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MILESTONE SCIENTIFIC INC/NJ
Form 10KSB
April 04, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

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

For the Fiscal Year ended December 31, 2004

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.
(Name of Small Business Issuer in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

220 South Orange Avenue, Livingston Corporate Park, Livingston, NJ 07039
(Address of Principal Executive Office) (Zip Code)
Registrant's telephone number (973) 535-2717

Securities registered under Section 12(b) of the Exchange Act:

| Title of Each Class ----- | Name of Each Exchange on Which Registered ----- |
|--|---|
| Common Stock, par value \$.001 per share | American Stock Exchange and Pacific Sto |
| Warrants, each to purchase one share of common stock | American Stock Exchange |

Securities registered under Section 12(g) of the Exchange Act:
None

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

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is contained herein, and will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

For the year ended December 31, 2004, the revenues of the registrant were \$4,751,186.

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The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, on the American Stock Exchange, on March 29, 2005 of \$3.45 as approximately \$23,346,047

As of March 29, 2005 the registrant has a total of 10,462,334 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

MILESTONE SCIENTIFIC, INC.

Form 10-KSB Annual Report

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FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-KSB 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

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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 and, therefore, there can be no assurance that the forward-looking statements included in this Report will prove to be accurate. 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.

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PART I

Item 1. Description of Business

All references in this report to "we," "us," "our" or "Milestone" refer to Milestone Scientific Inc., and its former subsidiary, Spintech, Inc. ("Spintech"), unless the context otherwise indicates. We have rights to the following trademarks: CompuDent(R), CompuMed(R), CompuFlo(TM), The Wand(R), The WandPlus(R), The SafetyWand(TM) and CoolBlue(TM) Wand. Milestone was incorporated in the State of Delaware in 1989. On December 10, 2004, Milestone merged its three subsidiaries into itself in order to reduce administrative expenses. Two of the subsidiaries were wholly owned. The third, Spintech, was merged into Milestone by a short-form merger. Also on December 10, 2004 we purchased a 19.9% interest in a German wholesale distributorship that sells dental products including our CompuDent technology and CoolBlue product lines in Germany, the world's 3rd largest dental market.

All share number and share price information in this report have been retroactively adjusted to reflect the 1-for-3 reverse stock split effected in January 2004.

BUSINESS

Background

Milestone Scientific Inc. is the world leader in advanced injection technology. Its principal product, a computer controlled, precision metered, local anesthetic injection system (the "CompuDent"), enables a dentist to consistently administer safe, effective and painless injections. CompuDent is a revolutionary device, considered one of the major advances in dentistry of the twentieth century. It has been favorably evaluated in approximately 50 peer reviewed or independent clinical research reports. In 2004 the CompuDent was prominently featured in the leading textbook on dental anesthesia, the "Handbook of Local Anesthesia" by Stanley F. Malamed, DDS.(1)

CompuDent, including its ergonomically designed single use hand-piece ("The Wand"), provides numerous, well documented benefits:

- o CompuDent minimizes the pain associated with palatal, mandibular

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block and other injections, resulting in a more comfortable injection experience for the patient;

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

Milestone also believes that use of CompuDent reduces tissue tearing and necrosis and results in less post-operative or post-procedure pain, but is awaiting further clinical evidence before publicly making these claims.

- (1) Dr. Malamed is widely recognized as the preeminent authority on dental anesthesia. New editions of his "Handbook of Local Anesthesia" are published once every seven years and are used in all major U.S. and many foreign dental schools. It is the largest selling textbook in dental anesthesia and is the third largest selling dental textbook. The current edition recommends use of the CompuDent and devotes 62 paragraphs to the device and its application. Milestone understands that this is the first instance in which Dr. Malamed's text has recommended a particular device.

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Despite CompuDent's many benefits, including the administration of painless injections, dentists in the United States have been reluctant to give up the use of traditional syringes. Dentists have all been trained to use syringes in dental school and often have become accustomed and comfortable in their use during many years of clinical practice. Thus, following a successful launch in early 1998 to "new adopters," sales were below expectations in 1999 and 2000. By the end of 2000, Milestone had limited financial resources(2) and was forced to choose between maintaining its leadership position in advanced injection technology or continuing to promote sales through high levels of sales and marketing expense, including trade show appearances. Milestone chose to maintain its technology leadership position and drastically reduced marketing and sales expense, thus allowing domestic sales of new units to suffer. However, despite limited marketing efforts, foreign sales continued to grow. Also increasing handpiece use by the domestic customer base resulted in rising handpiece sales.

