MILESTONE SCIENTIFIC INC/NJ
Form 10-K
March 17, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

or

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

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

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

220 South Orange Avenue, Livingston Corporate Park, 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. o Yes þ 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. o Yes þ 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. þ Yes o 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. o

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

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

As of June 30, 2008, 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 $5,565,591. This amount is based on the closing price of $0.62 per share of the Company s common stock as of such date, based on the Nasdaq Over-the-Counter Bulletin Board.

As of March 16, 2009 the registrant has a total of 12,925,694 shares of Common Stock, $0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980).

None

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FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K are forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995) regarding the plans and objectives of management for future operations. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Milestone 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 , Milestone or Milestone Scientific refer to Mil Scientific Inc., and its former subsidiary, Spintech, Inc. (Spintech), unless the context otherwise indicates. Milestone have rights to the following trademarks: *CompuDent*®, *CompuMed*®, *CompuFlo*®, *The Wand*®, *The Wand Plus*®, *The SafetyWand*®, *Cool Blue Wand*®, *Cool Blue Tooth Whitening System, Dynamic Pressure Sensing Technology*®, *STA Single Tooth Anesthesia* , *Ionic White*® (light emitting diode), and *Ionic White* (whitening toothpaste). Milestone was incorporated in the State of Delaware in 1989.

BUSINESS

Background

Milestone is engaged in pioneering proprietary, highly innovative technological systems and solutions for the medical and dental markets. From its inception, the Company has focused its energy and resources on redefining the global standard of care for injection techniques by making the experience more comfortable for the patient and by reducing the anxiety and stress of giving injections for the healthcare provider.

In 1997, Milestone first introduced *The Wand*® (*CompuDent*® system) 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 (CCLAD) system does not look like a syringe. It does not 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* systems 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 system, 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 CCLAD 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 system 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 injection procedures that currently rely upon over 150-year-old hypodermic syringe technology and the tactile senses and delivery expertise of the administrator.

On September 14, 2004, Milestone Scientific was issued United States Patent No. 6,786,885 for the *CompuFlo* technology, entitled Pressure/Force Computer Controlled Drug Delivery System with Exit Pressure. Proprietary software, working with an innovative technology, allows the system 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 System with Profiles and Pressure/Force Computer Controlled Drug Delivery with Automated Charging .

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In December 2005, Milestone submitted a pre-market notification to the US 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 self-administered drug delivery, arthritic joint pain management and epidurals.

After receiving FDA 510(k) Pre-market Notification acceptance for the marketing and sale of the *STA Single Tooth Anesthesia System* (*STA System*), Milestone introduced the instrument to market in February 2007 at the Chicago Dental Society s 143rd Midwinter Meeting. The *STA System* is a patented CCLAD system that 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 patient within one or two minutes, allowing for a significant savings of waiting time. The patient will suffer neither pain nor collateral anesthesia in the cheek, lips or tongue at any time. The *STA System* is also 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 System* achieves these injections predictably and reliably.

Initial market response to the *STA System* following its commercial debut in February 2007 proved to be less than robust. Moreover, at that time, the Company had granted exclusive US and Canadian distribution and marketing rights for the *STA System* 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 System*. The insight gained from this study led management to define and implement a new messaging platform, created to emphasize key benefits that Milestone discovered are of most value to dental professionals. This refined product messaging was launched in January 2008 and is in constant review.

During the second quarter of 2008, Milestone elected to forego renewing the exclusive marketing and distribution agreement originally signed with Henry Schein, Inc.; instead, the Company granted Schein non-exclusive distribution rights to both market and sell the *STA System* and related disposable handpieces to dental professionals in the U.S. and Canada. In June 2008, Milestone expanded the domestic distribution network with the addition of Patterson Dental Supply as a non-exclusive distributor. Patterson has the largest direct sales force in the industry, totaling approximately 1,400 sales representatives and equipment/software specialists addressing the needs of the U.S. and Canadian dental markets. Later in the year, Benco Dental, Burkhart Dental, Goetze Dental and Atlanta Dental Supply all notable regional distributors were granted non-exclusive distribution and marketing rights to the STA System, thereby expanding Milestone s domestic distribution network comprised of over 2,450 independent reps.

Despite being granted CE Mark approval of the *STA System* in June 2007 by European regulatory authorities, Milestone elected to initiate its international launch in the first quarter of 2008. Following the launch of the *STA System* s new messaging platform in early 2008, Milestone granted exclusive marketing and distribution rights to two foreign distributors: Istrodent Pty Ltd AB, a leading distributor serving the Southern Africa dental market; and Unident AB, a leading supplier of dental products in the Scandinavian countries of Denmark, Sweden, Norway and Iceland.

CompuFlo Advanced Injection Technology Core Technology

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 systems 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 correctly 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 air or saline.

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In the absence of curative procedures, arthritis patients are obliged to endure painful multiple annual 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.

The *CompuFlo* technology is patented and embedded in an FDA approved prototype. The technology is currently being used in the *STA System*, that is being sold worldwide in the dental market. Over 35 million patient injections have been given with these two instruments. The *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 System* in their practices. Over 70 publications have validated the efficacy and safety of the *CompuDent* and *CompuMed* technologies in a variety of medical injection applications. Milestone will continue to work to develop and introduce products that substantially improve the standard of care for patients around the world.

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 System (STA System)

The *STA Single Tooth Anesthesia System (STA System)* is a patented, computer-controlled local anesthesia delivery system 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 tooth in one minute and a multiple root tooth in two minutes, without first administering a general blocking injection and waiting up to 15 minutes (or longer if the blocking injection needs to be re-administered) before proceeding to anesthetize 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* system, such a device provides a compelling value in the marketplace. The *STA System* will generate recurring revenues from per-patient disposable handpieces.

Since its market introduction in the spring of 2007, the *STA System* has received rave reviews and awards from the dental industry. In July 2007, noted industry publication *Dentistry Today* featured the *STA System* 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 System* 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 System* 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 System* was also named as a *Dental Products Report* Top 100 2008 Product of Distinction.

CompuDent®

CompuDent (also known as the *Wand Plus*® in Europe) is Milestone s proprietary, patented Computer-Controlled Local Anesthetic Delivery (CCLAD) system and predecessor of the *STA System*. 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;

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new injections made possible with the *CompuDent* technology eliminate collateral numbness of the tongue, lips and facial muscles;

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

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

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

Despite *CompuDent s* many benefits, including the administration of less painful and more comfortable injections, dentists in the United States have been slow to give up the use of traditional syringes. Dentists have all been trained to use syringes in dental school and often have become accustomed to and 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 system 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 handpieces is used in conjunction with the *STA, CompuDent* and *CompuMed* systems. 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.

The SafetyWand®

The SafetyWand is the first, patented safety-engineered injection device that conforms to regulatory standards while also meeting the clinical needs of dental and medical practitioners. Following the adoption of the Federal Needlestick Safety and Prevention Act, Milestone developed, and in September 2003 the FDA approved marketing of, Milestone s *SafetyWand* disposable handpiece, a patented injection device that incorporates safety engineered sharp protection features to aid in the prevention of needlesticks. *The SafetyWand* is the first patented injection device to be fully compliant with OSHA regulations under the federal Needlestick Safety Act while meeting the clinical needs of dentists.

The *SafetyWand* represents the culmination of two years effort to develop a safer injection device for dentists, physicians and hygienists. While safety injection devices have been mandated since 2000 under federal law, OSHA had been unable to enforce this law against dentists because of the inadequacy of existing devices to meet both the requirements of the law and the clinical needs of dentists. The *SafetyWand* meets these requirements and provides dental practitioners with a safer retractable needle device, with single hand activation, which is reusable multiple

times during a single patient visit; yet small and sleek enough not to obscure the dentist s sometimes limited field of view. While *SafetyWand* is now available commercially, OSHA has not begun, in a meaningful way, to enforce existing regulations requiring the use of safety engineered devices. OSHA is empowered to levy substantial fines for failure to use these devices.

Competition

Milestone s proprietary, patented Computer-Controlled Local Anesthesia Delivery (CCLAD) systems 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.

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Milestone s systems 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 systems 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 System*, can be used for all dental injections that can be performed with a traditional dental syringe. Moreover, the *STA System* 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 as well as support this distribution with a strong marketing plan. Historically, Milestone has been unsuccessful in executing the marketing plans for the products, primarily due to resource constraints. New products must be approved by regulatory authorities before they may be marketed. Milestone cannot assure you that it can compete successfully; that competitors will not develop technologies or products that render the products less marketable or obsolete; or, that Milestone will succeed in improving the existing products, effectively develop new products, or obtain required regulatory approval for those products.

