s Republic of China approved Milestone s *Single Tooth Anesthesia System*® (STA System). Unfortunately, the SFDA bifurcated approval of the STA Systems from the *Wand*® handpieces. SFDA approval of the *Wand*® handpieces is expected in the coming months. Therefore, shipment of STA handpieces continue to be suspended pending the approval to sell and distribute this products in China. It is expected that the approval by the appropriate Chinese regulatory body will be received in 2013.

In November 2012, Milestone signed an exclusive distributor and marketing agent with a well know U.S. domestic distributor, for the sale and distribution of the *STA instrument* and handpieces in the United States and Canada.

According to a report published by the U.S. Department of Commerce, titled China s Emerging Markets: Opportunities in the Dental and Dental Lab Industry, China s dental market lags behind other healthcare services and has largely been neglected in the past. In fact, CS Market Research

reports that of China s 1.3 billion plus population, 50% of the adults and 70% of the children are estimated to have decayed tooth problems, and over 90% have periodontal disease. However, with increasing affluence of the Chinese population, as well as increasing attention towards personal care, demand for dental services has been growing. Market research firm Freedonia agrees, noting that demand for dental products in China is expected to climb to 21.5 billion RMB (U.S. $3.15 billion) by 2012, due primarily to escalating personal income levels and government programs promoting awareness of the benefits of good oral care.

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

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

In November 2012, Milestone signed an exclusive distributor and marketing agreement with a well known US domestic distributor, for the sale and distribution of the *STA* I*nstrument* 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.

CompuFlo® Advanced Injection Technology Core Technology

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

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

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

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

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

In the absence of curative procedures, arthritis patients are obliged to endure multiple painful injections 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 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 will have a positive impact on compliance, which is a major consideration when physicians are determining which drugs to prescribe.

In July 2011, Milestone entered into a definitive joint venture agreement with Beijing 3H (Heart-Help-Health) Scientific Technology Co., Ltd. (Beijing 3H) for the development, commercialization, manufacture and marketing of epidural and intra-articular injection instruments. Milestone has a 50% interest in the joint venture and Beijing 3H, whose shareholders are a number of individuals, including a large shareholder in Milestone who is also the principal of a supplier to Milestone, Bejing 3H also has a 50% interest in joint venture.

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The joint venture provided for Milestone s contribution of an exclusive worldwide royalty-free license to use its patents. Beijing 3H has contributed $1.5 million to the joint venture to design and develop two commercial instruments using Milestone s CompuFlo® technology and disposables. Milestone will have distribution responsibility in the U.S., Canada and the rest of the world, while Beijing 3H will distribute products exclusively in the People s Republic of China, Macao, Hong Kong and other regions of Asia.

Product Platform

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

STA Single Tooth Anesthesia Instrument™ (STA Instrument)

The *STA Single Tooth Anesthesia Instrument (STA Instrument)* is a patented, computer-controlled local anesthesia delivery instrument that incorporates the pressure feedback elements of Milestone s patented *CompuFlo* technology, thereby allowing dentists to administer injections accurately into the periodontal ligament space, effectively anesthetizing a single tooth. While the periodontal ligament injection has been available for some time, there has been no effective technology that allows dentists to easily perform the procedure painlessly, safely and predictably until now. With this unique procedure dentists can easily and predictably anesthetize a single tooth root in one minute and a multiple root tooth in two minutes, as compared to a general blocking injection and waiting up to 18 minutes (or longer if the blocking injection needs to be re-administered) before proceeding to perform a procedure on the target tooth. A device 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 a device provides a compelling value in the marketplace. The *STA Instrument* will generate recurring revenues from per-patient disposable handpieces.

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

CompuDent®

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

- *CompuDent* minimizes the pain associated with palatal, mandibular block and all other injections, resulting in a more comfortable injection experience for the patient;
- the pencil grip used with *The Wand* handpieces allows unprecedented tactile sense and accurate control;
- new injections made possible with the *CompuDent* technology eliminate collateral numbness of the tongue, lips and facial muscles;

bi-directional rotation of *The Wand* handpieces eliminates needle deflection resulting in greater success and more rapid onset of anesthesia in mandibular block injections;

the use of a single patient use, disposable handpieces minimizes the risk of cross contamination; and

the ergonomic design of *The Wand* handpieces makes an injection easier and less stressful to administer, lowering the risk of carpal tunnel syndrome.

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

CompuMed®

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

The Wand®

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

Medical Instrument for Joint Venture

In July 2011, we entered into a definitive joint venture agreement with Beijing 3H (Heart-Help-Health) Scientific Technology Co., Ltd. (Beijing 3H) for the development, commercialization, manufacture and marketing of epidural and intra-articular injection instruments. Milestone Scientific has a 50% interest in the joint venture and Beijing 3H together with a number of individuals, including a large shareholder in Milestone who is also the principal of a supplier to Milestone, Bejing 3H also has a 50% interest in joint venture.

Competition

Milestone s proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) instruments compete with disposable and reusable syringes that generally sell at lower prices and that use established and well-understood methodologies in both the dental and medical marketplaces.

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

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

or obsolete; or, that Milestone will succeed in improving the existing products, effectively develop new products, or obtain required regulatory approval for those products.

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Patents and Intellectual Property

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

	U.S. PATENT NUMBER	DATE OF ISSUE
Computer Controlled Drug Delivery Systems		
Dental Anesthetic and Delivery Injection Unit	6,022,337	2/8/2000
Design for a Dental Anesthetic Delivery System Holder	D422,361	4/4/2000
Design for a Dental Anesthetic Delivery System Housing	D423,665	4/25/2000
Design for a Dental Anesthetic Delivery System Handle	D427,314	6/27/2000
Cartridge Holder for Injection Device	6,132,414	10/17/2000
Dental Anesthetic Delivery Injection Unit	6,152,734	11/28/2000
Microprocessor-controlled Fluid Dispensing Apparatus	6,159,161	12/12/2000
Pressure/Force Computer Controlled Drug Delivery System	6,200,289	3/13/2001
Dental Anesthetic and Delivery Injection Unit with Automated Rate Control	6,652,482	11/25/2003
Pressure/Force Computer Controlled Drug Delivery System with Exit Pressure	6,786,885	9/14/2004
Pressure/Force Computer Controlled Drug Delivery System with Automated Charging	6,887,216	5/3/2005
Drug Delivery System with Profiles	6,945,954	9/20/2005
Cartridge Holder for Anesthetic and Delivery Injection Device	D558,340	12/25/2007
Design for Drive Unit for Anesthetic	D566,265	4/8/2008
Design for Drive Unit for Anesthetic	D579,540	10/28/2008
Drug Infusion Device with Tissue Identification Using Pressure Sensing	7,449,008	11/11/2008
Computer Controlled Drug Delivery Systems with Pressure Sensing	7,618,409	11/17/2009
Hand Piece for Fluid Administration	7,625,354	12/1/2009
Self-Administration Injection System	7,740,612	6/22/2010
Computer controlled drug delivery system with dynamic pressure sensing	7,896,833	3/1/2011
Engineered Sharps Injury Protection Devices		
Handpiece for Injection Device with a Retractable and Rotating Needle	6,428,517	8/6/2002
Safety IV Catheter Device	6,726,658	4/27/2004
Safety IV Catheter Infusion Device	6,905,482	6/14/2005
Handpiece for Injection Device with a Retractable and Rotating Needle	6,966,899	11/22/2005

During the 2012 and 2011 fiscal years, Milestone expensed $181,979 and $140,053, respectively, on research and development activities. The higher costs incurred in 2012 were primarily associated with the continued development of the Single Tooth Anesthetic (STA) delivery instrument and continuing efforts on developing medical products utilizing the *CompuFlo* technology.

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

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

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Government Regulation

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

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

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

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

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

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

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

As of March 13, 2013, China National Medicines has not received the appropriate registration approval from the regulatory body in China, therefore, shipment of STA handpieces continue to be suspended pending the approval to sell and distribute this product in China. It is expected that the approval by the appropriate Chinese regulatory body will be received in 2013.

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

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 the Company to claims of liability. Milestone maintains liability insurance in an amount that Milestone believes is adequate. However, there can be no assurance that the insurance coverage will be sufficient to pay product liability claims brought against the Company. A partially or completely uninsured claim, if successful and of significant magnitude, could have a material adverse effect on the Company.

Employees

On December 31, 2012, Milestone had a total of 16 employees, consisting of two executive officers, a director of International and Professional Relations, a director of engineering, a domestic sales manager, an international sales manager, five sales representatives (field and internal), two customer service representatives, a staff accountant, a bookkeeper and an administrative manager. Milestone also has a full time consultant who serves as a Director of Clinical Affairs.

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

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

Milestone has no history of profitable operations. Continuing losses could exhaust capital resources and force us to discontinue operations.

For the years ended December 31, 2012 and 2011, revenues were approximately $8.6 million and $8.4 million, respectively. In addition, Milestone has had losses for each year since the commencement of operations, including net losses of approximately $870,000 and $1,482,000 for 2012 and 2011, respectively. At December 31, 2012, Milestone had an accumulated deficit of approximately $62 million. At December 31, 2012, the Company had cash and cash equivalents $165,249 and a negative working capital of $775,742. The significant working capital increase of $535,193 in 2012 as compared to 2011 is the result of reduced expenses and managed inventory purchasing. Milestone management is examining all areas of the business to manage our cash flow. Milestone business in China is still suspended, pending regulatory approval of our *STA* handpieces. In 2012, our distributors in China received regulatory approval for the importation of *STA* instruments. Obtaining such regulatory approval was not a condition of the purchase order and sale with the distributor in China. As a result of this delay, the advance to the contract manufacturer has been allocated between current and long term. Additionally, the net accounts receivable for the China distributor has been allocated between current and long term (in the aggregate of $219,000), with a reserve of $308,350 provided against the accounts receivable. The Company 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.

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As of December 31, 2012, the Company believes that it does not have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. If the Company requires a need for a higher level of marketing and sales effort, or if the Company is unable to generate positive cash flows from its operating activities, it will need to raise additional capital. There is no assurance that the Company will be able to achieve positive operating cash flows or that additional capital can be raised on the terms and conditions satisfactory to the Company, if at all. If additional capital is required and it cannot be raised, then the Company would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost savings measures, any of which might negatively affect the Company s operating results.

The Company s recurring losses raise substantial doubt about its ability to continue as a going concern.

Milestone cannot become successful unless it gains greater market acceptance for its products and technology.

As with any new technology, there is substantial risk that the marketplace will not accept the potential benefits of this technology or be unwilling to pay for any cost differential with the existing technologies. Market acceptance of *CompuDent*, *STA Instrument*, the *SafetyWand*, *CompuMed* and *CompuFlo* depends, in large part, upon the ability to educate potential customers of the product s distinctive characteristics and benefits and will require substantial marketing efforts and expense. More than 35,000 instruments of the *STA Instrument* and its predecessors have been sold worldwide since 1998. Since being introduced to market in February 2007, more than 8,000 instruments of the *STA Instrument* have been sold. Milestone cannot assure that its current or proposed products will be accepted by practitioners or that any of the current or proposed products will be able to compete effectively against current and alternative products.

The Company s limited distribution channels must be expanded in order to become successful.

Future revenues depend on the Company s ability to market and distribute its computer-controlled injection products successfully. In the U.S., Milestone hired in July 2010 a Domestic Sales Director to spur our growth trend in the USA and Canada. The U.S. and Canadian market rely on several independent dental distributors, and a team of clinical product specialists comprised of independent dental hygienists who help to educate, train and sell our products to dental practitioners and group dental practices in key U.S. markets. Abroad, Milestone lacked appropriate distribution in many markets. In April 2010, the Company hired an International Sales Director to improve sales effort outside the USA. To be successful, the Company will need to engage additional distributors, provide for their proper training and ensure adequate customer support. In the spring of 2009, the Company signed an Exclusive Distribution and Marketing Agreement with China National Medicines Corporation, dba Sinopharm, which is China s largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and the country s largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone a blanket purchase order for 12,000 STA units and related handpieces to be delivered over 36 months, thereby marking the Company s initial penetration into China s emerging dental market. Milestone cannot assure that it will be able to hire and retain an adequate sales force or engage suitable distributors, or that the sales force or distributors will be able to successfully market and sell the products.

In early October 2012, the State Food and Drug Administration (SFDA) of the People s Republic of China approved Milestone s *Single Tooth Anesthesia System*® (STA System). Unfortunately, the SFDA bifurcated approval of the STA Systems from the *Wand*® handpieces. SFDA approval of the *Wand*® handpieces is expected in the coming months.