Technology Development

After curtailing sales and marketing efforts, Milestone focused on maintaining its technological leadership. First, it addressed a number of customer needs for its CompuDent unit by developing such improvements as a holster component for its handpiece which more effectively pierced anesthetic cartridge membranes, an overflow reservoir in the unit that eliminated problems occasionally caused by fluid from broken anesthetic cartridges shorting-out

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control components, a dual speed flow rate foot control pedal and an audio signal to alert the dentist to the speed at which the unit was operating. These and other improvements essentially eliminated all field complaints with the CompuDent unit before 2003.

To enhance its role as the world leader in advanced injection technology, Milestone has developed the following array of other technologically advanced products for the delivery of local anesthetics and liquid medicaments.

CompuMed

Milestone developed and in 2001 began limited marketing of "CompuMed(R)", a computer controlled injection system geared to the needs of the medical market and providing benefits similar to the CompuDent. CompuMed allows many medical procedures, now requiring IV sedation, to be performed with only local anesthesia because of the dramatic pain reduction. Also, dosages of local anesthetic can often be significantly reduced, thus reducing side effects, accelerating recovery times, lowering costs and eliminating complications. CompuMed is now gaining growing clinical evidence showing benefits from use in colorectal surgery, podiatry, dermatology, including MOH's surgery for the removal of basal cell carcinomas and other oncological dermatologic procedures, nasal and sinus surgery, including rhinoplasty, hair transplantation and plastic surgery.

SafetyWand

Following 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 engineering sharps 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. Since SafetyWand is now available commercially,

(2) It received a going concern limitation in its 2000 financial report.

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OSHA has begun to enforce existing regulations requiring the use of safety engineered devices. OSHA is empowered to levy substantial fines for failure to use these devices. We believe the Safety Wand will promote increased handpiece use by the more than 15,000 CompuDent anesthetic delivery systems previously sold in the United States while also providing new impetus for the purchase of these systems by new users.

CompuFlo

"CompuFlo", developed by Milestone, is a revolutionary new technology for

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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.

Risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications have long been tolerated as negative side effects from the use of traditional hypodermic drug delivery injection systems. This is well documented in dental and medical literature. 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 our development of CompuFlo.

In September 2004, Milestone Scientific was issued United States Patent No. 6,786,885 (date of issue September 14, 2004) on 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 appears to have many applications in both medicine and dentistry including epidural 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".

The Drug Delivery System with Profiles standardizes and simplifies the drug delivery process, while reducing the risk of medical complications by controlling parameters that are essential for the safe injection of local anesthetics and other medications, as well as the aspiration of bodily fluids. This is accomplished through an integrated injection database in the CompuFlo technology that contains the critical components of specific drugs, parameters of needles, tubing and syringes and all pertinent components for the safe and efficacious delivery of medications, including procedures such as epidural injections.

Pressure/Force Computer Controlled Drug Delivery with Automated Charging -- provides the means to deliver any volume of medication or infused fluid, such as a saline solution, into the human body. In many instances, the volume of medication or other liquid that is required for a medical procedure exceeds the capacity of the normal vessels used. This technology allows the smaller vessel to be automatically refilled from a larger one without interrupting the surgery or medical procedure.

Epidurals. In 2004, successful results of two independent pilot clinical studies confirmed the efficacy of the CompuFlo pressure/force computer controlled anesthetic delivery system in identifying the epidural space. Identifying when a hypodermic needle has entered the epidural space is a critically important factor in the safety and effectiveness of anesthetic injections administered during childbirth and in the course of pain management therapy. A report on the results of the study, conducted through the University of Texas Health Science Center at Houston under the guidance of Dr. Oscar Ghelber, Assistant Professor of Anesthesiology, was presented at the Society for Technology in Anesthesia (STA) meeting on October 28th,

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2004. Proper and consistent identification of the epidural space represents a critical step towards the adoption of Milestone's technology for the administration of epidural anesthesia.

In addition to products enhancing its position in advanced injection technology, in 2004 Milestone acquired rights to a proprietary dental enhancement system now named the CoolBlue Wand(TM).