Patents and Intellectual Property

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

	U.S. PATENT NUMBER	DATE OF ISSUE
Computer Controlled Drug Delivery Systems		
Hypodermic Anesthetic Injection Apparatus & Method	5,180,371	1/19/1993
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
Dental Anesthetic Delivery Injection Unit	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	9/17/2004
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
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 2008 and 2007 fiscal years, Milestone expensed $168,516 and $397,354, respectively, on research and development activities. The higher costs incurred in 2007 were primarily associated with the intensified effort towards the final development of the Single Tooth Anesthetic (STA) delivery system and continuing efforts on the *CompuFlo* technology.

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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. In 2006 Milestone began infringement actions in China against four companies Milestone believe are infringing the *CompuDent* patents. These and other litigations may be necessary to protect the intellectual property rights and could result in substantial cost to us and diversion of the efforts with no guarantee of success. One of the four infringement actions was resolved in favor of Milestone. The other three litigations remain in process. 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.

On October 2, 2008, Milestone announced that it had acquired additional patent rights with respect to painless anesthetic injections specifically rights related to controlling the flow rate or pressures used in providing these injections through the issuance of 260,000 shares of restricted common stock. In connection with the acquisition, Milestone also agreed to terminate its Declaratory Judgment action against Dr. Milton Hodosh related to claimed infringements of his patent rights and Dr. Hodosh agreed to terminate his infringement action against the Company. Each party was responsible for their own legal fees.

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.

Government Regulation

The FDA cleared the *CompuDent* system and its disposable handpieces for marketing in the U.S. for dental applications in July 1996; the *CompuMed* system 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 System* 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 System 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 90 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.

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Though the *STA System, 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.

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.

In June 2007, Milestone received a CE mark for the marketing of the *STA System* 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, 2008 Milestone had a total of 18 employees, consisting of three executive officers, a vice president of sales and marketing, a director of marketing, a director of International and Professional Relations, a director of engineering, five sales representatives, four customer service representatives, a staff accountant , 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, 2008 and 2007 revenues were approximately $6.6 million and $6.4 million, respectively. In addition, Milestone has had losses for each year since the commencement of operations, including net losses of approximately $1.2 million and $2.9 million for 2008 and 2007, respectively. At December 31, 2008,

Milestone had an accumulated deficit of approximately $57.2 million. At December 31, 2008, the Company had cash and cash equivalents $743,665 and working capital of $1,532,688. Additionally, the Company secured a line of credit in the aggregate amount of $1.0 million in 2007. This Line of Credit was amended to $1.3 million in 2008. Additionally, in 2008 the Company borrowed $450,000 as a Long Term Note. Both the Line of Credit and the Long Term Note were loaned from a stockholder, as discussed in Note H to the Financial Statements. 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, 2008, the Company believes that it has sufficient cash reserves to meet all of its anticipated obligations for the next 12 months. However, 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 and negative operating cash flows 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 System*, 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 30,000 instruments of the *CompuDent* or its predecessors have been sold worldwide since 1998. Since being introduced to market in February 2007, more than 1,700 instruments of the *STA System* 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 the anesthetic injection technology successfully. In the U.S. Milestone relies on several distributors, an outside sales representative group, and a direct sales team. Abroad, Milestone lacks appropriate distribution in many markets. To be successful, the Company will need to engage additional distributors, provide for their proper training and ensure adequate customer support. Milestone cannot assure that it will be able to hire and retain an adequate sales force or engage suitable distributors, or that the sales force or distributors will be able to successfully market and sell the products.

Milestone depends on three 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 System*, *CompuDent* and *CompuMed* instruments and with one of the principal manufacturers of the handpieces, for those instruments, respectively. Pursuant to the informal arrangements, they manufacture these products under specific purchase orders without minimum purchase commitment. Milestone has a manufacturing agreement with one of the principal manufacturers 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 System, CompuDent* and *CompuMed* since the commencement of production in 1998, one of the manufacturers of its handpieces since 2002 and the other manufacturer of 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 Milestone has established an alternate source of supply for the handpieces in China and other alternate sources of supply 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.

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 Chairman, Chief Executive Officer and Director of Clinical Affairs.

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

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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 $.20 and $3.62. 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 22.8% 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, 2008, Milestone had outstanding options and warrants to purchase 3,601,245, shares of common stock at prices ranging from $0.30 to $5.00 per share with a weighted average exercise price of $3.92. Holders of these warrants and 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.

In February 2009, 2,147,946 warrants at $4.89 to issue the equivalent number of shares of the Company s common stock expired.

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, 2008. 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. However, this annual report does not include an attestation report of the Company s registered public accounting firm regarding 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 2008 and 2007, the Company utilized the outside consultant on a quarterly basis to review compliance with the internal controls over financial reporting. This expense amounted to $71,478 and $67,333 in 2008 and 2007, respectively and the cost is expected to continue in 2009.

Item 1B. Unresolved Staff Comments

None

Item 2. Description of Property

The office is located in Livingston Corporate Park in Livingston, New Jersey. The Company leases approximately 6,300 square feet of office space, the lease term expires June 30, 2009 at a monthly cost of $7,317 which Milestone believes to be competitive. The Company is currently in the process of reviewing the current lease and negotiating with the landlord for possible extension of the lease term. The leased office space is in good condition. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis.

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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

In October 2008, Milestone announced that it acquired additional patent rights with respect to painless anesthetic injections specifically rights related to the flow rate or pressure used in providing these injections through the issuance of 260,000 shares of restricted common stock. In connection with this acquisition, Milestone also agreed to terminate its Declaratory Judgment action against Dr. Milton Hodosh related to claim infringements of his patent rights and Dr. Hodosh agreed to terminate his existing infringement action against the Milestone. Each party is responsible for their own legal fees.

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

Item 4. Submission of matters to a Vote of Security Holders

None.

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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 is traded on the NASDAQ s OTC Bulletin Board (OTCBB) under the symbol MLSS Milestone s warrants were traded on the OTCBB under the symbol MLSSW until February 2009, when the warrants expired. 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, as quoted by the OTCBB

	HIGH	LOW
2008		
First Quarter	$ 1.57	$ 0.75
Second Quarter	$ 1.05	$ 0.56
Third Quarter	$ 0.80	$ 0.30
Fourth Quarter	$ 0.40	$ 0.20
2007		
First Quarter	$ 3.62	$ 1.12
Second Quarter	$ 2.90	$ 1.52
Third Quarter	$ 2.49	$ 1.55
Fourth Quarter	$ 2.50	$ 1.55

Holders

According to the records of the transfer agent, there were approximately 54 and 67 shareholders of record of the common stock as of December 31, 2008 and 2007. However, the Company believes that there are approximately 2,400 and 2,600 beneficial owners of the Company s common stock at December 31, 2008 and 2007, 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 I STOCKHOLDERS EQUITY, to the financial statements for the issuance of unregistered securities.

ITEM 6. Selected Financial Data

Milestone are a smaller reporting company as defined by Regulations S-K and as such, are not providing 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

Through strict expense discipline and the implementation of key operational initiatives during 2008, the Company was able to make considerable progress with its efforts to achieve two primary strategic business goals for the year:

- Optimizing the tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with a proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the *STA System*; and
- Identifying and pursuing strategic collaborations with third parties to jointly develop new products utilizing the *CompuFlo* pressure force technology for novel new dental and medical applications.

In order to succeed in achieving these goals, it is essential that Milestone have the best people possible. In January of 2008, Joseph D Agostino joined Milestone as the Acting Chief Financial Officer, bringing the Company the skill, talent and experience that are necessary to help us grow and meet critical business plan objectives. Following a nine month performance assessment by the Board of Directors, Mr. D Agostino was officially named Milestone s Chief Financial Officer in October of this year.

Mr. D Agostino s addition to the senior management team has served to strongly complement the hiring of Robert Presutti, who joined Milestone as Vice President of Sales and Marketing in September 2007, and the appointment by the Board of Directors of former Bayer senior executive Joe Martin as the new CEO in December 2007.

Milestone has continued to leverage the product and market intelligence Milestone derived from in-depth customer and dental industry surveying that Milestone conducted in late 2007, to assess and evaluate pricing, positioning and marketing strategies related to the innovative dental injection solution, the *STA System*. The insight gained from these studies led management to define and implement a comprehensive new messaging platform created to emphasize key benefits that Milestone has discovered is of most value to dental professionals. This refined product messaging was launched in January 2008.