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

Milestone 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, the Company issued a purchase order to Tricor Corporation to manufacture 12,000 *STA Instruments,* over the next three years. In 2010, 1,000 *STA Instrument* were purchased and shipped against this purchase order. Milestone has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum purchase commitments. Milestone has been supplied by the manufacturer of the *STA Instrument, CompuDent* and *CompuMed* since the commencement of production in 1998, the manufacturer of its handpieces since 2003. However, termination of the manufacturing relationship with any of these manufacturers could significantly and adversely affect the ability to produce and sell the products. Though other alternate sources of supply for handpieces exist, Milestone would need to recover its existing tools or have new tools produced to establish relationships with new suppliers. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of the supply, whether or not as a result or termination of the relationship, would have an adverse affect.

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

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

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

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

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

Milestone s stock price has been extremely volatile, fluctuating over the last two years between closing prices of $1.45 and $0.25. The market price of common shares could continue to fluctuate significantly in response to a variety of factors, some of which may be beyond the Company s control.

Milestone is controlled by a limited number of shareholders.

Milestone s principal shareholders, Leonard Osser and K. Tucker Andersen, beneficially own 31% of the issued and outstanding shares of common stock. As a result, they have the ability to exercise substantial control over the Company 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 the Company s securities.

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

Sales of a substantial number of shares of Milestone s common stock in the public markets, or the perception that these sales may occur, could cause the market price of the stock to decline and could materially impair its ability to raise capital through the sale of additional equity securities. At December 31, 2012, Milestone had outstanding options to purchase 1,523,740 shares of common stock at prices ranging from $0.24 to $2.50 per share with a weighted average exercise price of $0.98. 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 the Company would be able to obtain additional equity capital on more favorable terms. Thus, the terms upon which the Company will be able to obtain additional equity capital may be adversely affected, since the holders of outstanding options and warrants can be expected to exercise them at a time when Milestone would, in all likelihood, be able to obtain any needed capital on terms more favorable than the exercise terms provided by such outstanding securities. The market price of the common shares has been volatile and may continue to fluctuate significantly because of various factors, some of which are beyond the Company s control.

Implementation of procedures to comply with the Sarbanes-Oxley Act and SEC rules concerning internal controls may be so costly that compliance could have an adverse effect on the Company.

The Management of the Company has assessed the effectiveness of internal control over financial reporting as of December 31, 2012. 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). The Company complied with Sarbanes-Oxley requirements to include in the annual report a management report on the effectiveness of the internal control over financial reporting. In 2005, Milestone hired an outside consultant to assist with the development and implementation of the necessary internal controls and reporting procedures. In 2012 and 2011, the Company utilized the outside consultant on a quarterly basis to review compliance with the internal controls over financial reporting. This expense amounted to $14,000 and $13,533 in 2012 and 2011, respectively and the cost is expected to continue in 2013.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Property

The headquarters for the Company is located at 220 South Orange Avenue, Livingston, New Jersey which consists of approximately 6,300 square feet of office space. The Company leases its headquarters at a monthly cost of $6,942, which it believes to be competitive and the lease term expires on June 30, 2014. The leased office space is in good condition. Additionally, since November 2010, Milestone leased a corporate apartment in Maplewood, New Jersey on a month-to-month basis which it terminated in December 2011. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosure

Not applicable.

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PART II

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

Market Information

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

Common Stock

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

	HIGH	LOW
2012		
First Quarter	$ 0.68	$ 0.33
Second Quarter	$ 0.55	$ 0.25
Third Quarter	$ 0.65	$ 0.31
Fourth Quarter	$ 1.45	$ 0.52
2011		
First Quarter	$ 1.05	$ 0.62
Second Quarter	$ 0.80	$ 0.41
Third Quarter	$ 0.78	$ 0.30
Fourth Quarter	$ 0.70	$ 0.25

* On February 19, 2011, Milestone s Common Stock began trading on the OTCQB. During the first quarter of 2011, prior to February 19, 2011, Milestone s Common Stock was trading on the OTC Bulletin Board.

Holders

According to the records of the transfer agent, there were approximately 145 and 91 shareholders of record of the common stock as of December 31, 2012 and 2011, respectively. However, the Company believes that there are approximately 1,800 beneficial owners of the Company s common stock at December 31, 2012 and 2011, respectively.

Dividends

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

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

Sales of Unregistered Securities

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

ITEM 6. Selected Financial Data

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

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

The following discussions of the financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this annual report. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Exchange Act, that involve risks and uncertainties. The actual results may differ materially from those anticipated in these forward-looking statements. See Certain Risk Factors on page 11 of this Form 10-K.

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OVERVIEW

Milestone remains focused on advancing efforts to achieve our two primary objectives; those being:

Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the *STA Single Tooth Anesthesia Instrument* (*STA Instrument*); and

Identifying and pursing strategic collaborations with third parties to jointly develop new products utilizing our patented *CompuFlo* pressure force technology for novel new medical applications.

STA Instrument Awards Industry Recognition

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 the *STA Instrument* s value proposition for dentists and patients alike. In April 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 Instrument* was one of only two winning products that serve dental practitioners.

In July 2010, the *STA Instrument* was recognized as one of Dentistry Today s , Top 100 Products, for the third consecutive year. This honor is significant because it is unprecedented in Milestone s history and serves to support our objective of establishing our instrument as the new global standard of care for painless dental injections.

STA Instrument Growth

Since its market introduction in early 2007, the *STA Instrument* and a prior computerized controlled local anesthesia delivery product, have been used to deliver over 52 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. The utility and value of the *STA Instrument* is perhaps best summarized by Dr. Joe Blaes, who wrote in the December 2008 edition of *Dental Economics*, I tried the *STA Instrument* and my patients absolutely love it. This is a no brainer go get one ASAP!

Global Distribution Network

North America Market

The *STA Instrument* and related hand pieces are marketed to the dental industry in the United States and Canada by many of the nation s leading dental supply companies, prior to November 2012, including Henry Schein, Inc., Patterson Dental Supply, Atlanta Dental, Benco Dental, Burkhart Dental, Darby Dental Supply, Dental Health Products, Goetze Dental, Iowa Dental, Nashville Dental and Newark Dental. In Canada, our independent distributors include Dental 2000, Mediclub, and Specialty Dental. In November 2012, Milestone entered an exclusive distribution and marketing agreement with well known U.S. domestic manufacturer and distribution, for the sale and distribution of the *STA instruments* and handpieces in United States and Canada.

In the third quarter of 2010, the Company added a Domestic Sales Director to refocus our attention on the U.S. and Canadian markets. The mission of the Domestic Sales Director is to grow our business through marketing our STA Instrument to Dental Group Practices, as well as individual dental practitioners. Through direct marketing to the Dental Group Practices and utilizing a group of independent hygienists, the instrument and handpiece sales should increase substantially in the future. The Company signed on its first Group Dental Practice in January 2011, Towncare Dental.

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 April 2009, we signed an Exclusive Distribution and Marketing Agreement with China National Medicines Corporation, d/b/a Sinopharm, which is China s largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and the country s largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone a blanket purchase order for 12,000 *STA* instruments to be delivered over 36 months, thereby marking the Company s initial penetration into China s emerging dental market.

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In early October 2012, the State Food and Drug Administration (SFDA) of the People s Republic of China approved Milestone s *Single Tooth Anesthesia System*® (STA System). Unfortunately, the SFDA bifurcated approval of the STA Systems from the *Wand*® handpieces. SFDA approval of the *Wand*® handpieces is expected in the coming months. It is expected that the approval by the appropriate Chinese regulatory body will be received in 2013.

As of March 13, 2013, China National Medicines has not received the appropriate registration approval from the regulatory body in China. It is expected that the approval by the appropriate Chinese regulatory body will be received in 2013.

According to a report published by the U.S. Department of Commerce, titled China s Emerging Markets: Opportunities in the Dental and Dental Lab Industry, China s dental market lags behind other healthcare services and has largely been neglected in the past. In fact, CS Market Research reports that of China s 1.3 billion plus population, 50% of the adults and 70% of the children are estimated to have decayed tooth problems, and over 90% have periodontal disease. However, with increasing affluence of the Chinese population, as well as increasing attention towards personal care, demand for dental services has been growing. Market research firm Freedonia agrees, noting that demand for dental products in China is expected to climb to 21.5 billion RMB (U.S. $3.15 billion) by 2012, 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 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 hand pieces. The new sales strategy provides for increasing hands-on oversight and support of our existing international distribution network, while also attracting new distributors throughout Europe, Asia and South America. To assist in this endeavor, Milestone added in the spring of 2010 an International Sales Director to focus on growth of our products outside the USA and Canada. The new addition to the company s staff has proven to be a positive improvement to our sales and marketing effort outside the USA and Canada.

In July 2011, we entered into a definitive joint venture agreement with Beijing 3H (Heart-Help-Health) Scientific Technology Co., Ltd. (Beijing 3H) for the development, commercialization, manufacture and marketing of epidural and intra-articular injection medical instruments. Milestone Scientific has a 50% interest in the joint venture and Beijing 3H has a 50% interest, whose shareholders are a number of individuals, including a large shareholder in Milestone who is also the principal of a supplier to Milestone.

The joint venture provided for Milestone s contribution of an exclusive worldwide royalty-free license to use its patents. Beijing 3H and others did contribute $1.5 million to the joint venture to design and develop two commercial instrument and related disposables using Milestone s CompuFlo® technology and disposables. Milestone will have distribution responsibility in the U.S. and Canada while Beijing 3H will distribute products exclusively in the People s Republic of China, Macao, Hong Kong and other regions of Asia. As of December 31, 2012, the Medical Joint Venture and the development project has been initiated.

In the fourth quarter of 2012, Milestone wrote off its investment in a German Distributor, $76,319, (cost basis) due to its continued low performance and continued losses.

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

	Years Ended December 31,			
	2012		2011	
DOMESTIC				
Instruments	$ 843,837	19.4%	$ 1,321,967	28.4%
Handpieces	3,397,193	78.2%	3,272,113	70.2%
Other	102,777	2.4%	64,247	1.4%
Total Domestic	$ 4,343,807	100.0%	$ 4,658,327	100.0%
INTERNATIONAL				
Instruments	$ 1,302,919	30.3%	$ 1,501,702	40.4%
Handpieces	2,946,828	68.5%	2,185,083	58.7%
Other	54,688	1.2%	32,982	0.9%
Total International	$ 4,304,435	100.0%	$ 3,719,767	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	$ 4,343,807	50.2%	$ 4,658,327	55.6%
International	4,304,435	49.8%	3,719,767	44.4%
Total Product Sales	$ 8,648,242	100.0%	$ 8,378,094	100.0%

The Company earned gross profits of 65% and 64% in the years ended December 31, 2012 and 2011, respectively. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses. Although the Company anticipates expending funds for research and development in 2013, these amounts will vary based on the operating results for each quarter. The Company has incurred operating losses and negative cash flows from operating activities since its inception, except for 2009. The Company, at December 31, 2012, believes that it does not have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. The Company is actively pursuing the generation of positive cash flows from operating activities through increase in revenue, assessment of current contracts and current negotiations. There is no assurance that the Company will be able to achieve positive operating cash flows or that additional capital raised on terms and conditions satisfactory to the Company, if at all. If additional capital is required and it cannot be raised, then the Company would be forced to curtail its development activities, reduce marketing for existing dental products or adopt other cost saving measures, any of which might negatively affect the Company s operating results.

In 2013, the Company plans to further support increased sales and marketing activity through our newly appointed exclusive distributor of the *STA instruments* and handpieces in the U.S. and Canada and 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.

In January 2011, the Company signed an agreement with its first group dental practice Towncare Dental Partnership for deployment of our *STA Instrument.* The *STA Instrument* will replace the syringe in this practice. This practice has agreed to expand development of the *STA* instrument into its remaining offices in 2013.

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

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

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Summary of Critical Accounting Policies and Significant Judgments and Estimates

Milestone s discussion and analysis of the financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles, generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to accounts receivable, inventories, stock-based compensation and contingencies. The Company 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, the Company believes that the following accounting policies and significant judgments and estimates are most critical in understanding and evaluating the reported financial results.

Accounts Receivable

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

Inventories

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

Investment in Medical Joint Venture

The Company has entered into a Medical Joint Venture with a third party for the development and commercialization of two medical products. The Company owns fifty percent of the joint venture and has recorded its investment on the equity basis of accounting. The Company s proportionate share of expenses incurred by the Joint Venture is charged to the Statement of Operations and adjusted against the Investment in Medical Joint Venture.