CoolBlue Wand Dental Enhancement System

The CoolBlue Wand(TM) dental enhancement system uses blue light emitting diodes for fast curing of dental composite material, trans-illumination of teeth and activation of whitening gels and pastes. Initially Milestone viewed the CoolBlue Wand as an aid to its sales force in gaining access to dental offices for sales of CompuDent. However, in view of the burgeoning consumer demand for tooth whitening, the professional product will also provide Milestone with access to the consumer tooth whitening market.

Consumer Tooth Whitening

In October 2004, Milestone announced the planned launch of its proprietary tooth whitening system, for the home-use consumer market. The system and consumable gels and rinses used with the system will be manufactured for Milestone by United Systems, Inc. under an exclusive license agreement requiring the purchase of a minimum of 1 million system Starter Kits from Milestone during the four year term of the agreement.

The \$400 million (annual revenues) consumer segment of the \$1 billion-plus tooth whitening market is one of the fastest growing areas in the oral hygiene industry. Milestone's system utilizes a unique blue LED intra-oral light (incorporated into a hand held battery-powered device) to activate proprietary tooth-whitening gels. The system is designed to provide a safe, convenient and time saving method of whitening teeth. When used on a regular basis with a specially formulated rinse, also to be offered by the licensee, the system will maintain the brightness of teeth on an ongoing basis.

The consumer tooth whitening product line includes a Starter Kit that contains the gels, the rinse and the intra-oral light. Continuity Kits with a 30-day supply of the specially formulated rinse will also be available. The product will be marketed through television spots, infomercials, print media and ultimately through retail outlets. Television infomercials began running in 23 markets on March 13, 2005.

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Milestone Renaissance

In 2003 we recognized that the domestic market had become ready to accept our CompuDent technology. An authoritative and growing body of peer reviewed and other independent clinical studies had established the superiority of the CompuDent to the traditional syringe in administering dental anesthesia; the CompuDent had been readily accepted in first world international markets, despite limited marketing efforts; and more than 16 million injections had been administered with CompuDent creating growing professional acceptance and consumer demand for the administration of painless injections by their dental practitioners. Two ingredients were missing, a new marketing approach and funds

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to support the new sales effort required by this marketing approach.

During 2003 we tested the use of our own highly trained force of independent sales representatives and inside sales support and sales staff to generate additional sales to our existing base, to increase handpiece usage and to both generate leads and to sell to new customers. Based on our pilot programs and studies we determined that a new sales program built around the following components could be successful:

- o An increased base price for CompuDent to new customers to provide sufficient gross profit to allow adequate compensation to a new sales force.
- o An inside sales support staff to generate leads for outside independent sales representatives and also to set appointments, provide technical support and customer service and foster increased handpiece use.
- o Providing ancillary products to its outside sales force, such as the CoolBlue Wand, to assist that force in gaining access to dental offices for sales of CompuDent.
- o Primary reliance on an inside sales force in the domestic market.
- o Use of independent highly trained exclusive outside sales representatives only in high density markets to prevent excessive costs.

The plan also contemplated increased marketing and promotional activities including increasing trade show appearances, advertising directed towards dental professionals and, possibly, to consumer advertising.

To fund this new marketing plan, we arranged for new equity funding through Paulson Investment Company, Inc. This offering was consummated in February, 2004 with a raise of gross proceeds of \$9,388,000 from the sale of 1,440,000 units, each consisting of two shares of common stock and one warrant to purchase an additional share of common stock at \$4.89 per share.

As contemplated in the offering, we used the proceeds to significantly expand the Company's sales capability by taking the following steps:

- o Expanding significantly its independent sales force, both inside and outside sales reps, and our sales support staff.
- o Conducting extensive training programs for our new sales force.
- o Beginning to implement new marketing and advertising campaigns directed at the professional dental market and, possibly, the consumer market.
- o Completing the final production, tooling and other work necessary to launch the SafetyWand
- o Taking the initial steps necessary to re-establish our dental and hygiene school teaching programs.

Because of the time required to rent additional facilities, install computer lines and an internal computer network, obtain high traffic telephone lines and otherwise create the essential infrastructure, hire and train managers, allow managers to hire or engage sales representatives and then the long training time necessary to provide the sales force with the skills required to sell CompuDent, the effects of these new initiatives only became apparent in

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the fourth quarter of 2004.

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Competition

Our anesthetic delivery systems compete with disposable and reusable syringes that generally sell at lower prices and that use established and well-understood methodologies and other local anesthetic delivery systems, in both the dental and medical marketplaces. When SafetyWand is commercially available, it will compete with other safety engineered products in the medical market and against a single product claiming to be compliant with OSHA regulations under the Needle Stick Act in the dental market.