Based on the fact that Milestone continues to achieve its month-over-month revenue and cash flow objectives in keeping with management s plan of execution and long term growth strategy, the Company believes its refined product positioning is resonating with dental professionals, helping to generate increasing sales and marketing activity within the independent distributor network.

First International C-CLAD Summit

A key 2008 event for Milestone was the first International C-CLAD Summit hosted by the Company in New Orleans this past February, where many of the dental industry s most prominent and respected authorities assembled to review, discuss and explore opportunities for the *STA System*. A monograph summarizing the Summit s proceedings was issued in early June 2008. Specifically, there was consensus among panel participants agreeing that use of the *STA System* provides the best way to administer a Palatal Injection and Intraligamentary Injection; agreement that the *STA System* is the instrument of choice to minimize pain disruptive behavior; and unanimous agreement that the *STA System* should become the standard of care for administering anesthesia by dental practitioners.

STA System Wins Broad Industry Recognition

Since its market introduction in the spring of 2007, the *STA System* has received rave reviews and awards from the dental industry. In July 2007, noted industry publication *Dentistry Today* featured the *STA System* as one of the Top 100 Products in 2007, helping to promote much broader recognition of the instrument and validating the *STA System* s value proposition for dentists and patients, alike. Earlier this year, *Medical Device & Diagnostic Industry* magazine distinguished the *STA System* 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 System* was one of only two winning products that serve dental practitioners. In December, the STA System was again recognized as one of the dental industry s best technological innovations, winning a Townie Choice Award from Dentaltown Magazine in the category Anesthetics: Technique System . This marked the second consecutive year that Milestone won a Townie Choice Award in 2007, the Company won the same award for its CompuDent/The Wand. Also in December 2008, Milestone s STA System was named as a *Dental Products Report* Top 100 2008 Product of Distinction. Each year, *DPR* spotlights the year s Top 100 products. Of these 100 products, 50 are the ones most often inquired about by *DPR* s readers via an online and Product Information Card reader service program. The other 50 represent New Classics, which recognize both old and newer products and categories chosen by *DPR* s editorial team

for their perceived impact on driving innovation or helping to establish a new, higher standard of care for patients. The *STA System* was recognized as a New Classic in the Technology category.

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Domestic Dental Distribution Network

In the second quarter of this year, Milestone turned its attention to expanding the domestic network of dental distributors, with a goal of increasing market awareness and promoting stronger sales growth of the *STA System*.

On the domestic front, the Company elected to forego renewing the exclusive marketing and distribution agreement originally signed in early 2007 with Henry Schein, Inc., the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets. Rather, the Company granted Schein non-exclusive distribution rights to both market and sells the *STA System* and related disposable handpieces to dental professionals in the United States and Canada; and in June of this year, welcomed Patterson Dental Supply as a non-exclusive distributor, as well. Patterson has the largest direct sales force in the industry, totaling approximately 1,400 sales representatives and equipment/software specialists addressing the needs of the United States and Canadian dental markets.

On July 16, 2008, Milestone announced that leading independent dental supply companies Benco Dental, Burkhart Dental, Inc., and Goetze Dental also joined the Company s growing domestic distribution network under non-exclusive agreements.

Founded in 1930, Benco is the largest independently owned dental supply company in the U.S., and one of the nation s fastest growing dental distributors. Burkhart Dental has thrived and prospered as a family owned and managed dental supply company for 120 years, now serving over 5,000 dental customers in the Western U.S. from offices in Alaska, Colorado, Oregon, Arizona, California, Nevada, Texas, Utah and Washington. Originally established in 1884 as the St. Joseph Drug Company, Goetze Dental has also endured as a family-owned and managed independent dental supplier for five generations. Currently, the Company markets a broad range of leading dental products and services to a customer base comprised of more than 10,000 dental professionals operating primarily in nine U.S. Midwestern states.

In October, Milestone added Atlanta Dental Supply to its U.S. distribution network. Atlanta Dental is an industry leading employee-owned dental supply and service company based in Duluth, Georgia that has been serving the U.S. Southeast dental community for 140 years.

Milestone is now actively engaged in the continuing process of training and providing ongoing sales and marketing support to more than 2,450 independent sales representatives serving the U.S. and Canadian markets. As of December 31, 2008, Milestone had completed training of approximately 80% of Patterson s national sales force, as well as a majority of the representatives employed by Benco, Burkhart and Goetze. Training of Atlanta Dental reps commenced in the fourth quarter and is expected to be completed in the first quarter of 2009.

International Dental Distribution Network

In June, the Company granted exclusive marketing and distribution rights to two foreign distributors Istrodent Pty Ltd AB, a leading distributor serving the Southern Africa dental market; and Unident AB, who is now introducing the *STA System* to dentists in the Scandinavian countries of Denmark, Sweden, Norway and Iceland. Both companies have proven to be among Milestone s strongest marketing allies outside of the U.S., achieving notable sales performance in their respective regions while supporting the historical worldwide marketing efforts for *The Wand*.

At the FDI Annual World Dental Congress held in Sweden in late September, Unident launched its formal *STA System* marketing program to the European dental community and enjoyed a strong and favorable response from show attendees.

Throughout 2009, the Company will continue to focus on expanding Milestone s worldwide sales and marketing resources to accelerate *STA System* sales momentum around the world. Particular emphasis will be on establishing defined distribution channels in Canada and South America. Moreover, Milestone will continue reinforcing and supporting the growing global independent sales and distribution network through training, Milestone-sponsored advertising and marketing campaigns, trade show participation and creative sales incentive programs.

New Product Development and Commercialization

In keeping with the Company s stated 2008 goal for leveraging the patented *CompuFlo* technology in new medical applications, Milestone s management team has also continued to identify and pursue opportunities to form strategic collaborations in the areas of self-administered drug delivery, injections for osteoarthritis pain management and epidurals. In 2009, Milestone will expand the field of potential applications in focus to include pediatric injections.

In November 2007, the Company entered into a collaborative agreement with a globally diversified healthcare company to conduct a feasibility study evaluating the potential application of the *CompuFlo* technology for injecting certain medicaments produced by this leading company. The initial study has been successfully completed and the Company hopes to leverage its findings to progress strategic partnering and product development opportunities.

The response to Milestone s proprietary technology from prospective new partners whom Milestone has engaged in meaningful teaming discussions has continued to be encouraging. Throughout 2008, the Company met with a variety of healthcare companies who expressed interest in potential applications of the CompuFlo technology. As Milestone progresses through 2009, the Company will maintain its pursuit of *CompuFlo*-based product development prospects that are deemed the most promising and commercially viable, and offer the greatest potential for allowing Milestone to fully realize the product development and commercialization opportunities.

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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:

	Twelve Months Ended December 31,			
	2008		2007	
DOMESTIC				
Instruments	$ 914,431	21.1%	$ 1,554,825	33.8%
Handpieces	3,373,159	77.7%	2,960,048	64.5%
Other	54,097	1.2%	78,783	1.7%
Total Domestic	$ 4,341,687	100.0%	$ 4,593,656	100.0%
INTERNATIONAL				
Instruments	$ 695,513	30.9%	$ 442,689	26.5%
Handpieces	1,550,992	68.8%	1,201,532	72.0%
Other	7,333	0.3%	24,731	1.5%
Total International	$ 2,253,838	100.0%	$ 1,668,952	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	$ 4,341,687	65.8%	$ 4,593,656	73.4%
International	2,253,838	34.2%	1,668,952	26.6%
Total Product Sales	$ 6,595,525	100.0%	$ 6,262,608	100.0%

The Company earned gross profits of 60% and 55% in the years ended December 31, 2008 and 2007, 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 2009, 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. The Company at December 31, 2008 expects to have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. Additionally, 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 and reduction in operating expenses. 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 for existing dental products or adopt other cost saving measures, any of which might negatively affect the Company s operating results.

In 2009, the Company plans to further support increased sales and marketing activity through trade show appearances, increased advertising to dental professionals, and costs associated with the support of the global distribution network.

Current Product Platform

Milestone has developed and in some cases brought to market a highly differentiated portfolio of industry innovations. Specifically, Milestone s proprietary solutions for application in professional dentistry and a wide range of medical applications include:

STA Single Tooth Anesthesia System (STA System) - In February of 2007, Milestone introduced to market the *STA System*, a patented CCLAD system that incorporates the pressure force 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. The *STA System* is also 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 System* achieves all of these injections predictably and reliably including the Periodontal-Intraligamentary injection (Single Tooth Anesthesia) that provides an almost immediate onset of profound anesthesia to a single tooth. Milestone received FDA 510(k) Pre-market Notification acceptance in August 2006 and was granted a CE Mark by European regulatory authorities in June 2007.