Impairment of Long-Lived Assets

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

Revenue Recognition

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

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Results of Operations

The following table sets forth for the consolidated results of operations for the year ended December 31, 2012 compared to 2011 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	Years Ended			
	December 31, 2012		December 31, 2011	
Total revenue	$ 8,648,242	100%	$ 8,378,094	100%
Cost of products sold	3,055,991	35%	3,016,642	36%
Gross Profit	5,592,251	65%	5,361,452	64%
Selling, general and administrative expenses	5,930,625	69%	6,445,001	77%
Research and development expenses	181,979	2%	140,053	2%
Operating expenses	6,112,604	71%	6,585,054	79%
Loss from operations	(520,353)	-6%	(1,223,602)	-15%
Total other expense	(349,952)	-4%	(258,498)	-3%
Net loss	$ (870,306)	-11%	$ (1,482,100)	-18%

Year ended December 31, 2012 compared to year ended December 31, 2011

Total revenues for the twelve months ended December 31, 2012 and 2011 were $8,648,242 and $8,378,094, respectively. The total increase in product sales is $270,148 or 3%. The decrease in sales volume of domestic instruments of $478,130, or 36% in 2012 over 2011, was directly related to management s implementation of a new sales and training strategy focused on concentrated geographical sales efforts and support (deploying independent hygienists) for all customers. In the domestic market, the *STA* handpiece sales increased by $238,503 or 30% as compared to 2011. *CompuDent* handpiece sales decreased by $113,424 year over year. The training component of our business is beginning to show positive results on the increased handpiece sales in the domestic market. On the international scene, instrument sales decreased in 2012 over 2011 by $198,783, or 13%, primarily due to a significant reduction in sales of the *CompuDent* instrument as customers are migrating to our *STA* instrument. The *Wand Plus* instrument is no longer being shipped to our European customers, due to a change in the regulations. As such, international sales of the *Wand Plus* instrument will be reduced in future years. On an international basis, 2012 revenues increased against 2011 revenues for *STA* instrument sales by $45,347, or 4%. The *CompuDent* instrument sales decreased by $244,130 year over year. The increase in handpiece sales internationally was $761,745 or 35% due to an increase in sales of *STA* handpieces of $460,980 and an increase in sales of *CompuDent* handpieces $300,765 or 18%. Although the sales of *Wand Plus* instruments to the European community will not continue, there are many *Wand Plus* users in Europe that continue to own and utilize the instrument. This trend is expected to continue into 2013.

Cost of products sold for the years ended December 31, 2012 and 2011 were $3,055,991 and $3,016,642, respectively. The $39,349, or 1% increase in product cost is primarily due to a write off of advance to contract manufacturer for *CompuDents* materials of $135,535, in 2012, offset by lower production costs of the *STA* instruments.

Milestone generated a gross profit of $5,592,251 or 65% in 2012 as compared to a gross profit of $5,361,452 or 64% in 2011. The total dollar increase in gross profit was $230,799 in 2012 over 2011.

Selling, general and administrative expenses for the years ended December 31, 2012 and 2011 were $5,930,625 and $6,445,001, respectively. The $514,376 or 8%, net decrease was focused on several expense categories. In 2012, sales expense decreased by $150,494. This decrease is primarily due to decreased travel and tradeshow attendance and hygienists. Marketing expense decreased by $136,887. The decrease was primarily in the areas of media placement $32,352, marketing key opinion leaders of $10,882; brochure and production design of $51,571 and promotions at trade shows (national and regional) of $56,043 and offset by printing cost of $13,411. Payroll expenses decreased by $200,547 due to a reduction in sales payroll by $53,268; decrease in bonus accrual by $184,998 offset by an increase in medical benefits by $22,236. Legal and patent expenses increased by $37,313 in the aggregate due to reduced general litigation expenses and offset by increased customary patent annuity payments throughout the world. Other general and administrative expenses decreased by $48,037 due to increase in payment of an international commission of $143,680; increased royalties of $15,200 as a result of an increased sales volume; increase in the success fees for

domestic and international business of $29,715; an increase in business consulting of $69,279; the write off of Investment in German due to the continued low performance in that company of $76,319; offset by a decrease in stock based compensation of $124,272; a decrease in international travel expense decrease of $33,687 directly related to our focused attention on cost containment; decrease in finder s fee for the joint venture of $17,122. Bad debt expense decreased by $121,531 in 2012 compared to 2011. In addition, the Company realized expense increases in the areas of professional accounting and audit fees of $19,275 and increase in filing fee of $30,352 related to XBRL filing and reduced insurance costs of $20,242; investor relations cost by $25,023 and the elimination of the New Jersey apartment rental cost of $47,500.

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Research and development expenses for the years ended December 31, 2012 and 2011 were $181,979 and $140,053 respectively. The increase of $41,926 is due primarily to reimbursement of expenses in 2011 that was previously incurred by the Company of $104,968 from the Medical Joint Venture.

The loss from operations for the years ended December 31, 2012 and 2011 was $520,353 and $1,223,602 respectively. The $703,250 or 57% decrease in loss from operations, is mainly attributable to decreased operating expenses of $514,377 and an increase in gross profit of $230,799.

Interest expense of $86,270 relating to the converted $1.3 million line of credit into common stock in December 2009 and the $450,000 long term note payable, was charged for the twelve months ended December 31, 2012, compared to $77,722 for the same period in 2011, (see Note I to the financial statements included elsewhere in this annual report). Additionally, Milestone accrued interest expense of $86,270 and $51,282 for the overdue accounts payable balance to the instrument manufacturer at December 31, 2012 and 2011, respectively.

The loss on earnings from the Medical Joint Venture, $171,016 in 2012 and $121,399 in 2011, relate to the development of two medical instruments. This loss is not a cash drain on Milestone, since the Joint Venture partner contributed the cash for the development project.

For the reasons explained above, net loss for the year ended December 31, 2012 was $870,306 as compared to a net loss of $1,482,100 for the year ended December 31, 2011. The $611,794 or 41%, decrease in net loss is primarily a result of an increase in gross profit of $230,799, complimented by a significant decrease in Selling, General and Administrative and Research and Development expenses of $703,250 and the increase in other expense of $91,455.

Liquidity and Capital Resources

As of December 31, 2012, the Company had cash and cash equivalents of $165,249 and a negative working capital of $775,742. Milestone had net losses of $807,306 and $1,482,100 for the years ended December 31, 2012 and 2011, respectively. The negative working capital of $775,742 in 2012 was the result of continued delay in obtaining regulatory approval to sell our instruments and handpieces in China. Based on the initial purchase order from our distributor in China in 2009, Milestone ramped up purchasing of parts in anticipation of significant sales in 2010 and future years. As a result of the delay in shipping, the advances to contract manufacturer initially increased in 2010 and 2011. At December 31, 2012, advance to contract manufacturers decreased, (current and long term), as compared to December 31, 2011 through payment of the outstanding long term liability. Accounts payable due this suppliers has decreased to $704,724 as of December 31, 2012 as compared to $1,751,758 as of December 31, 2011. And finally, the accounts receivable from the China distributor has been classified between current and long term net of a reserve of doubtful accounts of $308,350.

The Company entered a Medical Joint Venture agreement with a third party in 2011, for the development and commercialization of two medical instruments. The Company did not invest any funds into this Medical Joint Venture. See Note F to the Financial Statements.

As a result of this delay on shipments to China, current accounts receivable decreased by $175,477, inventories decreased by $151,933, through better purchasing control, and current advances to contract manufacturers decreased by $475,589. Also, cash increased by $68,925 for operations. Current liabilities decreased by $1,334,386, principally due to a decrease in accounts payable for the purchase of materials to produce instruments and handpieces by $1,445,406.

The Company has also decreased noncurrent advances to contract manufacturer of $103,471. The Company continues to take positive steps to maintain adequate inventory levels and advances to contract manufacturers to maintain available inventory to meet our domestic and international sales requirements. Milestone incurred net losses of $870,306 and $1,482,100 for the years ended 2012 and 2011, respectively. Cash flows from operating activities for the year ended December 31, 2012 was a negative $49,718 and for the year ended December 31, 2011 was a negative $570,730. The significant decrease in net cash used in operations, is a substantial improvement over prior years.

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For the year ended December 31, 2012, net cash used in operating activities was $49,718. This was attributable primarily to a net loss of $870,306 adjusted for noncash items of $813,178 and changes in operating assets and liabilities of $7,410. The decrease in noncash items in 2012 as compared to 2011 is principally due to the decrease in shares issued for compensation of $144,027 in 2012.

For the years ended December 31, 2012 and 2011, Milestone used $31,357 and $39,028, respectively, in investing activities, primarily attributable to legal fees related to payment for patent rights.

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

The Company has incurred operating losses and negative cash flows from operating activities since its inception, except for 2009. The Company was very close, negative $49,718 cash flow from operations, to achieving a positive cash flow in 2012. Management of the Company is focused on generating a positive cash flow in 2013. The Company 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. As of December 31, 2012, the Company believes that it does not have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. However, if the Company requires a higher level of marketing and sales effort, or if the Company is unable to continue generating positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that the Company will be able to continue to achieve positive operating cash flows or that additional capital can be raised on the terms and conditions satisfactory to the Company if at all. If additional capital is required and it cannot be raised, then the Company would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost savings measures, any of which might negatively affect the Company s operating results.

The Company s recurring losses and negative operating cash flows raise substantial doubt about its ability to continue as a going concern. The accompanying financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Off-Balance Sheet Arrangements

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

Contractual Obligations

The impact of the contractual obligations at December 31, 2012, expected on the liquidity and cash flows in future periods, is as follows:

		Payments Due by Period		
	Total	Less than 1 Year	1-3 Years	3-5 Years
Long-term debt obligations	$ 450,000	$	$ 450,000	$
Operating lease obligations	124,958	83,306	41,653	
Purchase obligations (1)	2,868,864	1,941,840	927,024	
Total	$ 3,443,822	$ 2,025,146	$ 1,418,677	$

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

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Item 8. Financial Statements

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

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

None.

Item 9A. Controls and Procedures

The Company s management, including the Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of the Company 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, the Company s Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of December 31, 2012 are effective to ensure that information required to be disclosed in the reports the Company 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 the Company s management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management s Annual Report on Internal Control Over Financial Reporting

Milestone management is responsible for establishing and maintaining an adequate instrument of internal control over financial reporting. The internal control over financial reporting includes those policies and procedures that:

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

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

Milestone management assessed the effectiveness of its instrument of internal control over financial reporting as of December 31, 2012. 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). Based on the assessment and the criteria set forth by COSO, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2012.

There have been no changes in the Company s internal control over financial reporting identified in connection with the evaluation that occurred during the Company s last fiscal quarter ended December 31, 2012 that have materially affected, or that are reasonably likely to materially affect, the Company s internal controls over financial reporting.

Item 9B. Other Information

None.

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PART III

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

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

The current executive officers and directors of Milestone and their respective ages as of March 13, 2013 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leslie Bernhard (2)	68	Chairman of the Board and Director	2003
Leonard A. Osser	65	Chief Executive Officer and Director	1991
Joseph D Agostino	61	Chief Financial Officer and Chief Operating Officer	
Pablo Felipe Serna Cardenas (1)	37	Director	2006
Leonard M. Schiller(1)(2)	71	Director	1997

(1) Member of the Audit Committee
(2) Member of the Compensation Committee

Key Personnel

The following are the names of individuals who are not executive officers of Milestone but are deemed key personnel of Milestone, their respective ages and positions as of March 13, 2013:

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	69	Director of Professional Relations
Mark Hochman, D.D.S.	55	Director of Clinical Affairs

Leslie Bernhard, Chairman of the Board

In October 2009, Leslie Bernhard assumed the position of Chairman of the Board, filing a position left vacant by Mr. Osser who assumed the position of Chief Executive Officer. Leslie Bernhard has been serving as an Independent Director (as defined below) of Milestone since May 2003 and was named Chairman of the Board in September of 2009. She co-founded AdStar, Inc. and since 1986 has served as its President, Chief Executive Officer and Executive Director. AdStar is an application service provider for the newspaper classified advertising industry. She serves on the Board of Directors of Universal Power Group (NYSE MKT:UPG) of Dallas, Texas and has done so since 2006. Ms. Bernhard s professional experience and background with AdStar and with us, as one of our directors since 2003, have given her the expertise needed to serve as Chairman of the Board.