Our 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 our systems reduce fear, pain and anxiety for some patients, and we believe that they can also reduce practitioner stress levels. CompuDent can be used for all local anesthesia techniques that can be performed with a syringe. CompuDent can also be used for new and modified techniques that cannot be performed with traditional syringes. These new techniques allow faster procedures shortening chair time, while minimizing numbing of the lips and facial muscles, enhance productivity, reduce stress and virtually eliminate pain and anxiety.

The Luer Lock needle, sold by us, competes with dental needles produced and distributed by a number of major manufacturers and distributors and other producers or distributors of dental products, many of whom have significant competitive advantages because of their size, strength in the marketplace, financial and other resources and broad product lines. We compete on the basis of convenience since we can package the product with an order for disposable handpieces.

We face intense competition from many companies in the medical and dental device industry, possessing substantially greater financial, marketing, personnel, and other resources. Most of our 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 our products. Current or new competitors could, at any time, introduce new or enhanced products with features that render our products less marketable or even obsolete. Therefore, we must devote substantial efforts and financial resources to improve our existing products, bring our products to market quickly, and develop new products for related markets. In addition, our ability to compete successfully requires that we establish an effective distribution network. New products must be approved by regulatory authorities before they may be marketed. We cannot assure you that we can compete successfully, that our competitors will not develop technologies or products that render our products less marketable or obsolete, or that we will succeed in improving our existing products, effectively develop new products, or obtain required regulatory approval for those products.

Patents And Intellectual Property

We hold the following U.S. utility and design patents:

U.S. PATENT
NUMBER

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COMPUDENT

| | |
|---|-----------|
| Hypodermic Anesthetic Injection Method | 4,747,824 |
| Hypodermic Anesthetic Injection Apparatus & Method | 5,180,371 |
| (CompuFlo, CompuMed, and CompuDent) | |
| Dental Anesthetic and Delivery Injection Unit | 6,022,337 |
| Dental Anesthetic Delivery Injection Unit (continuation of No. 6,022,337) | 6,152,734 |
| Dental Anesthetic Delivery Injection Unit (continuation of No. 6,022,337) | 6,132,414 |
| Design for a Dental Anesthetic Delivery System Handle | D427,314 |
| Design for a Dental Anesthetic Delivery System Holder | D422,361 |
| Design for a Dental Anesthetic Delivery System Housing | D423,665 |
| Dental Anesthetic and Delivery Injection Unit with Automated Rate Control | 6,652,482 |

SAFETYWAND

| | |
|---|-----------|
| Handpiece for Injection Device with a Retractable and Rotating Needle | 6,428,517 |
| Safety IV Catheter Device | 6,726,658 |

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COMPUFLO

| | |
|--|-----------|
| Pressure/Force Computer Controlled Drug Delivery System | 6,200,289 |
| Pressure/Force Computer Controlled Drug Delivery System with Exit Pressure | 6,786,885 |

OTHER

| | |
|--|-----------|
| Hypodermic Syringe and Method | 4,877,934 |
| Apparatus and Method for Sterilizing, Destroying and Encapsulating Medical Implement Wastes | 4,992,217 |
| Apparatus and Method for Verifiably Sterilizing Destroying and Encapsulating Regulated Medical Wastes | 5,078,924 |
| Apparatus and Method for Verifiably Sterilizing, Destroying and Encapsulating Regulated Medical Wastes | 5,401,444 |
| Self-Sterilizing Hypodermic Syringe and Method | 5,512,730 |
| Self-Sterilizing Hypodermic Syringe and Method | 5,693,026 |

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

The Drug Delivery System with Profiles standardizes and simplifies the drug delivery process, while reducing the risk of medical complications by controlling parameters that are essential for the safe injection of local anesthetics and other medications, as well as aspiration of bodily fluids. This is accomplished through an integrated injection database in the CompuFlo technology that contains the critical components of specific drugs, parameters of needles, tubing and syringes and all pertinent components for the safe and efficacious delivery of medications, particularly in procedures such as epidural injections.

The Pressure/Force Computer Controlled Drug Delivery with Automated Charging provides the means to deliver any volume of medication or infused fluid, such as a saline solution, into the human body. In many instances, the volume of medication or other liquid that is required for a medical procedure exceeds the capacity of the normal vessels used. This technology allows the smaller vessel to be automatically refilled from a larger one without

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interrupting the surgery or medical procedure.