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The *STA System* has been the subject of numerous articles published in leading trade magazines, dental journals and online blogging sites since its market introduction early in 2007. Since its market introduction in the spring of 2007, the *STA System* has received positive reviews and awards from the dental industry. In July 2007, noted industry publication *Dentistry Today* featured the *STA System* 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. Earlier this year, *Medical Device & Diagnostic Industry* magazine distinguished the *STA System* 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, the STA System was again recognized as one of the dental industry s best technological innovations, winning a Townie Choice Award from Dentaltown Magazine in the category Anesthetics: Technique System . This marked the second consecutive year in a row that Milestone won a Townie Choice Award in 2007, the Company won the same award for its CompuDent/The Wand. Also in December 2008, Milestone s STA System was named as a *Dental Products Report* Top 100 2008 Product of Distinction. Each year, *DPR* spotlights the year s Top 100 products. Of these 100 products, 50 are the ones most often inquired about by *DPR* s readers via an online and Product Information Card reader service program. The other 50 represent New Classics, which recognize both old and newer products and categories chosen by *DPR* s editorial team for their perceived impact on driving innovation or helping to establish a new, higher standard of care for patients. The *STA System* was recognized as a New Classic in the Technology category.

CompuDent® *CompuDent* was distinguished by *Dentaltown Magazine* as the winner of a 2006 Townie Choice Award , *CompuDent* is Milestone s proprietary, patented computer-controlled local anesthetic delivery system which delivers anesthesia at a precise and consistent rate below a patient s pain threshold. *CompuDent* has been widely heralded as a revolutionary device, considered one of the major advances in dentistry of the Twentieth Century and favorably evaluated in approximately 50 peer reviewed or independent clinical research reports. *CompuDent* is the predecessor device to the *STA System*.

CompuMed® *CompuMed* is a patented computer-controlled injection system 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* is now gaining growing 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 plastic surgery, among others.

The Wand® Used in conjunction with the *STA*, *CompuDent* or *CompuMed* systems, *The Wand* is an ergonomically designed and patented handpiece that enables all traditional and newer injections, such as AMSA, P-ASA and Modified-PDL, to be more comfortable and easier to deliver. Moreover, the pen-like grasp of *The Wand* allows bi-directional rotation during injection, which prevents needle deflection that can occur with a traditional syringe. A straighter path results in a more accurate injection, meaning fewer missed blocks, and more rapid onset of anesthesia.

The SafetyWand® *The Safety Wand* was the first, patented safety-engineered injection device that conforms to standards while also meeting the clinical needs of dental and medical practitioners. The Federal Needlestick Prevention Act (U.S.) has mandated the use of products with engineered safety injury protection to eliminate accidental needle sticks, thus providing Milestone with an invaluable marketing platform to position *The SafetyWand* as a powerful and capable alternative to traditional injection devices. *The SafetyWand* was the first patented injection device to be fully compliant with OSHA regulations under the Act.

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 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.

Inventories

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

Impairment of Long-Lived Assets

The long lived assets of 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 distributor on the date of arrival of the goods at the customer s location as 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. Customer acceptance is considered made at delivery. 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.

Royalty income is recognized as earned based on reports received from the licensee and related royalty expense is accrued during the same 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, 2008 compared to 2007 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	Twelve Months Ended			
	December 31, 2008		December 31, 2007	
Products sales, net	$ 6,595,525	99%	$ 6,262,608	98%
Royalty income	28,282	1%	128,105	2%
Total revenue	6,623,807	100%	6,390,713	100%
Cost of products sold	2,681,116	40%	2,898,048	45%
Gross Profit	3,942,691	60%	3,492,665	55%
Selling, general and administrative expenses	5,502,762	83%	6,577,086	103%
Research and development expenses	168,516	3%	397,354	6%
Operating expenses	5,671,278	86%	6,974,440	109%
Loss from operations	(1,728,587)	-26%	(3,481,775)	-54%
Other income	541,133	8%	543,079	8%
Net loss	$ (1,187,454)	-18%	$ (2,938,696)	-46%

Year ended December 31, 2008 compared to year ended December 31, 2007

Total revenues for the twelve months ended December 31, 2008 and 2007 were $6,623,807 (product sales of $6,595,525 and royalty income of $28,282) and $6,390,713 (product sales of $6,262,608 and royalty income of $128,105), respectively. The total increase in product sales of $332,917, or 5%, is a direct result of the continued implementation of the new sales distribution model and price change that began in the second quarter of 2008, along with improvement in the international market. The decrease in sales volume of domestic instruments by $640,394, or 41% in 2008 over 2007, was due to the distributor s slow sell through of instruments sold into distribution in 2007. Instruments sold to a distributer in 2007 did not arrive at the end users until 2008. In the domestic market, handpiece sales increased by $413,111, ($277,142 increase in *CompuDent* sales, $135,969 increase in *STA*) or 14%. On the international scene, instrument sales increased in 2008 over 2007 by $252,824, or 57%, principally due to the increase in *STA* instruments ($271,984). Internationally, handpiece sales increased. The increase in handpiece sales internationally was $349,460 or 29% due to increased sales of CompuDent handpieces ($241,208) and STA ($108,252) handpieces.

Royalty income resulted from granting United Systems Inc. a license to manufacture, market, and sublicense Tooth Whitening System to the consumer market. Royalty income for the years ended December 31, 2008 and 2007, respectively, was $28,282 and $128,105. The decrease of $99,823 or 78% reflected increased retail competition in this increasingly highly competitive market. In January 2009, the Company abandoned its rights to a portfolio of technology centered around the use of blue light emitting diodes (LED) for a variety of dental treatments and diagnostic applications. At the same time, the Company terminated its license agreement for the use of the technology with United Systems Inc. There were no costs or expenses related to this abandoning of rights or the termination of the licensee agreement.

Cost of products sold for the years ended December 31, 2008 and 2007 were $2,681,116 and $2,898,048, respectively. The $216,932 decrease in product cost or 7% is primarily attributable to product mix. Slow moving and overstocked inventories totaling approximately $82,000 and $62,000 were charged off to cost of products sold during the year ended December 31, 2008 and 2007, respectively.

For the year ended December 31, 2008, Milestone s gross profit increased by 5% over year ended December 31, 2007, due to product mix, with higher handpiece sales. For the years ending December 31, 2008 and 2007, Milestone generated a gross profit of $3,942,691 or 60% as compared to a gross profit of $3,492,665 or 55%, respectively. The total dollar increase in gross profit was $450,026 in 2008. Additionally, included in gross profit for the years ended December 31, 2008 and 2007, the Company recorded a write-down of slow moving inventory in the aggregate of $82,000 and $62,000, respectively.

Selling, general and administrative expenses for the years ended December 31, 2008 and 2007 were $5,502,762 and $6,577,086, respectively. The $1,074,324 or 16%, net decrease spanned several key areas of the Company. Marketing expense decreased in 2008 by net $16,440, with an increase of $210,000 in advertising media placement in 2008, offset by a reduction in the 2007 *STA* launch program of $214,000. General and administrative expenses decreased by $1,092,772 primarily due to a decrease in professional fees (accounting and legal) by $590,396 and a reduction in bad debt write offs ($69,378). Additionally, there was a 2007 write-off of molds and tooling ($233,000) that did not occur in 2008. Sales expenses increased by $223,257, due to an increase in commissions to an outside sales representative of $170,000 and an increase in relocation expense of $24,000. Salaries for the year ended December 31, 2008 were relatively consistent as compared to the same period in 2007.

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Research and development expenses for the years ended December 31, 2008 and 2007 were $168,516 and $397,354, respectively. The decrease of $228,838 was attributable to a reduction in such cost in 2008 after the launch of the *STA* product in the first quarter of 2007.

The loss from operations for the years ended December 31, 2008 and 2007 was $1,728,587 and $3,481,775, respectively. The $1,753,188 or 50% decrease in loss from operations is explained above.

Interest expense was $116,374 and amortization of debt issuance was $27,446, relating to the Line of Credit and Long Term Note. See Note H to the Financial Statements.

Other Income includes $675,930 and $552,005 in 2008 and 2007, represent the sale of tax credits under the New Jersey Technology Business Tax Certificate Program, net of interest income and expense for the respective periods.