Leonard Osser, Chief Executive Officer

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

Joseph D Agostino, Chief Financial Officer and Chief Operating Officer

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

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

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

Dr. Eugene Casagrande, Director of International & Professional Relations

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

Leonard M. Schiller, Director

Mr. Schiller has been a director of Milestone since April 1997. Mr. Schiller has been a partner in the Chicago law firm of Schiller, Klein & McElroy, P.C. since 1977. He has also been President of The Dearborn Group, a residential property management and real estate acquisition company since 1980. Mr. Schiller became a Director of the Gravitas Cayman Corporation in February 2010. Gravitas Cayman Corporation is an Investment Fund. Mr. Schiller s professional experience and background as an attorney and a partner of a law firm and with us, as one of our directors since 1997, have given him the expertise needed to serve as one of our directors.

Pablo Felipe Serna Cardenas, Director

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

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and person who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten-percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. Based solely on review of the copies of such forms furnish to us, or written representations that no Forms 5 were required, we believe that all Section 16(a) filing requirements applicable to our officers and director were complied with during the fiscal year ended December 31, 2012 except that each of Leonard Osser and Joseph D Agostino did not timely file one Form 4.

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Code of Ethics

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

Item 11. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2012 and 2011 by (i) Milestone s CEO and (ii) the most highly compensated executive officers, other than the CEO who were serving as executive officers at the end of the 2012 fiscal year and whose salary as determined by Regulation S-K, Item 402, exceeded $100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the Named Executive Officers).

SUMMARY OF COMPENSATION TABLE

NAME AND PRINCIPAL POSITION	YEAR	Salary	Bonuses	Other Compensation	Option Awards (2)	Total
Leonard A. Osser						
Chief Executive Officer	2012	$ 300,000	$ 200,000 (1)	$ 29,831 (1)	$ 100,000	$ 629,831
	2011	$ 300,000	$ 400,000 (1)	$ 75,708 (1)	$	$ 775,708
Joseph D Agostino	2012	$ 171,600	$ 50,000 (3)	$ 29,609 (3)	$ 100,000	$ 351,209
Chief Financial Officer	2011	$ 171,600	$ 100,000 (3)	$ 27,442	$ 100,000	$ 399,042

(1) Payment of $100,000 of the bonuses have been deferred and will be paid in common stock upon the termination of his employment with the Company in accordance with the terms of his employment agreement. Other compensation represents payments made for personal use of corporate apartment, health insurance coverage and car allowance.

(2) The amounts in this column reflect the fair value of the options at date of grant. For details used in the assumption calculating the fair value of the option reward, see Note B to the Financial Statements for the year ended December 31, 2012 and 2011, which is located on pages F-7 through F-11 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, 2012.

(3) Payment of the bonuses have been deferred and will be paid in common stock upon the termination of his employment with the Company in accordance with the terms of his employment agreement. Other compensation represents payments made for health insurance coverage and car allowance.

Employment Contracts

As of September 1, 2009, the Company entered into a five-year employment agreement with Leonard Osser as its Chief Executive Officer. The term of the 2009 agreement is automatically extended for successive one-year periods unless prior to August 1 of any year, either party notifies the other that he or it chooses not to extend the term. Under the 2009 agreement, the CEO receives base compensation of $300,000 per year. In addition, the CEO, may earn annual bonuses up to an aggregate of $400,000, payable one half in cash and one half in common stock, contingent upon achieving targets set for each year by the Compensation Committee of the Board of Directors . In addition, if in any year of the term of the agreement the CEO earns a bonus, he shall also be granted five-year stock options to purchase twice the number of bonus shares earned. Each such option is to be exercisable at a price per share equal to the fair market value of a share on the date of grant (110%) of the fair market value if the CEO is a 10% or greater stockholder on the date of grant). The options shall vest and become exercisable to the extent of one-third of the shares covered at the end of each of the first three years following the date of grant, but shall only be exercisable while the CEO is employed by Milestone or within 30 days after the termination of his employment. In 2012 the CEO waived the option component of his bonus for that year.

In accordance with the employment contract, 1,182,493 shares of common stock are to be paid out at the end of the contract in settlement of$1,208,333 at December 31, 2012 and 1,025,735 shares of common stock are to be paid out at the end of the contract in settlement of $1,058,333 at December 31, 2011 of accrued deferred compensation and, accordingly, such shares have been classified in stockholders equity with the common shares classified as to be issued.

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This 2009 agreement suspended the previous 2008 employment with 40-months remaining in its term. Under the 2008 agreement Mr. Osser is employed as an executive, but not the CEO. In March 2013, the 2008 agreement was amended to extend its remaining term to 120-months.

Objective of Executive Compensation Program

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

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

The compensation program is designed to reward teamwork, as well as each manager s individual contribution. In measuring the Named Executive Officers contribution, the Compensation Committee considers numerous factors including the growth, strategic business relationships and financial performance. Regarding most compensation matters, including executive and director compensation, the management provides recommendations to the Compensation Committee; however, the Compensation Committee does not delegate any of its functions to others in setting compensation. Milestone does not currently engage any consultant to 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 s common stock is subject to a variety of factors outside of the control. Milestone does not have an exact formula for allocating between cash and non-cash compensation.

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

Outstanding Equity Awards at December 31, 2012

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

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	2012 Options Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that have not vested (#) (2)	Market Value of Number of Shares or Units of Stock that have not vested (#) (3)
Leonard Osser	74,071	59,263	$ 0.75	1/9/2017	1,182,493	$ 1,714,615
	28,128	14,065	$ 1.74	12/17/2014		
	0	73,333	$ 1.40	11/2/2014		
Joseph D Agostino	26,042	52,084	$ 1.28	12/28/2017	343,775	$ 498,474
	153,704	124,074	$ 0.36	12/31/2016		
	77,777	22,223	$ 1.00	12/20/2015		
	66,666	33,334	$ 1.00	12/20/2015		
	38,888	11,112	$ 1.15	12/17/2014		
	31,646		$ 1.58	12/17/2014		
	50,000		$ 1.15	9/1/2014		
	60,000		$ 0.40	3/31/2014		
Total	504,723	242,827				

(1) Represents stock option grants at fair market value on the date of grant.
(2) Issuance of the shares of common stock has been deferred until the termination of his employment with the Company in accordance with the terms of his employment agreement.
(3) Based on the closing price per share of $1.45 as reported on the OTCQB on December 31, 2012.

Compensation of Directors

Director Compensation

Name	2012 Stock Awards (1)	Fees Earned or Paid in Cash ($)	Total ($)
Leonard M. Schiller	$ 15,000	$ 15,000	$ 30,000
Leslie Bernhard	$ 15,000	$ 15,000	$ 30,000
Pablo Felipe Serna Cardenas	$ 15,000	$ 15,000	$ 30,000

(1) Represents the aggregate grant-date fair value of the awards computed in accordance with the FASB ASC Topic 718. 51,724 Shares, valued at $0.29 per share on June 6, 2012, were issued to each director

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

The following table, together with the accompanying footnotes, sets forth information, as of March 13, 2013, regarding stock ownership of all persons known by Milestone to own beneficially more than 5% of Milestone s outstanding common stock, Named Executives, all directors, and all directors and officers of Milestone as a group:

Names of Benefical Owner (1)	March 13, 2013 Shares of Common Stock Beneficially Owned (2)	Percentage of Ownership
Executive Officers and Directors		
Leonard Osser	2,686,701 (3)	16.01%
Joseph D Agostino	877,729 (4)	5.23%
Leonard Schiller	146,490 (5)	*
Pablo Felipe Serna Cardenas	133,262 (6)	*
Leslie Bernhard	56,538 (7)	*

All directors & executive officers as group (5 persons)	3,900,720 (8)	23.24%
K. Tucker Andersen	2,511,230	14.96%
Tom Cheng	1,002,862	5.98%

* Less than 1%

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(1) The addresses of the persons named in this table are as follows: Leonard Osser and Joseph D Agostino are at 220 South Orange Avenue in, New Jersey 07039; Leonard M. Schiller, c/o Schiller, Klein & McElroy, P.C., 33 North Dearborn Street, Suite 1030, Chicago, Illinois 60602; Pablo Felipe Serna Cardenas, Via Camillo Golgi 2 Opera, Italy 20090; Leslie Bernhard, c/o AdStar, Inc., 4553 Glencoe Avenue, Suite 325, Marina del Rey, California 90292; K. Tucker Andersen, c/o Cumberland Associates LLC, 1114 Avenue of the Americas, New York, New York 10036.

(2) A person is deemed to be a beneficial owner of securities that can be acquired by such person within 60 days from March 13, 2013, as applicable, upon the exercise of options and warrants or conversion of convertible securities. Each beneficial owner s percentage ownership is determined by assuming that options, warrants and convertible securities that are held by such person (but not held by any other person) and that are exercisable or convertible within 60 days from the filing of this report have been exercised or converted. Except as otherwise indicated, and subject to applicable community property and similar laws, each of the persons named has sole voting and investment power with respect to the shares shown as beneficially owned. All percentages are determined based on the number of all shares, including those underlying options exercisable within 60 days from the filing of this report held by the named individual, divided by 16,781,726 outstanding shares on March 13, 2013, plus those shares underlying options exercisable within 60 days from the filing of this report held by the named individual or the group.

(3) Includes 1,430,137 shares held by Mr. Osser or family, 1,182,493 Shares to Be Issued at the termination of his employment agreement, and 102,199 shares subject to options; 28,128 at $1.74 and 74,071 at $.75.

(4) Includes 343,775 shares to be issued at the termination of employment. Also 29,231 shares held by Mr. D Agostino at March 13, 2013. Additionally, this includes 504,723 shares subject to options as follows: 60,000 shares at $0.40; 88,888 shares at $1.15; 31,646 shares at $1.58; 144,443 shares at $1.00; 153,704 shares at $0.36 and 26,042 shares at $1.28.

(5) Includes 45,000 stock options as follows: 25,000 shares at $0.55 and 20,000 shares at $0.74.

(6) Includes 45,000 stock options as follows: 25,000 shares at $0.55 and 20,000 shares at $0.74.

(7) Includes 45,000 stock options as follows: 25,000 shares at $0.55 and 20,000 shares at $0.74.

(8) Includes 750,834 shares of Common Stock underlying outstanding options.

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Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes the (i) options granted under the Milestone 2004 Stock Option Plan, (ii) options and warrants granted outside the Milestone 2004 Stock Option Plan, as of December 31, 2012, and (iii) options granted under the Milestone 2011 Stock Option Plan. The shares covered by outstanding options and warrants are subject to adjustment for changes in capitalization, stock splits, stock dividends and similar events. No other equity compensation has been issued.

	Number of Securities to be issued upon exercise of outstanding options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance under equity compensation plan
Equity compensation plan approved by stockholders			
Grants under our 2004 Stock Option Plan (1)	64,600	$ 2.60	685,400
Grants under our 2011 Stock Option Plan (3)	589,237	$ 0.55	1,622,222
Equity compensation plan not approved by stockholders (2)			Not applicable
Aggregate individual option and warrants grants	869,903	$ 1.15	
Total	1,523,740	$ 0.98	

(1) In July 2004 the Board of Directors approved the adoption of the 2004 Stock Option Plan. The 2004 Stock Option Plan provides for the grant of options to purchase up to 500,000 shares of Milestone s common stock. Options may be granted to employees, officers, directors and consultants of Milestone for the purchase of common stock of Milestone at a price not less than the fair market value of the common stock on the date of the grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. No options were exercised in 2011.
In March 2008, the Board of Directors authorized an additional 250,000 options to this Plan.

(2) The aggregate individual option grants outside the Stock Option Plans referred to in the table above include options issued as payment for services rendered to us by outside consultants and providers of certain services. The aggregate individual warrant grants referred to in the table above include warrants granted to investors in Milestone as part of private placements and credit line arrangements. 100,000 options were exercised at $ 0.24 per share in 2011.

(3) In June 2011, the Stockholders approved the adoption of the 2011 Stock Option Plan. The 2011 Stock Option Plan provides for the grant of options to purchase 2,000,000 shares of Milestone s Common Stock. Options may be granted to employees, directors and consultants of Milestone for the purchase of Common Stock of Milestone at a price not less than the fair market value of the Common Stock on the date of grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. No options were exercised in 2011.

Stock Plan

In 2006 Milestone adopted an equity compensation plan for the issuance of up to 300,000 shares of the common stock in lieu of cash compensation for services performed by employees, officers, directors and consultants (the 2006 Stock Plan). The purpose of the 2006 Stock Plan is to conserve cash while allowing the Company to adequately compensate existing employees, officers, directors and consultants, or new employees, officers, directors and consultants, whose performance will contribute to the long-term success and growth. Milestone believe that the availability of these shares will also strengthen the ability to attract and retain employees, officers, directors and consultants of high competence, increase the identity of interests of such people with those of the stockholders and help maintain loyalty to us through recognition and the opportunity for stock ownership. All shares granted under this plan will be at fair market value, or at a premium to that value, on the date of grant.