We also have several patent applications pending before the U.S. Patent and Trademark Office, and hold a number of corresponding patents in Europe and other major markets.

During the 2004 and 2003 fiscal years, we expensed \$187,992 and \$131,015, respectively, on research and development activities. The higher costs incurred during 2004 were primarily associated with the development of the SafetyWand.

We rely on a combination of patent, copyright, trade secret, and trademark laws and employee and third party nondisclosure agreements to protect our intellectual property rights. Despite the precautions taken by us to protect our products, unauthorized parties may attempt to reverse engineer, copy, or obtain and use products and information that we regard as proprietary, or may design products serving similar purposes that do not infringe on our patents. Litigation may be necessary to protect our intellectual property rights and could result in substantial cost to us and diversion of our efforts with no guarantee of success. Our failure to protect our proprietary information and the expenses of doing so could have a material adverse effect on our operating results and financial condition.

While there are no current claims that our products infringe the proprietary rights of third parties, there can be no assurance that third parties will not assert infringement claims against us in the future with respect to current or future products or that any such assertion may not require us to cease selling such products, or to enter into arrangements that require us to pay royalties, or to engage in costly litigation. Although we have received no claims of infringement, it is possible that infringement of existing or future patents or proprietary rights of others may occur. In the event that our products infringe upon patent or proprietary rights of others, we may be required to modify our processes or to obtain a license. There can be

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no assurance that we 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 us.

Government Regulation

The FDA cleared CompuDent system and its disposable handpiece 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 SafetyWand for marketing in the U.S. for dental applications in September 2003. For us to commercialize our other products in the United States, we will have to submit additional 510(k) applications with the FDA.

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 United States. 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

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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, premarket 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 premarket 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 premarket approval, the manufacturer or distributor may seek FDA marketing clearance for the device by filing a 510(k) Premarket Notification. The 510(k) Premarket 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) Premarket 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) Premarket Notification. At this time, the FDA typically responds to the submission of a 510(k) Premarket 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 United States. 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 our products and could have a material adverse effect on us. If a device that has obtained 510(k) Premarket 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) Premarket Notification clearance must be obtained before the modified device can be marketed in the United States. 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 premarket approval of the proposed device, a more difficult procedure requiring extensive data, including pre-clinical and human clinical trial data, as well as extensive literature, to prove the safety and efficacy of the device.

Though CompuDent, the SafetyWand and CompuMed have received FDA marketing clearance, there can be no assurance that any of our other products under development will obtain the required regulatory clearance on a timely basis, 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 our 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

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commercialization of our development products 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 us.

We are 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 we 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, our officers or employees. Any action by the FDA could result in disruption of our operations for an undetermined time.

In June 2003 we received CE mark in the European Common Market for marketing in Europe of the SafetyWand and The Wand Handpiece with Needle. In July 2003, we obtained regulatory approval to sell CompuDent and its handpieces in Australia and New Zealand.

Product Liability

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

Employees

On December 31, 2004, Milestone had 31 full-time employees, including three executive officers, a clinical director, three domestic sales managers, five sales support representatives, fifteen inside sales representatives, an international sales manager, an assistant controller, a bookkeeper, and an administrative assistant. In addition, 14 independent sales representatives sell our CompuDent system.

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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:

We have no history of profitable operations. Continuing losses could exhaust our capital resources and force us to discontinue operations.

Although our operations commenced in November 1995, until 1998 we had limited revenues. For the years ended December 31, 1998, 1999, 2000, 2001, 2002, 2003, and 2004, our revenues were approximately \$8.8 million, \$2.9 million, \$5.7 million, \$4.1 million, \$4.1 million, \$4.0 million, and 4.8 million, respectively. In addition, we have had losses for each year since the commencement of operations, including net losses of approximately \$2.4 million and \$3 million for 2003 and 2004, respectively. At December 31, 2004, we had an accumulated deficit of approximately \$47 million. Unless we can significantly increase sales of our CompuDent units, handpieces or other injection devices, we expect to incur losses for the foreseeable future.

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

As with any new technology, there is substantial risk that the marketplace will not accept the potential benefits of this technology or be unwilling to pay for any cost differential with the existing technologies. Market acceptance of CompuDent, the SafetyWand, CompuMed and CompuFlo depends, in large part, upon our ability to educate potential customers of their distinctive characteristics and benefits and will require substantial marketing efforts and expense. More than 26,000 units of the CompuDent or its predecessors have been sold worldwide since 1998. Sales of disposable handpieces in 2003 reflect a moderate increase in the world wide usage of our dental and medical systems. We cannot assure you that our current or proposed products will be accepted by practitioners or that any of the current or proposed products will be able to compete effectively against current and alternative products.