For the reasons explained above, net loss for the year ended December 31, 2008 was $1,187,454 as compared to a net loss of $2,938,696 for the year ended December 31, 2007. The $1,751,242, or 60%, decrease in net loss is primarily a result of a significant increase in gross margin dollars and a reduction in selling, general and administrative expenses.

Liquidity and Capital Resources

As of December 31, 2008, the Company had cash and cash equivalents of $743,665 and working capital of $1,532,688. The working capital increased by $40,426 from December 31, 2007. Net current assets decreased by approximately $707,000, principally in inventories ($917,000) and advances to contract manufacturers ($402,000), offset by an increase in accounts receivable of $579,000 and prepaid expenses of $49,000. Current liabilities decreased by net $748,000 principally by a reduction in accounts payable of approximately $1,027,000, offset by an increase in accrued expenses, primarily accrued commissions (77,000), accrued bonuses ($90,000) and accrued interest ($86,000). The Company has taken positive steps to reduce inventory levels and advances to contract manufacturers and will continue this effort in the future. Milestone incurred net losses of $1,187,454 and $2,938,696 and negative cash flows from operating activities of $442,006 and $1,150,670 for the years ended December 31, 2008 and 2007, respectively.

For the year ended December 31, 2008, net cash used in operating activities was $442,006. This was attributable primarily to a net loss of $1,187,454 adjusted for noncash items of $507,284 and changes in operating assets and liabilities of $238,164. The decrease in noncash items in 2008 of $730,581 as compared to 2007 is principally due to elimination of bad debts write off ($69,378) and loss on write-off of patent rights ($157,640), along with reduction in Common Stock and options issued for compensation, consulting, and vendor services ($270,064) and loss on sale/disposal of equipment ($239,275).

For the year ended December 31, 2008, Milestone used $309,332 in investing activities, primarily attributable to legal fees related to payment for patent rights.

As of December 31, 2008 and 2007, Milestone recorded on the Balance Sheet a $1.3 million and $1.0 million, respectively, Line of Credit from a stockholder. The borrowings require a one percent fee at the date of borrowing and an interest rate of six percent per annum, payable at the maturity of the note. The Company borrowed an additional $450,000 from the same shareholder in 2008. In December 2008, the Company refinanced the $450,000 note, extending the due date to June 30, 2012. The Line of Credit and the additional borrowing in 2008 are classified as a Long Term Note Payable on the Balance Sheet at December 31, 2008. See Note H Line of Credit to the Financial Statements.

The Company has incurred operating losses and negative cash flows from operating activities since its inception. 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, 2008, the Company believes that it has sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. However, 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 and negative operating cash flows raises 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.

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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, 2008, 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	$ 1,750,000	$	$ 1,300,000	$ 450,000
Capital lease obligations				
Operating lease obligations	66,384	52,294	14,090	
Purchase obligations (1)	1,359,668	1,359,668		
Total	$ 3,176,052	$ 1,411,962	$ 1,314,090	$ 450,000

(1) Purchase obligations include agreements for the purchase of units and handpieces. The agreements are referred as purchase orders. All handpieces and STA units purchase orders are for delivery in less than one year.

Recent Accounting Pronouncements

See Note B-19 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

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

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, 2008 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, to allow timely decisions regarding disclosure.

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Management s Annual Report on Internal Control Over Financial Reporting

Milestone management is responsible for establishing and maintaining an adequate system 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 systems, no matter how well designed, have inherent limitations. Therefore, even those systems 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 system of internal control over financial reporting as of December 31, 2008. 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 did maintain effective internal control over financial reporting as of December 31, 2008.

This annual report does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management s report in this annual report.

There have been no significant 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 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.

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 as the pleasure of the Board of Directors.

The current executive officers and directors of Milestone and their respective ages as of March 16, 2009 are as follows:

NAME	AGE	POSITION	DIRECTOR SINCE
Leonard A. Osser	61	Chairman	1991
Joe W. Martin	56	Chief Executive Officer	2008
Joseph D Agostino	57	Chief Financial Officer	
Pablo Felipe Serna Cardenas (2)	33	Director	2006
Leonard M. Schiller (1)(2)	67	Director	1997

Jeffrey Fuller (1)	63	Director	2003
Leslie Bernhard (1)(2)	64	Director	2003

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

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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 16, 2009:

NAME	AGE	POSITION
Eugene Casagrande, D.D.S.	65	Director of Professional Relations
Mark Hochman, D.D.S.	51	Director of Clinical Affairs
Robert A. Presutti	56	Vice President of Sales and Marketing

Leonard Osser, Chairman of the Board

Leonard Osser has served as Milestone s Chairman since 1991. From 1991 through 2007, he also served as Chief Executive Officer of the Company. From 1980 until the consummation of Milestone s public offering in November 1995, he 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.

Joe W. Martin, Chief Executive Officer

Joe Martin originally joined Milestone Scientific in May 2007 as CEO of the Company s medical division, Milestone Medical, and was subsequently appointed as the Company s new CEO in December 2007. Prior to Milestone, he served as President of the Diabetes Care Division (DCD) at Bayer HealthCare. He also served as a member of the Bayer HealthCare Executive Committee. From 1992 through 2004, Mr. Martin rose through the ranks at Bayer in managerial posts that included Senior Vice President and General Manager, Self-Testing Business Segment at Bayer AG Diagnostics Division; Senior Vice President and General Manager, Point of Care Business Segment; Country Manager United Kingdom and Ireland; and Vice President, Marketing Immunodiagnostic Business Unit. From 1980 through 1992, Mr. Martin held various sales, marketing and general management roles of increasing responsibility, both domestically and internationally, at Abbott Laboratories - Diagnostic Division. He is a graduate of the University of Houston where he earned a Bachelors of Business Administration degree in Marketing and Accounting. Mr. Martin is the Past President of the Biomedical Marketing Association and served on the Board of Directors of Life Treatment Centers in South Bend, Indiana.

Joseph D Agostino, Chief Financial 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. 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.

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 Systems, Dr. Hochman has published numerous articles in this area, and shares in the responsibility for inventing much of the technology currently available from Milestone.

Robert (Bob) A. Presutti, Vice President of Sales and Marketing

Bob Presuitti brings Milestone nearly 30 years of professional sales and marketing experience, primarily within the medical and dental industries, with emphasis on new product introductions. As Director of Professional Sales at Optiva/Philips Healthcare, Inc., he helped to establish *Sonicare* as the #1 most recommended and dispensed electric toothbrush among dental professionals, and drove product sales from $5 million to over $28 million in a five year period. Immediately prior to joining Milestone, Mr. Presutti served as Director of Professional Sales at Grinrx Corporation, a start-up dental company in Washington. In May of 2005, he was recruited by the CEO of Brite Smile, Inc. to serve as Executive Vice President of Sales. In this role, he led the rebuilding of the dental product company s sales organization and relaunched its in-office whitening procedure in the professional dental channel. While at Thermoscan, Inc. and Medtronic, Nortech Division, Mr. Presutti held various sales management and market development positions of increasing responsibility. Mr. Presutti holds a Bachelor of Arts degree in Business Administration from Monmouth University.

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Dr. Eugene Casagrande, Director of International & Professional Relations

Since 1998, Dr. Casagrande has served as Director of 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 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.

Jeffrey Fuller has been a director of Milestone since January 2003. Mr. Fuller has been president and owner of two municipal water supply systems, Hudson Valley Water Co. and Lake Lenape Water Co. since 1983 and in addition has been an executive recruiter since 1995. Early in his career, for a period of two years, he was an auditor with Arthur Andersen LLP, and thereafter, for four years, a senior internal auditor with the Dreyfus Corp. Mr. Fuller has been an adjunct professor since 2002 at Berkeley College, NY, teaching several courses including Accounting.

Leslie Bernhard has been a director of Milestone since May 2003. Ms. Bernhard co-founded AdStar, Inc., and since 1986 has been its President, Chief Executive Officer and a director. AdStar is an application service provider for the newspaper classified advertising industry.

Pablo Felipe 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.

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 members are all independent directors. The Audit Committee meets with management and Milestone s independent auditors to determine the adequacy of internal controls and other financial reporting matters. The Board of Directors has determined that Jeffrey Fuller qualifies as an Audit Committee Financial Expert pursuant to Item 407 (d)(5) of Regulation S-B. Mr. Fuller is independent, as that term is defined in the listing standards of the NYSE Alternext.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires Milestone s officers and directors, and persons who own more than ten percent (10%) of a registered class of Milestone s equity securities to file reports of ownership and changes in ownership with the Securities and Exchange Commission (SEC). Officers, directors and greater than ten percent (10%) stockholders are required by SEC regulations to furnish Milestone with copies of all Section 16(a) forms they file.