As of December 31, 2012 there are no shares remaining under this plan.

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

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At December 31, 2012 and 2011 there was $11,316, respectively, available to be issued under this plan.

The Vendor Shares were issued in reliance upon the exemption from the registration requirements of the Act, as provided in Section 4(6) and thereof, as a transaction by an issuer not involving a public offering. Milestone reasonably believed that each vendor had such knowledge and experience in financial and business matters to be capable of evaluating the merits and risks of the investment, each vendor represented an intention to acquire the securities for investment only and not with a view to distribution thereof and appropriate legends were affixed to the stock certificates. No commissions were paid in connection with such issuances.

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

On June 28, 2007 the Company secured a $1 million line of credit from K. Tucker Andersen, a stockholder, beneficially owning approximately 18% of the Company s outstanding stock. This borrowing was amended to $1,300,000 as of September 30, 2008 under the same terms and conditions as the original. In December 2009, the Company converted the $1.3 million principal amount of the borrowing under the line of Credit into 822,785 shares of Common Stock at a price of $1.58 per share. Additionally, the interest due on the principal is payable over a two year period (quarterly payments of $23,000). Interest continues to accrue and no payment were made in 2012 and $23,000 was paid in 2011.

The Company borrowed an additional $450,000 from the same stockholder in 2008. The borrowing was originally on short term loan with a maturity date of January 19, 2009. In December 2008 and again on June 30, 2011, this borrowing was refinanced with the shareholder with a due date of January 3, 2014. The borrowing includes a twelve percent interest rate, interest compound quarterly, with interest and principle due at the maturity. Further, the note provides for the issuance of warrants to the stockholder that is exercisable for five years at the price of $0.32 per share for 45,000 shares of stock. The warrants were valued using the Black-Scholes model and are reflected as a discount against the debt. These warrants expired in June 2012. The Company did not have any other related party transactions pursuant to Item 404 of Regulation S-K of the Exchange Act. Milestone has adopted a policy that, in the future, the Audit Committee must review all transactions with any officer, director or 5% stockholder. The amount outstanding to the stockholder was $450,000 for both years ending December 31, 2012 and 2011. Interest expense accrued on this debt was $87,016 and $77,722 for the years ended December 31, 2012 and 2011, respectively.

Tom Cheng, a shareholder, is also a supplier of handpieces to the Company. Mr. Cheng is also an investor along with 3H Bejing, in a 50 percent ownership in the Medical Joint Venture.

Director Independence

The Board has determined that Leonard M. Schiller, Leslie Bernhard and Pablo Felipe Serna Cardenas (the Independent Directors) are independent as that term is defined in the listing standards of the NYSE MKT. As disclosed above, Pablo Felipe Serna Cardenas and Leonard M. Schiller members of the Audit Committee and are independent for such purposes, and Leonard M. Schiller and Leslie Bernhard are members of the Compensation Committee and are independent for such purposes.

In determining director independence, the Board considered the stock awards to the Independent Directors for the year ended December 31, 2012, disclosed in Item 11 Executive Compensation Director Compensation above, and determined that such awards were compensation for services rendered to the Board and therefore did not impact their ability to continue to serve as Independent Directors.

Item 14. Principal Accounting Fees and Services

Audit Fees

Milestone incurred audit and financial statement review fees totaling $151,307 and $132,033, respectively from Holtz Rubenstein Reminick LLP, its principal accountant for 2012 and 2011.

Audit Related Fees

There were no audit related fees to the principal accountant Holtz Rubenstein Reminick LLP in 2012 and 2011.

Tax Fees

There were no fees for services related to tax compliance, tax advice and tax planning billed by the principal accountant in 2012 and 2011.

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All Other Fees

There were no other fees billed during 2012 and 2011 by Milestone s principal accountants.

Audit Committee Administration of the Engagement

The engagement with Holtz Rubenstein Reminick LLP, the principal accountants, was approved in advance by the Board of Directors and the Audit Committee. No non-audit or non-audit related services were approved by the Audit Committee in 2012.

Audit Committee Pre-Approval Policies and Procedures

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

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PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

Report of Independent Registered Public Accounting Firm (Holtz Rubenstein Reminick LLP -2012 and 2011)

Balance Sheets at December 31, 2012 and 2011

Statements of Operations for the years ended December 31, 2012 and 2011

Statement of Changes in Stockholders Equity for the years ended December 31, 2012 and 2011

Statements of Cash Flows for the years ended December 31, 2012 and 2011

Notes to Financial Statements

2. *Financial Statement Schedule*

Schedules are omitted because the information required is not applicable or the required information is shown in the consolidated financial statements or notes thereto

3. *Exhibits*

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

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Exhibit NO.	Description
3.1	Certificate of Incorporation of Milestone (1)
3.2	Certificate of Amendment filed July 13, 1995 (2)
3.3	Certificate of Amendment filed December 6, 1996 (3)
3.4	Certificate of Amendment filed December 17, 1997 (4)
3.5	Certificate of Amendment filed July 23, 2003 (5)
3.6	Certificate of Amendment filed January 8, 2004 (5)
3.7	Certificate of Designation filed January 15, 2004 (5)
3.8	By-laws of Milestone (1)
4.1	Speciman stock certificate (2)
4.3	Form of warrant agreement, including form of warrant (7)
10.1	Lease dated November, 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (3)
10.2	Agreement with DaVinci Instruments, dated July 30, 2003 (5)
10.3	Agreement with Strider, dated September 3, 2003 (5)
10.4	Agreement with Len Osser and K. Tucker Andersen, dated October 9, 2003 (5)
10.5	Agreement with Morse, Zelnick, Rose & Lander, dated December 22, 2003 (5)
10.6**	Employment Agreement with Leonard Osser, dated December 20, 2003 (5)
10.7	Agreement with United Instruments, dated October 20, 2004 (6)
10.8	Agreement with Mark Hochman, dated January 1, 2005 (6)
10.9	Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. And Milestone (6)
10.10	Agreement with DaVinci regarding exclusive license over patented products, dated June 1, 2004 (8)
10.11**	Employment Agreement with Leonard Osser, dated September 1, 2009 (9)
10.12	Loan agreement of $1 million from K. Tucker Andersen, dated June 29, 2007 (10)
10.13	Amendment to the loan agreement of $1.3 million from K. Tucker Andersen, dated April 18, 2008 (10)
10.14	Promissory note in the principal amount of $450,000 held by K. Tucker Andersen, dated December 24, 2008 (10)
10.15	Amendment to the $450,000 promissory note held by K. Tucker Andersen, dated June 30, 2011 (11)
10.16	2004 Stock Option Plan (11)
10.17	2011 Stock Option Plan (12)
10.18	Amendment to the $450,000 promissory note held by K. Tucker Andersen, effective May 10, 2012*
10.19*	Amendment to the Employment Agreement with Leonard Osser, dated March 6, 2013*
14	Code of Ethics (6)
23.1	Consent of Holtz Rubenstein Reminick LLP*
31.1	Rule 13a-14(a) Certification-Chief Executive Officer*
31.2	Rule 13a-14(a) Certification-Chief Financial Officer*
32.1	Section 1350 Certifications-Chief Executive Officer*
32.2	Section 1350 Certifications-Chief Financial Officer*
101.INS***	XBRL Instance Document

101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.
** Indicates management contract or compensatory plan or arrangement
*** Furnished with this report. In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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(1) Incorporated by reference to Milestone s Registration Statement on Form SB-2 No. 333-92324.
(2) Incorporated by reference to Amendment No. 1 to Milestone s Registration Statement on Form SB-2 No. 333-92324.
(3) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 1996.
(4) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 1999.
(5) Incorporated by reference to Milestone s Registration Statement on Form S-2 No. 333-110376, Amendment No. 3.
(6) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 2004.
(7) Incorporated by reference to Milestone s Registration Statement on Form S-2 No. 333-110367, Amendment No. 5.
(8) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 2005.
(9) Incorporated by reference to Milestone s Form 10-K for the year ended December 31, 2009.
(10) Incorporated by reference to Milestone s Form 10-K for the year ended December 31, 2010.
(11) Incorporated by reference to Milestone s Form 10-K for the year ended December 31, 2011.
(12) Filed as Appendix C to the Company s Proxy Statement filed with the SEC on June 28, 2004 and incorporated herein by reference.
(13) Filed as Appendix A to the Company s Proxy Statement filed with the SEC on May 2, 2011 and incorporated herein by reference.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Milestone Scientific Inc.

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

Date: March 13, 2013

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

Signature	Date	Title
/s/ Leonard Osser Leonard Osser	March 13, 2013	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Joseph D Agostino Joseph D Agostino	March 13, 2013	Chief Financial Officer (Principal Financial Officer)
/s/ Leonard Schiller Leonard Schiller	March 13, 2013	Director
/s/ Leslie Bernhard Leslie Bernhard	March 13, 2013	Chairman and Director
/s/ Pablo Felipe Serna Cardenas Pablo Felipe Serna Cardenas	March 13, 2013	Director

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Milestone Scientific Inc.

We have audited the accompanying balance sheets of Milestone Scientific Inc. as of December 31, 2012 and 2011 and the related statements of operations, stockholders equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Milestone Scientific Inc. as of December 31, 2012 and 2011 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A to the financial statements, the Company has suffered recurring losses from operations since inception, which raises substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are described in Note A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Holtz Rubenstein Reminick LLP

New York, New York

March 13, 2013

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MILESTONE SCIENTIFIC INC.

BALANCE SHEETS

December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 165,249	$ 96,324
Accounts receivable, net of allowance for doubtful accounts of $179,259 in 2012 and $182,880 in 2011	978,982	1,154,459
Inventories	638,561	790,494
Advances on contracts	476,969	952,558
Prepaid expenses and other current assets	239,061	304,180
Total current assets	2,498,822	3,298,015
Accounts receivable-long term, net of allowance for doubtful accounts of $167,971 in 2012 and $372,000 in 2011	119,201	261,256
Advances on contracts	2,350,477	2,453,948
Investment in distributor, at cost		76,319
Investment in Medical Joint Venture		124,179
Furniture, Fixtures & Equipment net of accumulated depreciation of $458,708 as of December 31, 2012 and $446,484 as of December 31, 2011	36,624	52,309
Patents, net of accumulated amortization of $420,556 as of December 31, 2012 and $344,238 as of December 31, 2011	648,662	698,357
Other assets	7,317	27,819
Total assets	$ 5,661,103	$ 6,992,202
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,336,594	$ 3,931,531
Accrued expenses and other payable	581,407	407,872
Accrued interest on Notes Payable	356,563	269,547
Total current liabilities	3,274,564	4,608,950
Long-term Liabilities:		
Notes payable-net of discount of $0 and $3,065, respectively	450,000	446,935
Total long-term liabilities	450,000	446,935
Commitments and Contingencies		
Stockholders Equity		
Common stock, par value $.001; authorized 50,000,000 shares; 16,563,306 shares issued 1,635,709 shares to be issued and 16,529,973 shares outstanding as of December 31, 2012; 15,556,878 shares issued, 1,501,457 shares to be issued, and 15,523,545 shares outstanding as of December 31, 2011	18,199	17,058
Additional paid-in capital	64,560,224	63,690,837
Accumulated deficit	(61,730,368)	(60,860,062)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)

Total stockholders equity		1,936,539		1,936,317
Total liabilities and stockholders equity	$	5,661,103	$	6,992,202

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.

STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2012 AND 2011

	2012	2011
Product sales, net	$ 8,648,242	$ 8,378,094
Cost of products sold	3,055,991	3,016,642
Gross profit	5,592,251	5,361,452
Selling, general and administrative expenses	5,930,625	6,445,001
Research and development expenses	181,979	140,053
	6,112,604	6,585,054
Loss from operations	(520,353)	(1,223,602)
Other income (expense)		
Interest income	34	35
Interest expense	(175,905)	(131,838)
Amortized debt issuance	(3,065)	(5,296)
Loss on Earnings from Medical Joint Venture	(171,016)	(121,399)
Total other expense	(349,952)	(258,498)
Net loss applicable to common stockholders	$ (870,306)	$ (1,482,100)
Loss per share applicable to common stockholders basic and diluted	$ (0.05)	$ (0.10)
Weighted average shares outstanding and to be issued basic and diluted	16,080,474	15,174,893

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.