Our limited distribution channels must be expanded for us to become successful.

Our future revenues depend on our ability to market and distribute our anesthetic injection technology successfully. In the United States, we rely on a limited number of independent representatives and in-house sales people. Abroad, we lack distributors in many markets. To be successful we will need to hire and retain additional sales personnel, provide for their proper training and ensure adequate customer support. We cannot assure you that we will be able to hire and retain an adequate sales force or engage suitable distributors, or that our sales force or distributors will be able to successfully market and sell our products.

We depend on two principal manufacturers. If we cannot maintain our existing relationships or develop new ones, we may have to cease our operations.

We have informal arrangements with the manufacturer of our CompuDent and CompuMed units and the principal manufacturer of our handpieces for those units pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. We have been supplied by these manufacturers since the commencement of production in 1998. However, termination of the manufacturing relationship with any of these manufacturers could significantly and adversely affect our ability to produce and sell our products. Though we have established an alternate source of supply for our handpieces in China and other alternate sources of supply exist, we would need to recover our 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

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the supply, whether or not as a result or termination of the relationship, would adversely affect us.

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

We could be subject to claims for personal injury from the alleged malfunction or misuse of our dental and medical products. While we carry liability insurance that we believe is adequate, we cannot assure you 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 us.

We rely on the continuing services of our chairman and chief executive officer, president and director of clinical affairs.

We depend on the personal efforts and abilities of our Chairman and Chief Executive Officer, our President who was promoted to this position from that of Senior Vice President in September 2003, and our Director of Clinical Affairs. We maintain a key man life insurance policy in the amount of \$1,000,000 on the life of our Chairman and Chief Executive Officer. However, the loss of his services or the services of each of our President or Director of Clinical Affairs, on whom we maintain no insurance, could have a materially adverse effect on our business.

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

Our stock price has been extremely volatile, fluctuating over the last three years between closing prices of \$.42 and \$7.77. These fluctuations have been unrelated to or disproportionately affected by our operating performance. The market price of our common shares could continue to fluctuate significantly in response to a variety of factors, some of which may be beyond our control.

We currently have outstanding options, warrants and series A convertible preferred stock to purchase 3,229,407 shares of our common stock at prices ranging from \$.87 to \$13.50 per share with a weighted average exercise or conversion price of \$4.86. Holders of these warrants and options are given the opportunity to profit from a rise in the market price of our common stock and are likely to exercise their securities at a time when we would be able to obtain additional equity capital on more favorable terms. Thus, the terms upon which we 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 we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than the exercise terms provided by such outstanding securities. The market price of our common shares has been volatile and may continue to fluctuate significantly because of various factors, some of which are beyond our control.

We are controlled by a limited number of shareholders.

Our principal shareholders, Leonard Osser and K. Tucker Andersen, own 30.97% of the issued and outstanding shares of our common stock. As a result, they have the ability to exercise substantial control over our affairs and corporate actions requiring shareholder approval, including electing directors, selling all or substantially all of our assets, merging with another entity or amending our certificate of incorporation. This de facto control could delay,

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deter or prevent a change in control and could adversely affect the price that investors might be willing to pay in the future for our securities.

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

Sales of a substantial number of shares of our common stock in the public markets, or the perception that these sales may occur, could cause the market price of our stock to decline and could materially impair our ability to raise capital through the sale of additional equity securities. We currently have outstanding options and warrants to purchase 3,225,017 shares of our common stock at prices ranging

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from \$.87 to \$13.50 per share with a weighted average exercise or conversion price of \$4.86. Holders of these warrants and options are given the opportunity to profit from a rise in the market price of our common stock and are likely to exercise their securities at a time when we would be able to obtain additional equity capital on more favorable terms. Thus, the terms upon which we 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 we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than the exercise terms provided by such outstanding securities. The market price of our common shares has been volatile and may continue to fluctuate significantly because of various factors, some of which are beyond our control. Currently, there are 9,824,287 shares of common stock actually issued and 9,790,954 outstanding. Also, there are another 4,246,292 shares of common stock reserved for future issuance as follows:

- o up to 1,440,000 shares underlying the warrants issued in the Public Offering;
- o up to 335,614 shares underlying warrants granted to satisfy obligations in connection with the 2004 public offering;
- o up to 432,000 shares underlying the representative's warrants issued in the Public Offering, including the shares underlying the warrants included in the representative's warrants;
- o up to 314,333 shares underlying stock options previously granted, or to be granted, under our 1997 Stock Option Plan
- o up to 500,000 shares underlying stock options to be granted under our 2004 Stock Option Plan;
- o up to 1,219,955 shares underlying other stock options and warrants that were granted and remained outstanding as of December 31, 2004;
- o and
- o 4,390 shares of common stock underlying our series A convertible preferred stock;

We have 9,790,954 shares of common stock outstanding, of which 5,824,287 are freely tradable. The remaining 3,966,667 shares are either held by "affiliates", as defined by the rules and regulations promulgated under the Securities Act of 1933, or are "restricted securities" as defined in Rule 144

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promulgated under the Securities Act of 1933. Of this amount, 271,303 restricted shares not held by affiliates and 3,695,364 restricted or non-restricted shares held by "affiliates," can only be sold in compliance with the timing and volume limitations of Rule 144 promulgated under the Securities Act of 1933.

The decrease of our outstanding shares as a result of the reverse stock split, without change to our authorized capitalization, increased the ability of our board of directors to issue shares without stockholder approval. Issuance of shares may dilute the value of our outstanding shares or have a negative impact on the trading price of the common stock.

The 1-for-3 stock split effected in January 2004 reduced our outstanding shares from 18,338,033 to 6,112,678 (9,663,907 shares after giving effect to the consummation of the Public Offering and related issuances of units). Since the reverse stock split was effected without change in our authorized shares, the differential between outstanding shares and authorized shares increased, thus providing the Board of Directors with increased ability to effect issuances of stock without stockholder authorization. For example, shares may be issued in capital raising transactions, mergers or acquisitions or for compensatory reasons where other governing rules or statutes do not separately require stockholder approval. The issuance of these shares for less than their book value or for less than value paid by purchasers in the recently completed offering could have a dilutive effective on purchasers in this offering. Further the issuance of the shares could also have a negative impact on the trading price of our then outstanding common stock, including the stock issued in the recently completed offering

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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 us.

We must comply with Sarbanes-Oxley requirements requiring a management report on internal control over financial reporting disclosure requirements in our annual report for our financial year ending December 31, 2006. It may be time-consuming, costly and difficult for us to develop and implement the necessary internal controls and reporting procedures, possibly requiring us to hire additional personnel. These additional costs could have an adverse effect on our profitability.

If we are unable to satisfy the American Stock Exchange maintenance requirements, our common stock may be delisted from the American Stock Exchange and, as a result, our liquidity and the value of our common stock may be impaired.

Shares of our common stock are currently listed on the American Stock Exchange. Continued listing on the American Stock Exchange requires that we maintain at least \$6,000,000 in stockholders' equity since we have sustained losses in our five most recent fiscal years. We received notice from the American Stock Exchange on January 4, 2005 indicating that we were below the Exchange's continued listing standards requiring stockholders' equity of \$6 million. On January 14, 2005 we submitted a plan to the Exchange for regaining compliance with the Exchange's stockholder equity continued listing requirement by the end of the plan period on June 30, 2005. On January 27, 2005 the Exchange determined that this plan made a reasonable demonstration of our ability to regain compliance with the continued listing standards by the end of the plan period. As a result of the acceptance of this plan, we will remain listed on the Exchange until the end of the plan period, subject to periodic review by the Exchange to determine whether we are progressing consistent with the plan.

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However, failure to make such progress could result in our being delisted earlier from the Exchange. If our securities are delisted from the Exchange, trading, if any, in our securities would be conducted in the over the counter market on the NASD's "OTC Bulletin Board". Consequently, the liquidity of our securities could be impaired, not only in the number of securities that could be bought and sold, but also through delays in the timing of transactions, reduction in security analyst and news media coverage of Milestone, and lower prices for our securities than might otherwise be obtained.

Item 2. Description of Property

Our offices are located in Livingston Corporate Park in Livingston, New Jersey. We lease approximately 4,503 square feet of office space including 1,810 square feet of additional office space acquired in April 2004. As part of this expansion, the lease term was extended through June 30, 2009 at a monthly cost of \$7,317 which we believe to be competitive. We may have to increase our office space again in the future, and we believe that we will be able to find adequate premises on comparable terms. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month to month basis.