To the best of Milestone s knowledge, based solely on review of the copies of such forms furnished to Milestone, or written representations that no other forms were required, Milestone believes that all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent (10%) shareholders were complied with during 2008.

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.

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Item 11. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2008 and 2007 by (i) Milestone s Chairman and (ii) the most highly compensated executive officers, other than the Chairman who were serving as executive officers at the end of the 2008 fiscal year and whose salary as determined by Regulation S-B, 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	2008	$ 200,000(1)		$ 18,408		$ 218,408
Chairman	2007	$ 300,000(1)		$ 16,660(1)		$ 316,660
Joe W. Martin	2008	$ 300,000	$ 70,000	$ 3,696	$ 80,000(2)	$ 453,696
Chief Executive Officer	2007	$ 184,483	$ 80,000	$ 909		$ 265,392
Joseph D Agostino	2008	$ 165,000	$ 28,000	$ 2,737		$ 195,737
Chief Financial Officer	2007	$				$

(1) Includes $100,000 and $150,000 in deferred compensation in 2008 and 2007, respectively, in accordance with his employment agreement to be paid in common stock and not paid until the termination of the agreement in 2012 (under new employment agreement) or thereafter, if further extended. Other compensation represents payments made for health insurance coverage.

(2) The amounts in this column reflect the expense recognized for financial statement reporting purposes for the fiscal year ended December 31, 2008, in accordance with SFAS 123(R), Share-based Payments. for outstanding stock options granted as part of the stock option plan. 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, 2008, which is located on pages F-7 through F-11 of the Annual Report on Form 10-K. Compensation cost is generally recognized over the vesting period of the award. The number of shares underlying this option award totaled 80,000 shares. See the table below

entitled
Outstanding
Equity Awards
at December 31,
2008 and 2007.

Employment Contracts

In December 2003, Milestone entered into an employment agreement with Mr. Osser for a five-year term commencing January 1, 2004. This agreement was terminated effective December 31, 2007. Milestone entered into a new agreement with Mr. Osser effective January 1, 2008. The new agreement is for five years ending on December 31, 2012. As part of the new agreement the Chairman has relinquish the title and position of CEO and concentrate on assisting the new CEO of the Company in (i) management and oversight of vendors in China and other key vendors, (ii) arranging for, and consummating financing transactions and (iii) conducting investor relations. Under the new agreement, the Chairman will receive a base compensation of $200,000 per year payable, one half in cash and one half in common stock valued at the closing price of the common stock on January 31 of each year with respect to the then current year. While the number of shares to be issued will be determined each year, the stock will not be issued until the end of the term of the agreement.

In accordance with his employment contract, 83,333 shares of common stock were recorded as of January 31, 2008, to be paid out at the end of the contract. At December 31, 2008 the full settlement amount under the current and previous employment contracts is $700,000, 504,639 shares of common stock of deferred compensation and, accordingly, such amount has been classified in stockholder s equity, with the common shares classified as to be issued.

In accordance with the employment contract, an additional 181,818 share of common stock were recorded as of January 31, 2009, to be paid out at the end of the contract. As of January 31, 2009, the full settlement amount under the current and previous employment contract is $800,000 and 686,457 share of common stock.

Milestone entered into an agreement with Joe W. Martin, CEO effective May 2, 2007. The term of the contract is for a five year period ending on December 31, 2012. Under this agreement the CEO will receive a base cash compensation of $300,000 per year, $150,000 of which may be payable in stock at the CEO s election upon written notice to the Company. The stock would be valued at the average closing price of the common stock, during the first 15 trading days of the last full month of each 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 Milestone achieving predetermined annual cash flow, revenue, unit sales and earnings as defined in the employment agreement.

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 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 agreement.

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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 executive chief 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, 2008 and 2007

The following table includes certain information with respect to the value of all unexercised options previously awarded to the Named Executive Officers. There were no stock awards granted in 2008 and 2007.

	2008 Options Awards			2007 Options Awards		
Name	Number of Securities Underlying Unexercised Options Exercisable	Option Exercise Price ($)	Option Expiration Date	Number of Securities Underlying Unexercised Options Exercisable	Option Exercise Price ($)	Option Expiration Date
Leonard Osser				16,667(1)	$ 0.87	1/1/2008
Joe W. Martin	80,000	$ 1.00	4/25/2013			

(1) fully vested on 1-1-06

Compensation of Directors

Milestone paid no cash or stock based compensation to its directors in 2008 and 2007. On June 5, 2008 and 2007, Milestone awarded to each of its independent directors stock options expiring on June 4, 2013 and 2012, respectively,

for the purchase of 20,000 shares of its common stock, one half of each grant was exercisable immediately and the remaining one half exercisable one year after the grant, at $0.74 at $1.68 per share for the options granted on June 5, 2008 and 2007, respectively, with respect to the years ending with Milestone s 2008 and 2007 annual meeting.

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The following table provides compensation information for the year ended December 31, 2008 and 2007 for each of the independent directors. Milestone does not pay any directors fees. Directors are reimbursed for the costs relating to attending board and committee meetings.

Director Compensation

Name	2008 Option Awards (1)	2007 Option Awards (1)
Leonard M. Schiller	$ 14,800(2)	$ 22,200(3)
Jeffrey Fuller	$ 14,800(2)	$ 22,200(3)
Leslie Bernhard	$ 14,800(2)	$ 22,200(3)
Pablo Felipe Serna Cardenas	$ 14,800(2)	$ 22,200(3)

(1) Amounts are calculated using the provisions of Statement of Financial Accounting Standards (SFAS) No. 123R, Share-based Payments.

(2) On June 5, 2008, each of Milestone s independent directors was awarded options exercisable for 20,000 shares of common stock at $0.74 per share.

(3) On June 5, 2007, each of Milestone s independent directors was awarded options exercisable for 20,000 shares of common stock at $1.68 per share.

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 16, 2009 and 2008, regarding stock ownership of all persons known by Milestone to own beneficially more than 5% of Milestone s outstanding common stock, Named Executives, all directors, and all directors and officers of Milestone as a group:

	March 16, 2009	**March 31, 2008**

Names of Benefical Owner (1)	Shares of Common Stock Beneficially Owned (2)	Percentage of Ownership	Shares of Common Stock Beneficially Owned (2)	Percentage of Ownership
Executive Officers and Directors				
Leonard Osser	1,353,413(3)	11.34%	1,465,406(3)	12.53%
Joe W. Martin	426,061(4)	3.30%		*
Joseph D Agostino	29,231(5)	*		*
Leonard Schiller	113,228(6)	*	93,228(6)	*
Pablo Felipe Serna Cardenas	50,000(7)	*	30,000(7)	*
Jeffrey Fuller	90,000(8)	*	76,667(8)	*
Leslie Bernhard	80,000(9)	*	66,667(9)	*
All directors & executive officers as group (7 persons)	2,141,933	16.57%	1,731,968	14.81%
K. Tucker Andersen	1,475,033(10)	11.41%	1,483,969(10)	12.68%

* Less than 1%

(1) The addresses of the persons named in this table are as follows: Leonard A. Osser, Joe W. Martin and Joseph D Agostino are all at 220 South Orange Avenue, Livingston Corporate Park, Livingston, NJ 07039; Leonard M. Schiller, 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; Jeffrey Fuller, Eagle Chase,

Woodbury, NY 11797; Leslie Bernhard, AdStar, Inc., 4553 Glencoe Avenue, Suite 325, Marina del Rey, California 90292; K. Tucker Anderson, 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 16, 2009 and 2008, 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 12,925,694 and 11,697,837 outstanding shares on March 16, 2009 and March 31, 2008, respectively, plus those shares

underlying options exercisable within 60 days from the filing of this report held by the named individual or the group.

(3) March 31, 2008 includes 120,994 shares issuable upon the exercise of warrants within 60 days of the date hereof, which are exercisable at $4.89. The warrants noted in 2008 expired in February 2009.

(4) March 16, 2009 includes 190,505 shares held by Mr. Martin, 80,000 options at $1.00 per share issued in April 2008 and 155,556 options at $0.45 per share issued in February 2009. The stock options are exercisable to the extent of one third (1/3) of the option granted at the expiration of each of the first three years, beginning one year after the

date of grant.

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(5) Includes 29,231 shares held by Mr. D Agostino.