STATEMENT OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2012 AND 2011

	Common Stock		Additional Paid-in	Accumulated	Treasury	
	Shares	Amount	Capital	Deficit	Stock	Total
Balance, January 1, 2011	15,552,972	$ 15,552	$ 62,606,043	$ (59,377,962)	$ (911,516)	$ 2,332,117
Options issued to employees and consultants			255,899			255,899
Options exercised	100,000	100	24,900			25,000
Common stock to be issued to employee for bonuses	748,990	749	419,251			420,000
Common stock to be issued to employee for compensation	12,153	12	4,363			4,375
Common stock to be issued to consultants	103,300	103	60,710			60,813
Sale of common stock	99,999	100	29,900			30,000
Common stock issued for directors compensation	75,000	75	44,925			45,000
Common stock issued for payment of consulting services to settle accounts payable	327,222	327	190,886			191,214
Proceeds on sale of option rights			24,000			24,000
Common stock issued for payment of employee compensation	38,699	39	29,961			30,000
Net Loss				(1,482,100)		(1,482,100)
Balance, December 31, 2011	17,058,335	17,058	63,690,837	(60,860,062)	(911,516)	1,936,317
Options issued to employees and consultants			177,987			177,987
Common stock to be issued to employee for bonuses	229,705	230	236,770			237,000
Sale of common stock	107,143	107	149,893			150,000
Common stock issued for directors compensation	155,172	155	44,845			45,000
Common stock issued for payment of consulting services to settle accounts payable	543,209	543	216,872			217,415
Common stock issued for payment of employee compensation	105,451	105	43,020			43,125
Net Loss				(870,306)		(870,306)
Balance, December 31, 2012	18,199,015	$ 18,199	$ 64,560,224	$ (61,730,368)	$ (911,516)	$ 1,936,539

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.

STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2012 AND 2011

	2012	2011
Cash flows from operating activities:		
Net loss	$ (870,306)	$ (1,482,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	18,816	22,094
Amortization of patents	76,317	83,297
Amortization of debt discount	3,065	5,296
Common stock and options issued for compensation, consulting, and vendor services	673,691	864,555
Bad debt reversal	(207,650)	(86,120)
Loss on sale/disposal of equipment	1,604	
Loss on Earnings from Joint Venture	171,016	121,399
Write-off of Investment in Germany	76,319	
Changes in operating assets and liabilities:		
Decrease (Increase) in accounts receivable	525,182	(172,214)
Decrease in inventories	151,933	196,453
Decrease (Increase) to advances on contracts	579,060	(962,221)
Decrease to prepaid expenses and other current assets	65,119	17,717
Decrease in other assets	20,502	47,432
(Decrease) Increase in accounts payable	(1,594,937)	607,568
Increase in accrued expenses	173,535	111,392
Increase in accrued interest for notes payable	87,016	54,722
Net cash used in operating activities	(49,718)	(570,730)
Cash flows from investing activities:		
Purchases of property and equipment	(4,735)	(7,467)
Payment for patent rights	(26,622)	(31,561)
Net cash used in investing activities	(31,357)	(39,028)
Cash flows from financing activities:		
Proceeds from the sale of stock options rights		24,000
Proceeds from the exercise of stock options		25,000
Proceeds from the sale of common stock	150,000	30,000
Net cash provided by financing activities	150,000	79,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	68,925	(530,758)
Cash and cash equivalents at beginning of year	96,324	627,082
Cash and cash equivalents at end of year	$ 165,249	$ 96,324
Supplemental disclosure of cash flow information:		
Interest expense paid in cash	$	$ 23,000
Supplemental disclosure of non cash activities:		
Shares issued to directors for compensation	$ 45,000	$ 45,000

Shares issued to employees in lieu of cash compensation	$ 43,125	$ 30,000
Shares issued to settle accounts payable	$ 217,415	$ 191,214
Non-Cash		
Transfer of assets to JV	$	$ 194,765

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.

NOTES TO FINANCIAL STATEMENTS

NOTE A ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Milestone Scientific Inc. (Milestone) or (the Company) or (our) was incorporated in the State of Delaware in August 1989. Milestone has developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of *The Wand*, a single use disposable handpiece. The instrument is marketed in dentistry under the trademark *CompuDent, Wand Plus and STA (Single Tooth Anesthesia)* and in medicine under the trademark *CompuMed. CompuDent* is suitable for all dental procedures that require local anesthetic. *CompuMed* and *Wand Plus* are suitable for many medical procedures regularly performed in Plastic Surgery, Hair Restoration Surgery, Podiatry, Colorectal Surgery, Dermatology, Orthopedics and a number of other disciplines. The instruments are sold in the United States and in over 47 countries abroad. Milestone s products are manufactured by a third-party contract manufacturer.

Milestone had incurred operating losses since its inception. The Company had negative cash flows from operating activities at December 31, 2012 of $49,718 and a negative cash flow from operating activities at December 31, 2011 of $570,730. At December 31, 2012, the Company had cash and cash equivalents and a negative working capital of $165,249 and $775,742, respectively. The negative working capital decrease of $535,193 as compared to 2011 is due to the Company s continued reduction by payment of our commitment of purchasing parts in anticipation of significant sales to our distributor in China. Such sales have been delayed. As a result of this delay, the advances to contract manufacturer has been allocated between current and long term. Additionally, the accounts receivable from the China distributor had been allocated between current and long term, with a reserve of $308,350 provided against the accounts receivable. Additionally, the Company borrowed $450,000 in 2008 from a shareholder, with a due date of January 2009. This additional borrowing was refinanced at December 31, 2008 and June 30, 2011 and the due date was extended to January 3, 2014. The Company is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue based upon management s assessment of present contracts and current negotiations and reductions in operating expenses. As of December 31, 2012, the Company does not expect to have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. The Company may require the need for a higher level of marketing and sales efforts that at present it cannot fund. If the Company is unable to generate positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that the Company will be able to achieve positive operating cash flows or that traditional capital can be raised on terms and conditions satisfactory to the Company, if at all. If positive cash flow cannot be achieved or if additional capital is required and it cannot be raised, then the Company would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost saving measures, any of which might negatively affect the Company s operating results.

Milestone s recurring losses, and the matters discussed above, raise substantial doubt about its ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE B SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1. Cash and Cash Equivalents

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

2. Accounts Receivable

The realization of Accounts Receivable current and long-term will have a significant impact on the Company. Consequently, Milestone estimates losses resulting from the inability of its customers to make payments for amounts billed. The collectability of outstanding amounts is continually assessed.

3. Product Return and Warranty

Milestone does not accept non-defective returns from its customers. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Warranty Policy. Returns not within the Warranty Policy are charged to the customer. Warranty expense was $87,544 and $63,445 for 2012 and 2011, respectively. Non-Warranty repairs are collected from the customers. Non-Warranty repair income was $107,868 and $100,017 for 2012 and 2011, respectively.

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4. Inventories

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

5. Investment in Medical Joint Venture

Milestone has entered into a Joint Venture with a third party for the development and commercialization of two medical instruments. The Company owns fifty percent of the joint venture and has recorded its investment on the equity basis of accounting. The Company s proportionate share of losses incurred by the Joint Venture is charged to the Statement of Operations and adjusted against the Investment in Joint Venture.

6. Furniture, Fixture and Equipment

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

7. Investments

Investments in less than twenty percent owned entities are accounted for under the cost basis and are reviewed for impairment periodically. The Company does not have any significant control over the operations of this investee. In the fourth quarter of 2012, the Company wrote off its total investment of $76,319 based on low performance and continued losses with that distributor. This expense is included within the selling, general and administrative expenses on the statement of operation for the year ended December 31, 2012.

8. Patents

Patents are recorded at actual cost to prepare and file the applicable documents with the United States Patent Office, or internationally with the applicable governmental office in the respective country. Although certain patents have not yet been approved, the costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. If the applicable patent application is ultimately rejected, the remaining unamortized balance will be expensed in the period in which the Company receives a notice of such rejection. Patent applications filed and patents obtained in foreign countries are subject to the laws and procedures that differ from those in the United States. Patent protection in foreign countries may be different from patent protection under United States laws and may not be favorable to the Company. The Company also attempts to protect the proprietary information through the use of confidentiality agreements and by limiting access to the facilities. There can be no assurance that the program of patents, confidentiality agreements and restricted access to the facilities will be sufficient to protect the proprietary technology.

9. Impairment of Long-Lived Assets

Milestone reviews long-lived assets for impairment whenever events or circumstances indicate that the carrying amounts may not be recoverable. The carrying value of the assets is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets. Milestone adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. The Company has reviewed long-lived assets for impairment and concluded no impairment exist as of December 31, 2012 and December 31, 2011, respectively.

10. Revenue Recognition

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

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11. Shipping and Handling Costs

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

12. Research and Development

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

13. Advertising Expenses

Milestone expenses advertising costs as they are incurred. For the years ended December 31, 2012 and 2011, Milestone recorded advertising expenses of $51,412 and $83,764, respectively.

14. Income Taxes

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

15. Basic and diluted net loss per common share

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

Since Milestone had net losses for 2012 and 2011, the assumed effects of the exercise of outstanding stock options and warrants were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 1,523,740 at December 31, 2012 and 1,599,281 at December 31, 2011.

16. Use of Estimates

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

17. Fair Value of Financial Instruments

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

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

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

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

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

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18. Stock-Based Compensation

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

The weighted-average fair value of the options granted during 2012 and 2011 was estimated as $0.95 and $0.33, respectively, on the date of grant. The fair value for 2012 and 2011 was determined using the Black-Scholes option-pricing model with the following weighted average assumptions:

	December 31,	
	2012	**2011**
Volatility	172%	181%
Risk-free interest rate	0.79%	0.84%
Expected life	3 years	3 years
Dividend yield	0%	0%
Forfeiture Rate	6%	6%

Issuances of common stock, stock options or other equity instruments to non-employees as consideration for goods or services received by Milestone are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of any options or similar equity instruments issued is estimated based on the Black-Scholes option-pricing model, and the assumption that all of the options or other equity instruments will ultimately vest. Such fair value is measured as of an appropriate date pursuant to the guidance in the consensus of the party becomes committed to provide goods or services or the date performance by the other party is complete and capitalized or expensed as if Milestone had paid cash for the goods or services.

Expected volatilities are based on historical volatility of Milestone s common stock over a period commensurate with expected term. Milestone uses historical data to estimate option exercise and employee termination within the valuation model. The Company has granted performance based options to the chief executive officer. Such performance based options are earned based on specific criteria established by the Company. The Company records these options based on the likelihood of the officer achieving the specified performance objective and accrues these costs over the performance period. The estimates inherent in making this assessment are reviewed periodically by management and the resulting changes are booked through the statement of operations.

19. Concentration of Credit Risk

Milestone s financial instruments that are exposed to concentrations of credit risk consist primarily of cash and trade accounts receivable, and advances to contract manufacturer. Milestone places its cash and cash equivalents with large financial institutions. At times, such investments may be in excess of the Federal Deposit Insurance Corporation insurance limit. Milestone has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks. Financial instruments which potentially subject Milestone to credit risk consist principally of trade accounts receivable, as Milestone does not require collateral or other security to support customer receivables, and advances to contract manufacturer. Milestone entered into a purchase agreement with a vendor to supply Milestone with 5,000 instruments of *CompuDent* and 12,000 *STA Instrument*. As part of these agreements, Milestone has advanced approximately $2,827,000 and $3,407,000 to the vendor for purchase of materials at December 31, 2012 and 2011, respectively. The advance will be credited to Milestone as the goods are delivered. Milestone does not believe that significant credit risk exists with respect to this advance to the contract manufacturer at December 31, 2012 and 2011.

Milestone closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. On a periodic basis, Milestone evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit conditions. Management has provided a reserve that it believes is sufficient to record accounts receivable at net realizable value as of December 31, 2012 and 2011.

A five percent shareholder of the Company is also a shareholder of a major supplier of handpieces to the Company. In addition, he is an investor in the PRC entity, Beijing 3H, which entered into a joint venture agreement with Milestone.

The Company purchased $1,966,077 and $2,006,885 from the supplier for the years ended December 31, 2012 and 2011, respectively. The Company owed $808,908 and $1,207,280 to this supplier as of December 31, 2012 and 2011, respectively.

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20. Reclassifications

Certain reclassifications have been made to the 2011 balances to conform to the presentation used in 2012. These reclassifications had no effect on operating results previously reported.

21. Recent Accounting Pronouncements

Fair Value Measurement. In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): *Amendments to Achieve Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. This update clarifies existing guidance about how fair value should be applied where it already is required or permitted and provides wording changes that align this standard with International Financial Reporting Standards (IFRS). We are required to apply this guidance prospectively beginning with our first quarterly filing in 2012. The adoption of this new guidance has not had an impact on our financial position or results of operations.

Comprehensive Income. In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income*. This update increases the prominence of other comprehensive income in financial statements, eliminating the option of presenting other comprehensive income in the statement of changes in equity, and instead, requiring the components of net income and comprehensive income to be presented in either one or two consecutive financial statements. We are required to comply with this guidance prospectively beginning with our first quarterly filing in 2012. The adoption of this new guidance has not had an impact on our financial position or results of operations.

Intangibles Goodwill and Other. In September 2011, the FASB issued ASU No. 2011-08, Intangibles Goodwill and Other (Topic 350): *Testing Goodwill for Impairment*. This update allows entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of the reporting unit (i.e., step one of the two-step goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required. The amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this new guidance has not had an impact on our financial position or results of operations.

In December 2011, the FASB issued ASU No. 2011-12, Comprehensive Income (Topic 220): *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*. This update delays the effective date of the requirement to present reclassification adjustments for each component of accumulated other comprehensive income in both net income and other comprehensive income on the face of the financial statements.

In July 2012, the FASB issued ASU 2012-02, Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment in Accounting Standards Update No. 2012-02. This update amends ASU 2011-08, Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment and permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test in accordance with Subtopic 350-30, Intangibles Goodwill and Other General Intangibles Other than Goodwill. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted, including for annual and interim impairment tests performed as of a date before July 27, 2012, if a public entity s financial statements for the most recent annual or interim period have not yet been issued or, for nonpublic entities, have not yet been made available for issuance. The adoption of ASU 2012-02 is not expected to have a material impact on the Company s financial position or results of operations.

In February 2013, the FASB issued ASU No. 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* This update adds new disclosure requirements for items reclassified out of accumulated other comprehensive income. We are required to apply this guidance prospectively beginning with our first quarterly filing in 2013. The adoption of this new guidance will not impact our financial position or statement of operations, other than changes in presentation.

NOTE C ACCOUNTS RECEIVABLE CURRENT AND LONG TERM

The Company sells a significant amount of its product on credit terms to its major distributors. The Company estimates losses from the inability of its customers to make payments on amounts billed. A majority of credit sales are due within ninety days from invoicing. In 2010, the Company shipped a significant order to a major international distributor. At the time of the shipment, regulatory approval to sell the product in the respective country was in process. Obtaining such regulatory approval was not a condition of the purchase order and sale to the distributor. The regulatory approval has been delayed and as such the customer has not paid the full amount of the invoiced shipment. The Company is receiving periodic payments from the international distributor. Based on the periodic payment plan prepared by the international distributor, the Company has recorded a long term net accounts receivable of $119,201 as of December 31, 2012. The current portion of this net accounts receivable is approximately $99,621. The Company reserved $308,350 of the total accounts receivable from this distributor as December 31,

2012.

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NOTE D INVENTORIES

	December 31	
	2012	2011
Inventories consist of the following:		
Finished Goods	$ 476,340	$ 604,320
Component parts and other materials	162,221	186,175
	$ 638,561	$ 790,494

NOTE E ADVANCES ON CONTRACTS

The Company has entered into fixed arrangements with a contract manufacturer to manufacture *STA*, *CompuDent* and *Wand Plus*. The contract manufacturer bills the Company as the work progresses and it is the Company s policy is to record these billings as advances on contracts. These advances are reclassified into inventory when the contract manufacturer ships the product and title passes to the Company. The balance of the advances as of December 31, 2012 and 2011 totaled $2,827,446 and $3,406,506, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory. The Company also has an outstanding accounts payable of $705,000 and $1,752,000 at December 31, 2012 and 2011, respectively to the contract manufacturer related to the progress billings received. Milestone charged to operations approximately $135,000 of parts for the *CompuDent* and *Wand Plus* at December 31, 2012, due to the high cost of producing additional instruments.

NOTE F INVESTMENT IN MEDICAL JOINT VENTURE

In March 2011, Milestone entered into an agreement with a People s Republic of China (PRC) entity (Beijing 3H), to establish a Medical Joint Venture entity in the PRC to develop intra-articular and epidural drug delivery instruments utilizing Milestone s patented *CompuFlo* technology. Beijing 3H Scientific Technology Co., Ltd, agreed to contribute up to $1.5 million to this Medical Joint Venture entity, based on progress reports from Milestone and subject to refund if the instruments are not developed because of technological problems within 30 months of the inception date. Milestone evaluates the technological feasibility of the products to be developed using the CompuFlo technology periodically and at every reporting date to establish if circumstances indicate that the technology continues to be feasible. Based on the available evidence Milestone concluded that the contingency associated with the return of capital to Beijing 3H would be remote as of December 31, 2012 and accordingly no amounts have been accrued in the accompanying financial statements relating to this contingency. Milestone, with the consent of Beijing 3H, organized a domestic research and development corporation to which Beijing 3H made a capital contribution of $1,500,000. The Medical Joint Venture entity is owned fifty percent by the Beijing 3H and fifty percent by Milestone. Milestone contributed an exclusive worldwide royalty-free license to use CompuFlo technology to the Medical Joint Venture which has been valued at approximately $245,000 and has accounted for its investment in the Medical Joint Venture using the equity method of accounting.

The Medical Joint Venture reimbursed Milestone approximately $105,000 for previously incurred research and development expenses, which has been included as a credit to research and development expenses in the accompanying statement of operations in March 2011. The Medical Joint Venture s expenses for the year ending December 31, 2012 were approximately $846,000 of which Milestone s share of approximately $171,000 has been included in the accompanying statement of operations as the proportionate share of losses from the Medical Joint Venture. As of December 31, 2012, Milestone has reduced its investment to Medical Joint Venture to zero. The additional amount of the loss on Medical Joint Venture, approximately $346,000 has not been charged to the statement of operations as of December 31, 2012. This additional loss will not be charged to the statement of operations as Milestone has not guaranteed and has no obligation to fund future losses of the Medical Joint Venture in excess of its equity contribution. Further, Milestone was authorized by the Medical Joint Venture to manage and oversee the development of the two products for the Medical Joint Venture. In connection with this, Milestone also entered into an agreement with a significant vendor to develop the two instruments included in the Medical Joint Venture.

Milestone will have distribution responsibility in the U.S. and Canada and the rest of the world, while Beijing 3H will distribute products exclusively in the PRC, Macao, Hong Kong and other regions of Asia. As of December 31, 2012, Bejing 3H has contributed $1,500,000 to the Joint Venture and the development project has been initiated.

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NOTE G FURNITURE, FIXTURES AND EQUIPMENT

	December 31	
	2012	2011
Furniture, Fixtures and Equipment consist of the following:		
Leasehold improvements	$ 22,317	$ 22,317
Office furniture and equipment	96,703	98,268
Molds	7,200	7,200
Trade show displays	89,395	89,395
Computers and software	184,488	186,384
Tooling equipment-STA & Wand	31,477	31,477
STA Trials Instruments	63,752	63,752
Total	495,332	498,793
Less accumulated depreciation	(458,708)	(446,484)
	$ 36,624	$ 52,309

Depreciation expense was $18,816 and $22,094 for the years ended December 31, 2012 and 2011, respectively.

NOTE H PATENTS

Patents are being amortized by the straight-line method over estimated useful lives ranging from 10 to 20 years, with a weighted average amortization period of 12 years. Amortization expense amounted to $76,317 in 2012 and $83,297 in 2011. Estimated amortization expense of existing patents for each of the next five fiscal years amounts to approximately $77,000 per year.

NOTE I NOTES PAYABLE

Milestone borrowed $450,000 from a shareholder in 2008. The loan was originally a short term loan with a maturity date of January 19, 2009. In December 2008, and again on May 30, 2012, this loan was refinanced with the shareholder and the due date has been extended to January 3, 2014. The loan accrues 12% per annum, interest compounds quarterly, and interest and principal is due at the maturity. Further, the lender was granted 45,000 warrants exercisable at $0.32 per share, which expired in 2012.

Interest expense, relating to the notes payable, for the years ended December 31, 2012 and 2011 was $83,344 and $74,050, respectively. Accrued interest payable related to the note payable were $283,891 and $200,547 for years ended December 31, 2012 and 2011, respectively. The Company had also secured a line of credit, from this shareholder, for $1.3 million which was converted into equity in 2009. However, the accrued interest remaining on the line of credit was not converted and the remaining balance at December 31, 2012 and 2011 was $72,672 and $69,000, respectively and accrues interest at 6% per annum. The charge for amortization of Debt Discount related to the outstanding line of credit is $3,065 and $5,296 for the years ended December 31, 2012 and 2011, respectively.

NOTE J STOCKHOLDERS EQUITY

ISSUANCES OF COMMON STOCK

During 2012, Milestone issued 155,172 shares valued at $45,000 for the directors compensation.

During 2012, Milestone issued 543,209 shares valued at $217,415 for payment of consulting services.

During 2012, Milestone issued 105,451 shares valued at $43,125 for payment of employee compensation.

During 2012, Milestone sold 107,143 shares valued at $150,000.

During 2012, Milestone s to be issued shares are 229,705 valued at $237,000 for employee for bonus compensation.

During 2012, Milestone converted 83,300 to be issued shares to issued shares, valued at $50,813, for consulting services.

During 2012, Milestone converted 12,153 to be issued shares to issued shares, valued at $4,375, for employee compensation.

During 2011, Milestone issued 75,000 shares valued at $45,000 for the directors compensation.

During 2011, Milestone issued 327,222 shares valued at $191,214 for payment of consulting services.

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During 2011, Milestone issued 38,699 shares valued at $30,000 for payment of employee compensation.

During 2011, Milestone sold 99,999 shares valued at $30,000.

During 2011, Milestone s to be issued shares are 12,153 valued at $4,375 for the officer s deferred compensation.

During 2011, Milestone s to be issued shares are 748,990 valued at $420,000 for employee for bonus compensation.

During 2011, Milestone s to be issued shares are 103,300 valued at $60,813 for the consulting services.

SHARES TO BE ISSUED

As of December 31, 2012 and 2011, there were 1,635,709 and 1,501,457 shares that have been deferred from being issued, subject to employment agreements with the Chief Executive Officer, Chief Financial Officer and employees of the Company. Such shares will be issued to each party upon termination of their employment.

OUTSTANDING WARRANTS

At December 31, 2011, there were 45,000 warrants outstanding, which expired in June 2012.

There were no warrants issued in 2012 and 2011.

SHARES RESERVED FOR FUTURE ISSUANCE

At December 31, 2012 and 2011 there were 3,752,782 and 3,694,072 shares reserved for future issuance; 1,523,740 and 1,599,281 shares underlying other stock options and warrants that were outstanding at December 31, 2012 and 2011, respectively: 1,635,709 shares in 2012 and 1,501,457 shares in 2011 to be issued in settlement of deferred compensation to Officers of the Company; and 593,334 shares in 2012 and 593,334 shares in 2011, for Performance Options issued to an Officer of the Company.

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

NOTE K STOCK OPTION PLANS

In July 2004, the Board of Directors approved the adoption of the 2004 Stock Option Plan. The 2004 Stock Option Plan provides for the grant of options to purchase up to 750,000 shares of Milestone s common stock. Options may be granted to employees, officers, directors and consultants of Milestone for the purchase of common stock of Milestone at a price not less than the fair market value of the common stock on the date of the grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant.

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

In November 2009, the Board of Directors authorized 666,667 options be reserved for a special bonus to the Chief Executive Officer of the Company, for obtaining a three year purchase order for the sale of 12,000 STA Instruments and related handpieces over a four year period. These options were reserved and 73,333 were granted but not vested in 2010. The remaining 593,334 were reserved until specific performance targets are achieved. The options will be issued upon achievement of the specific target on a yearly basis. The options were valued at $1.49 per share.

In June 2011, the Shareholders of the Company approved the 2011 Stock Option Plan (the 2011 Plan) that provides for stock options to our employees, directors and consultants an incentive and non-qualified stock options to purchase up to 2,000,000 shares of Common Stock. Such future shares are included in the above noted shares reserved for future issuances.