(6) March 16, 2009 includes 110,000 stock options, the 80,000 options listed in March 31, 2008, an additional 20,000 shares at $0.74 issued in June 2008 and 13,228 shares held by Mr. Schiller. March 31, 2008, includes 80,000 shares subject to stock options, one half of each grant was exercisable immediately and the remaining one half exercisable one year after the grant date as follows: 20,000 shares at $3.27 per share, 20,000 shares at $1.40 per share, 20,000 shares at $0.83 per share and 20,000 shares at $1.68. Also included is 13,228 shares held by Mr. Schiller.

(7) March 16, 2009 includes 50,000 stock options,

the 30,000 options listed in March 31, 2008 and an additional 20,000 shares at $0.74 issued in June 2008. March 31, 2008 includes 30,000 shares subject to stock options, one half of each grant was exercisable immediately and the remaining one half exercisable one year after the grant date as follows: 10,000 shares at $0.83 per share and 20,000 shares at $1.68.

(8) March 16, 2009 includes 90,000 stock options, 20,000 shares at $0.74 issued in June 2008, 20,000 shares at $3.27 per share, 20,000 shares at $1.40 per share, 10,000 shares at $0.83 and 20,000 shares at $1.68 per share. March 31, 2008 includes 76,667 shares subject to stock options, one half of each grant was exercisable immediately and the remaining one half

exercisable one year after the grant date as follows: 6,667 shares at $1.50 per share, 20,000 shares at $3.27 per share, 20,000 shares at $1.40 per share, 10,000 shares at $0.83 per share and 20,000 shares at $1.68.

(9) March 16, 2009 includes 80,000 stock options, 20,000 shares at $3.27, 20,000 shares at $1.40, 20,000 shares at $1.68 and 20,000 shares at $0.74. March 31, 2008 includes 66,667 shares subject to stock options, one half of each grant was exercisable immediately and the remaining one half exercisable one year after the grant date as follows: 6,667 shares at $1.50 per share, 20,000 shares at $3.27 per share, 20,000 shares at $1.40 per share and 20,000 shares at $1.68.

(10) March 16, 2009 includes 175,000 stock

options, 130,000 at $5.00 and 45,000 at $0.32. March 31, 2008 included 183,946 shares subject to warrants all of which are exercisable within 60 days of the date hereof at $4.89 these warrants expired in February 2009. The 2008 amount includes 100,000 shares subject to warrants at $5.00 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

The following table summarizes the (i) options granted under the Milestone 1997 and 2004 Stock Option Plans, and (ii) options and warrants granted outside the Milestone 1997 and 2004 Stock Option Plans, as of December 31, 2008. 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 (1) to be issued upon exercise of outstanding options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities (1) remaining available for future issuance under equity compensation plan
Equity compensation plan approved by stockholders (1)			
Grants under our 1997 Stock Option Plan	84,000	$ 3.74	177,999
Grants under our 2004 Stock Option Plan	486,832	1.01	428,000
Equity compensation plan not approved by stockholders (2)			Not applicable
Aggregate individual option and warrants grants	3,030,413	4.40	
Total	3,601,245	3.92	

(1)

Consisting of the 1997 stock option plan covering a total of 333,333 common shares underlying options issuable to officers and other key employees and excluding 2,333 options, which were exercised in October 2003, 16,667 options, which were exercised in December 2003, 333 options which were exercised in April 2005 and 26,666 shares exercised in 2007. The plan has a term of 10 years and is administered by a committee appointed by the board of directors. The committee, in its sole discretion, determines who is eligible to receive these incentive stock options, how many options they will receive, the term of the options, the exercise price and other conditions relating to the exercise of the options. Stock options granted

under the plan must be exercised within a maximum of 10 years from the date of grant at an exercise price that is not less than the fair market value of the common shares on the date of the grant. Options granted to shareholders owning more than 10% of the outstanding common shares must be exercised within five years from the date of grant and the exercise price must be at least 110% of the fair market value of the common shares on the date of the grant. No options were exercised in 2008 and options exercised in 2007 were 6,667.

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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 2008 and options exercised in 2007 were

60,000.

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.

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.

During 2008, no shares were issued under this plan.

During 2007, 28,269 shares of common stock valued at $62,196 were granted under the 2006 Stock Plan as part of annual compensation and 84,270 shares of common stock valued at $150,000 in settlement of officers deferred compensation.

Additionally, in satisfaction of payables owed in connection with warehousing and fulfillment services and exhibition facilities, Milestone issued 44,068 shares valued at $46,000 to two of the vendors (the Vendor Shares).

As of December 31, 2008 and 2007, shares available to be issued under this plan were 45,304.

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 2008, the Company issued the following shares under this Plan; 156,448 shares valued at of $262,746 for Vendor Services, 356,063 shares valued at $316,099 for Consulting Services, 135,602 shares valued at $98,419 for Employee Compensation, 83,333 shares valued at $100,000 for Officer s Deferred Compensation and 260,000 shares valued at $93,600 for Settlement of the Hodosh Lawsuit.

At December 31, 2008, there was $1,129,136 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.

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Item 13. Certain Relationships and Related Transactions and Director Independence

On June 28, 2007 the Company secured a $1 million line of credit from a stockholder. This borrowing was amended to $1,300,000 as of September 30, 2008 under the same terms and conditions as the original. Borrowings bear interest at 6% per annum, with one year s interest at 1% payable in advance on each draw. Monies may be drawn by Milestone under the line in multiples of $100,000 upon 5 days written notice to the stockholder from either Milestone s Chief Executive Officer or Chief Financial Officer. Monies under the line in excess of $1,000,000 may be drawn in multiples of $25,000. Borrowings may be prepaid at any time in multiples of $100,000, without penalty. All borrowings and interest thereon must be repaid by June 30, 2010, and after the expiration date of the line, may be repaid by Milestone in cash or, at its option, in shares of common stock valued at the lower of $2.00 per share or 80% of the average closing price of its shares during the 20 trading days ending with December 31, 2008. At December 31, 2008, the conversion price at 80% of the average closing price of the Company s stock was $0.26 per share. After December 31, 2008, and before June 30, 2010, the lender may convert all or any part of the then outstanding balance and interest thereon into shares of Common Stock at $4.00 per share. Three year warrants exercisable at $5.00 per share, in an amount determined by dividing 50% of the amount borrowed by $5.00 will be issued on each drawdown. There is no facility fee on the line. The warrants have been valued as of each draw down using the Black-Scholes model and are reflected as a discount against the debt incurred under this line of credit. At December 31, 2008 the remaining balance of debt discount was $52,530. The full amount of the line of credit and amendment, $1.3 million, has been drawn at September 30, 2008. This borrowing was amended to $1,300,000 as of September 30, 2008 under the same terms and conditions as the original borrowing. The Company borrowed an additional $450,000 from the same shareholder in 2008. The borrowing was originally on short term loan with a maturity date of January 19, 2009. In December 2008, this borrowing was refinanced with the shareholder with a due date of June 30, 2012. 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. The Company did not have any other related party transactions pursuant to Item 404 of Regulation S-K of the Exchange Act. Milestone have adopted a policy that, in the future, the Audit Committee must review all transactions with any officer, director or 5% stockholder.

Director Independence

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

In determining director independence, the Board considered the option awards to the Independent Directors for the year ended December 31, 2008, disclosed in Item 10 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 $137,975 and $84,338, respectively from Holtz Rubenstein Reminick LLP, the principal accountant for 2008 and 2007.

Audit Related Fees

There were no audit related fees to the principal accountant Holtz Rubenstein Reminick LLP in 2008 and 2007.

Tax Fees

There were no fees for services related to tax compliance, tax advice and tax planning billed by the principal accountant in 2008 and 2007.

All Other Fees

There were no other fees billed during 2008 and 2007 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 2008.