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A summary of option activity for employees under the plans as of December 31, 2012 and 2011, and changes during the year then ended is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Outstanding, January 1, 2011	928,504	1.07	3.92	115,849
Granted	277,778	0.36	5.00	
Exercised				
Forfeited or expired	(67,000)	1.17		
Outstanding, December 31, 2011	1,139,282	0.89	3.62	1,000
Exercisable, December 31, 2011	638,176	0.89	2.79	1,000
Granted	211,459	0.95	4.38	
Exercised during 2012				
Forfeited or expired	(67,000)	1.58		
Outstanding, December 31, 2012	1,283,741	0.79	3.07	768,692
Exercisable, December 31, 2012	849,066	0.81	2.43	527,370

	Number of Options	Weighted Averaged Exercise Price $
VESTED OPTIONS		
Outstanding, January 1, 2011	471,722	0.95
Exercised during 2011		
Vested Options during 2011	233,454	0.83
Forfeited during 2011	(67,000)	1.17
Outstanding, December 31, 2011	638,176	0.89
Exercised during 2012		
Vested Options during 2012	277,222	0.92
Forfeited during 2012	(66,332)	1.58
Outstanding, December 31, 2012	849,066	0.81
NONVESTED OPTIONS		
Nonvested, January 1, 2011	456,782	1.20
Granted during 2011	277,778	0.36
Vested during 2011	(233,454)	0.83
Forfeited during 2011		
Nonvested, December 31, 2011	501,106	0.90
Granted during 2012	211,459	0.95
Vested during 2012	277,222	0.92
Forfeited during 2012	668	1.15
Nonvested, December 31, 2012	434,675	0.91

Milestone recognizes compensation expense on a straight line basis over the requisite service period and in case of performance based options over the period of the expected performance. During the years ended December 31, 2012 and 2011 Milestone recognized $142,770, and $225,257 of total employee compensation cost related to options that vested each year, respectively. As of December 31, 2012 and 2011, there was $169,764 and $156,753 of total unrecognized compensation cost related to non-vested options which Milestone expects to recognize over a weighted average period of 1.60 years and 2.3 years for December 31, 2012 and December 31, 2011, respectively.

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A summary of option activity for non-employees under the plans as of December 31, 2011 and 2012, and changes during the year ended is presented below:

	Number of Options	Weighted Averaged Exercise Price $	Weighted Average Remaining Contracted Life (years)	Aggregate Intrinsic Options Value $
Outstanding, January 1, 2011	534,999	1.85	1.51	99,617
Exercisable, December 31, 2011	514,998	1.87	1.41	99,311
Granted during 2011	100,000	0.24	2.50	
Forfeited during 2011	(120,000)	1.75		
Outstanding, December 31, 2011	414,999	1.87	1.43	12,000
Exercisable, December 31, 2011	399,443	1.90	1.36	12,000
Forfeited during 2012	(175,000)	1.79		
Outstanding, December 31, 2012	239,999	1.56	1.32	168,166
Exercisable, December 31, 2012	234,442	1.57	1.29	166,944

	Number of Options	Weighted Averaged Exercise Price $
VESTED OPTIONS		
Outstanding, January 1, 2011	514,998	1.87
Exercised during 2011	(100,000)	0.25
Vested during 2011	104,445	0.29
Forfeited during 2011	(120,000)	1.75
Outstanding, December 31, 2011	399,443	1.90
Exercised during 2012		
Vested during 2012	9,999	1.10
Forfeited during 2012	(175,000)	1.79
Outstanding, December 31, 2012	234,442	1.57
NONVESTED OPTIONS		
Nonvested January 1, 2011	20,001	1.21
Granted during 2011	100,000	0.24
Vested during 2011	(104,445)	0.29
Forfeited during 2011		
Nonvested December 31, 2011	15,556	1.16
Granted during 2012		
Exercised during 2012		
Vested during 2012	9,999	1.10
Outstanding, December 31, 2012	5,557	1.27

The fair value of the options was estimated on the date of grant using the Black Scholes option-pricing model. For the year ended December 31, 2011, the following weighted average assumptions were used in calculating fair value; expected life of 3 years; volatility of 117.82 and risk-free interest rate of 1.64%. There were no non-employee options granted for the year ending December 31, 2012. During the year ended December 31, 2012 and 2011, Milestone recognized $2,217 and $44,002 of expense related to non-employee options that vested, respectively. The total unrecognized compensation cost related to nonvested options was zero and $2,358 as of December 31, 2012 and 2011.

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NOTE L EMPLOYMENT CONTRACT AND DEFERRED COMPENSATION

Employment Contracts

As of September 1, 2009, the Company entered into a five-year employment agreement with Leonard Osser as its Chief Executive Officer. The term of the 2009 agreement is automatically extended for successive one-year periods unless prior to August 1 of any year, either party notifies the other that he or it chooses not to extend the term. Under the 2009 agreement, the CEO receives base compensation of $300,000 per year. In addition, the CEO, may earn annual bonuses up to an aggregate of $400,000, payable one half in cash and one half in common stock, contingent upon achieving targets set for each year by the Compensation Committee of the Board of Directors . In addition, if in any year of the term of the agreement the CEO earns a bonus, he shall also be granted five-year stock options to purchase twice the number of bonus shares earned. Each such option is to be exercisable at a price per share equal to the fair market value of a share on the date of grant (110%) of the fair market value if the CEO is a 10% or greater stockholder on the date of grant). The options shall vest and become exercisable to the extent of one-third of the shares covered at the end of each of the first three years following the date of grant, but shall only be exercisable while the CEO is employed by Milestone or within 30 days after the termination of his employment. In 2012 the CEO waived the option component of his bonus for that year.

In accordance with the employment contract, 1,182,493 shares of common stock are to be paid out at the end of the contract in settlement of$1,208,333 at December 31, 2012 and 1,025,735 shares of common stock are to be paid out at the end of the contract in settlement of $1,058,333 at December 31, 2011 of accrued deferred compensation and, accordingly, such shares have been classified in stockholders equity with the common shares classified as to be issued.

This 2009 agreement suspended the previous 2008 employment with 40-months remaining in its term. Under the 2008 agreement Mr. Osser is employed as an executive, but not the CEO. In March 2013, the 2008 agreement was amended to extend its remaining term to 120-months.

NOTE M INCOME TAXES

The Company s expected federal income tax benefit computed at the statutory rate (34%) on the pre-tax loss amounted to $296,000 in 2012 and $504,000 in 2011. Such benefit was not recognized in the accompanying financial statements due to Milestone s history of past operating losses, which required full valuation allowances for all of Milestone s deferred tax assets at December 31, 2012 and 2011.

Deferred tax attributes resulting from differences between financial accounting amounts and tax bases of assets and liabilities at December 31, 2012 and 2011 are as follows:

	2012	2011
Current Assets		
Allowance for doubtful accounts-short term	$ 72,000	$ 73,000
Inventory allowance	79,000	79,000
Warranty reserve	10,000	10,000
Impairment of German Investment	31,000	
Deferred officers compensation	600,000	527,000
Subtotal	792,000	689,000
Valuation allowance	(792,000)	(689,000)
Current deferred tax asset	$	$
Non-current assets		
Allowance for doubtful accounts-long term	$ 67,000	$ 149,000
Net operating loss carryforward	16,675,000	16,715,000
Subtotal	16,742,000	16,864,000
Valuation allowance	(16,742,000)	(16,864,000)

Non-current deferred tax asset	$	$

As of December 31, 2012 and 2011, Milestone has federal net operating loss carryforwards of approximately $48,537,000 and $48,805,000, respectively that will be available to offset future taxable income, if any, through December 2031. Milestone has state net operating losses of $2,875,000 and $2,028,000 in 2012 and 2011, respectively, expiring through December 2015.The utilization of Milestone s net operating losses may be subject to a substantial limitation due to the change of ownership provisions under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carry forwards before their utilization. Milestone has established a 100% valuation allowance for all of its deferred tax assets due to uncertainty as to their future realization.

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

	2012	2011
Statutory rate	(34)%	(34)%
State income tax all states	(6)%	(6)%
	(40)%	(40)%
Current year valuation allowance	40%	40%
Benefit for income taxes	0%	0%

Accounting for Uncertain Tax Positions:

The Company follows the Income Taxes Topic of the FASB Accounting Standards Codification, which provides clarification on accounting for uncertainty in income taxes recognized in an enterprise s financial statements. The guidance prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and also provides guidance on derecognition, classification, interest and penalties, disclosure and transition. At December 31, 2012, no significant income tax uncertainties have been included in the Company s Balance Sheets. The Company s policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Statements of Operations. No interest and penalties are present for periods open. Tax returns for the 2009, 2010, and 2011 years are subject to audit by federal and state jurisdictions.

NOTE N PRODUCT SALES AND SIGNIFICANT CUSTOMERS AND VENDORS

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

	Year End December 31,	
	2012	2011
Instruments	$ 2,146,756	$ 2,823,669
Handpieces	6,344,021	5,457,196
Other	157,465	97,229
	$ 8,648,242	$ 8,378,094
United States	$ 4,343,807	$ 4,658,327
Canada	553,984	468,786
Other foreign	3,750,451	3,250,981
	$ 8,648,242	$ 8,378,094

The Company has informal arrangements with the manufacturer of the *STA*, *CompuDent* and *CompuMed* instruments, one of the principal manufacturers for those instruments pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Purchases from this supplier were $444,852 (18%) and $2,049,103 (50%) in 2012 and 2011, respectively. Milestone has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum purchase commitments. Purchases of handpieces from this vendor in China were $1,966,077 (82%) and $2,006,885 (40%) in 2012 and 2011, respectively. As further described in Note B, a five percent shareholder of the Company is also a shareholder of this vendor. All other purchases from other suppliers were not significant in either 2012 or 2012.

For the year ended December 31, 2012, Milestone had two customers (distributors) that had approximately 36%, (21% and 15%) of its net product sales. Accounts receivable, current and long term, for the three major customers amounted to approximately $421,890, or 38%, (8%, 10% and 20%) of gross accounts receivable. For the year ended December 31, 2011, Milestone had two customers (distributors) that had

approximately 43%, (30%, and 13%) of its net product sales. Accounts receivable from these three customers amounted to approximately and $917,575, or 65% (28, 12% and 25%) of gross accounts receivable.

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NOTE O COMMITMENTS AND OTHER

(1) Lease Commitments

The headquarters for the Company is located at 220 South Orange Ave, Livingston, New Jersey. The Company leases approximately 6,300 square feet of office space. The lease term expires June 30, 2014 at a monthly cost of $6,942. Additionally, since November 2010, Milestone leased a corporate apartment in Maplewood, NJ on a month-to-month basis which it terminated in December 2011. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

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

Year Ending December 31,		
2013	$	90,615
2014		48,962
2015		7,309
2016		5,965
2017		5,965
	$	158,816

For the years ended December 31, 2012 and 2011, respectively, rent expense amounted to $83,273 and $130,806 respectively.

(2) Contract Manufacturing Arrangement

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

The termination of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone s ability to produce and sell its products. Although alternate sources of supply exist and new manufacturing relationships could be established, Milestone would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, whether or not as a result of termination of such a relationship, would adversely affect Milestone.

(3) Other Commitments

The technology underlying the *SafetyWand* and *CompuFlo,* and an improvement to the controls for *CompuDent* were developed by the Director of Clinical Affairs and assigned to us. Milestone purchased this technology pursuant to an agreement dated January 1, 2005, for 43,424 shares of restricted common stock and $145,000 in cash, payable on April 1, 2005. In addition, the Director will receive additional payments of 2.5% of the total sales of products using certain of these technologies, and 5% of the total sales of products using certain other of the technologies. In addition, he is granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant, 8,333 shares of the common stock upon the issuance of each additional patent relating to these technologies. If products produced by third parties use any of these technologies (under license from us) then he will receive the corresponding percentage of the consideration received by Milestone for such sale or license. Milestone expensed the Director s royalty fees of $306,983 and $291,783 in 2012 and 2011, respectively. Additionally, Milestone expensed consulting fee to the Director $156,000 for year ended 2012 and 2011.

In January 2010, the Company issued a purchase order to Tricor Instruments for the purchase of 12,000 *STA Instruments* to be delivered over the next three years. The purchase order is for $5,261,640. The Company has a remaining balance of approximately $609,000 on the advance and will continue to make periodic payments in 2013 to purchase the parts necessary to complete this production. As of December 31, 2012, the Company s production and sales of instruments to this commitment has been delayed. Consequently, advances to contractor has been classified as current and long term at December 31, 2012.

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(4) Subsequent Events

Subsequent to December 31, 2012, Milestone issued 218,420 shares of common stock for various reasons. The largest valued of shares (100,000 shares, $140,000) were issued to a supplier that purchased handpieces for the Company.

Milestone established a joint venture, Milestone Education, LLC, in the first quarter of 2013. Milestone contributed $50,000 as did the other joint venture partner. Each of the partners owns fifty (50) percent of the joint venture. The joint venture is expected to provide training and education to our dentists throughout the world.

In March 2013, the term of the suspended 2008 employment agreement between the Company and Leonard Osser (under which he is employed as an executive, but not the CEO) was extended from 40-months to 120-months.

NOTE P PENSION PLAN

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