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

(a) Exhibits

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

EXHIBIT NO.	DESCRIPTION
3.1	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 (6)
3.6	Certificate of Amendment filed January 8, 2004. (6)
3.7	Certificate of Designation filed January 15, 2004 (6)
3.8	By-laws of Milestone (1)
4.1	Specimen stock certificate (2)
4.3	Form of warrant agreement, including form of warrant (8)
10.1	Lease dated November 25, 1996 between Livingston Corporate Park Associates, L.L.C. and Milestone (3)
10.2	Agreement with DaVinci Systems dated July 30, 2003 (6)
10.3	Agreement with Strider dated September 3, 2003 (6)
10.4	Agreement with Len Osser and K. Tucker Andersen, dated October 9, 2003 (6)
10.5	Agreement with Morse, Zelnick, Rose & Lander dated December 22, 2003 (6)
10.6**	Employment Agreement with Leonard Osser dated December 20, 2003 (6)
10.7	Agreement with United Systems dated October 20, 2004 (9)
10.8	Agreement with Mark Hochman dated as of January 1, 2005 (9)
10.9	Lease amendment dated April 28, 2004 between Livingston Corporate Park Associates, L.L.C. and Milestone (9)
10.10	Agreement with DaVinci regarding exclusive license over patented products dated June 1, 2004 (10)
10.11**	Employment Agreement with Leonard Osser dated January 1, 2008* (11)
10.12**	Employment Agreement with Joe W. Martin dated May 2, 2007* (11)
14	Code of Ethics (7)
23.1	Consent of Holtz Rubenstein Reminick LLP*
31.1	Rule 13a-14(a) Certifications Chief Executive Officer*
31.2	Rule 13a-14(a) Certifications Chief Financial Officer*
32.1	Section 1350 Certifications- Chief Executive Officer*
32.2	Section 1350 Certifications- Chief Financial Officer*

* Filed herewith.

** Indicates management contract or compensatory

plan or
arrangement

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(1) Incorporated by reference to Milestone s Registration Statement on Form SB-2 No. 33-92324.

(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. 1.

(6) Incorporated by reference to Milestone s Registration

Statement on Form S-2 No. 333-110376, Amendment No. 3.

(7) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 2003.

(8) Incorporated by reference to Milestone s Registration Statement on Form S-2 No. 333-110367, Amendment No. 5.

(9) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 2004.

(10) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 2005.

(11) Incorporated by reference to Milestone s Form 10-KSB for the year ended December 31, 2007.

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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/ Joe W. Martin
Chief Executive Officer

Date: March 16, 2009

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/ Joe W. Martin	March 16, 2009	Chief Executive Officer
Joe W. Martin		
/s/ Joseph D Agostino	March 16, 2009	Chief Financial Officer
Joseph D Agostino		
/s/ Leonard Osser	March 16, 2009	Director
Leonard Osser		
/s/ Leonard Schiller	March 16, 2009	Director
Leonard Schiller		
/s/ Jeffery Fuller	March 16, 2009	Director
Jeffrey Fuller		
/s/ Leslie Bernard	March 16, 2009	Director
Leslie Bernhard		
/s/ Pablo Felipe Serna Cardenas	March 16, 2009	Director
Pablo Felipe Serna Cardenas		

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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 sheet of Milestone Scientific Inc. as of December 31, 2008 and 2007 and the related statements of operations, stockholders equity, and cash flow for the two 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 audit.

We conducted our audit 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 audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Milestone Scientific Inc. as of December 31, 2008 and 2007 and the results of its operations and its cash flows for the two 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 and has a net capital deficiency, 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
Melville, New York
March 9, 2009

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MILESTONE SCIENTIFIC INC.
BALANCE SHEETS
December 31, 2008 and 2007

	December 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 743,665	$ 745,003
Accounts receivable, net of allowance for doubtful accounts of $5,000 in 2008 and 2007	925,742	346,347
Royalty receivable		15,358
Inventories	719,902	1,636,744
Advances to contract manufacturer	250,110	651,854
Prepaid expenses and other current assets	218,296	169,727
Total current assets	2,857,715	3,565,033
Advances to contract manufacturer	415,780	540,730
Investment in distributor, at cost	76,319	76,319
Furniture, Fixtures & Equipment net of accumulated depreciation of $345,377 as of December 31 ,2008 and $284,144 as of December 31, 2007	152,574	220,808
Patents, net of accumulated amortization of $135,406 as of December 31, 2008 and $79,498 as of December 31, 2007	901,045	559,378
Other assets	7,317	27,297
Total assets	$ 4,410,750	$ 4,989,565
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 829,130	$ 1,855,835
Accrued expenses and other payable	495,897	216,936
Total current liabilities	1,325,027	2,072,771
Long-term Liabilities:		
Accounts payable-long term		443,847
Line of credit-net of discount of $52,530 and $65,371, respectively	1,247,470	934,629
Notes Payable-net of discount of $11,927	438,073	
Total long-term liabilities	1,685,543	1,378,476
Commitments and Contingencies		

Stockholders Equity		
Common stock, par value $.001; authorized 50,000,000 shares; 12,695,685 shares issued 504,639 shares to be issued and 12,662,352 shares outstanding as of December 31, 2008; 11,787,572 shares issued, 421,306 shares to be issued, and 11,754,239 shares outstanding as of December 31, 2007	13,200	12,210
Additional paid-in capital	59,531,865	58,483,539
Accumulated deficit	(57,233,369)	(56,045,915)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total stockholders equity	1,400,180	1,538,318
Total liabilities and stockholders equity	$ 4,410,750	$ 4,989,565

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2008 AND 2007

	2008	2007
Product sales, net	$ 6,595,525	$ 6,262,608
Royalty income	28,282	128,105
Total revenue	6,623,807	6,390,713
Cost of products sold	2,681,116	2,898,048
Gross profit	3,942,691	3,492,665
Selling, general and administrative expenses	5,502,762	6,577,086
Research and development expenses	168,516	397,354
	5,671,278	6,974,440
Loss from operations	(1,728,587)	(3,481,775)
Other income & (expense)		
Other income	675,930	552,005
Interest income	9,023	17,440
Interest expense	(116,374)	(19,752)
Amortized debt issuance	(27,446)	(6,614)
Total other income	541,133	543,079
Net loss	$ (1,187,454)	$ (2,938,696)
Net loss applicable to common stockholders	$ (1,187,454)	$ (2,938,696)
Loss per share applicable to common stockholders basic and diluted	$ (0.09)	$ (0.24)
Weighted average shares outstanding and to be issued basic and diluted	12,666,979	12,141,525

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.
STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY
YEARS ENDED DECEMBER 31, 2008 AND 2007

	Common Stock		Additional Paid-in	Accumulated	Treasury	
	Shares	Amount	Capital	Deficit	Stock	Total
Balance, December 31, 2006	12,029,672	12,031	57,720,129	(53,107,219)	(911,516)	3,713,425
Options issued for payment of consulting services			285,282			285,282
Common stock issued from exercise of options	66,667	67	71,134			71,201
Common stock and options issued for payment of employee compensation	28,269	28	185,093			185,121
Common Shares to be issued in settlement of deferred compensation	84,270	84	149,916			150,000
Warrants issued in connection with Line of Credit			71,985			71,985
Net Loss				(2,938,696)		(2,938,696)
Balance, December 31, 2007	12,208,878	12,210	58,483,539	(56,045,915)	(911,516)	1,538,318
Options issued to employees and consultants			151,920			151,920
Common stock issued for payment of services to settle accounts payable	156,448	156	262,590			262,746
Common stock issued for payment of consulting services to settle accounts payable	356,063	356	315,743			316,099
Common stock issued for payment of employee compensation	135,602	135	98,284			98,419
Common shares to be issued in settlement of deferred compensation	83,333	83	99,917			100,000
Common stock issued for patents in settlement of lawsuit	260,000	260	93,340			93,600
Warrants issued in connection with amendment to Line of Credit			12,579			12,579
Warrants issued in connection with refinancing of Notes Payable			13,953			13,953
Net loss				$ (1,187,454)		(1,187,454)
Balance, December 31, 2008	13,200,324	$ 13,200	$ 59,531,865	$ (57,233,369)	$ (911,516)	$ 1,400,180

See Notes to Financial Statements

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MILESTONE SCIENTIFIC INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2008 AND 2007

	2008	2007
Cash flows from operating activities:		
Net loss	$ (1,187,454)	$ (2,938,696)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	71,336	104,740
Amortization of patents	55,908	37,560
Amortization of debt discount	27,446	6,614
Common stock and options issued for compensation, consulting, and vendor services	350,339	620,403
Bad debt expense		69,378
Loss on sale/disposal of equipment	2,255	241,530
Loss on write-off of patent rights		157,640
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(579,395)	(69,106)
Decrease in royalty receivable	15,358	44,749
Decrease (Increase) in inventories	916,842	(313,406)
Decrease (Increase) to advances to contract manufacturer	526,694	(114,713)
(Increase) to prepaid expenses and other current assets	(48,569)	(72,654)
Decrease (Increase) in other assets	19,980	(13,144)
(Decrease) Increase in accounts payable	(891,707)	1,103,575
Increase (Decrease) in accrued expenses	282,294	(30,973)
(Decrease) in deferred compensation	(3,333)	15,833