Item 3. Legal Proceedings

Not applicable

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

Not applicable.

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PART II

Item 5. Market for Common Equity and Related Stockholder Matters

Market Information

Milestone's Common Stock is traded on the American Stock Exchange under the symbol "MS" and the Pacific Stock Exchange under the symbol "MS." As of March 18, 2004, Milestone's warrants are traded on the American Stock Exchange under the symbol "MS.WS". Milestone's units, each consisting of two shares of common stock and one warrant to purchase one share of common stock traded, under the symbol "MSE.U" for a limited 30 day period beginning on February 18, 2004 and ending on March 17, 2004 at prices ranging from \$5.50 to \$5.62.

Common Stock

The following table sets forth the high and low sales prices of our Common Stock, as quoted by the American Stock Exchange after adjustment for the 1-for-3 reverse stock split in January 2004.

| | HIGH | LOW |
|---------------------|--------|--------|
| | ---- | --- |
| 2003 | | |
| First Quarter..... | \$0.96 | \$0.45 |
| Second Quarter..... | \$1.20 | \$0.54 |
| Third Quarter..... | \$4.98 | \$0.81 |
| Fourth Quarter..... | \$7.77 | \$3.09 |
| 2004 | | |
| First Quarter | \$4.20 | \$2.38 |

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| | | |
|---------------------|--------|--------|
| Second Quarter..... | \$2.46 | \$1.75 |
| Third Quarter..... | \$2.48 | \$1.67 |
| Fourth Quarter..... | \$1.85 | \$1.55 |

Warrants

The following table sets forth the high and low sales prices of our warrants, each to purchase one share of common stock, as quoted by the American Stock Exchange, commencing on March 18, 2004, their first day of trading.

| | | |
|--|-------|-------|
| 2004 | | |
| | HIGH | LOW |
| | ---- | --- |
| First Quarter (Commencing March 18 and ending March 31)... | \$.65 | \$.55 |
| Second Quarter..... | \$.70 | \$.25 |
| Third Quarter..... | \$.60 | \$.26 |
| Fourth Quarter..... | \$.52 | \$.26 |

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Holder's

According to the records of our transfer agent, there were approximately 3,000 holders of record of our common stock as of December 31, 2004.

Dividends

The holders of our 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.

Sales of Unregistered Securities

In July 2002, we issued 62,500 units consisting of one share of common stock and one warrant to purchase an additional share of common stock to a vendor in accordance with the agreement valued at \$150,000.

In August 2002, we issued 66,667 shares of common stock in exchange for payment of \$90,000 of outstanding legal fees.

On August 13, 2002 we received a binding commitment (modifying and confirming a March 29, 2002 undertaking), requiring our legal counsel to purchase equity securities, valued at fair market value, in payment of \$200,000 of then accrued legal fees. The specific timing of this issuance is governed by a December 22, 2003 agreement. Pursuant to the agreement, we issued and delivered 30,675 Units in February 2004. The investor is an accredited investor.

In June 2003 we issued a 6% convertible note in the amount of \$50,000 and warrants to purchase 53,419 shares of our common stock at \$1.56 per share.

In September 2003 we issued a 6% convertible note in the amount of \$50,000 and warrants to purchase 5,000 shares of our common stock at \$6.00 per share.

In October 2003 we issued 1,646,419 shares of common stock in satisfaction of 6% / 12% Secured and Senior Secured Notes in the aggregate amount of approximately \$5 million. We also committed to issue 25,365 shares of 8% convertible preferred stock in satisfaction of \$25,365 of principal and accrued interest. The preferred stock will be convertible into 4,390 shares of common stock at \$5.79. Subsequently, we issued 94,327 additional shares of common stock to these former noteholders as consideration for their previous consent to

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extend the maturity date of these notes.

On October 9, 2003 we entered into a binding agreement with our CEO and a major investor under which we have sold and issued to them 246,044 units, each consisting of two shares of common stock and one warrant to purchase one share of common stock (the "Units") in payment of \$1,604,204 of debt and interest due to our CEO and a major investor, and approximately 58,896 Units in payment of \$384,000 of accrued compensation due to our CEO. The Units were issued on the date of our offering. Both investors are accredited investors.

On October 31, 2003 we issued 102,195 shares of our common stock to principal vendors, in satisfaction of trade payables in the aggregate amount of approximately \$503,000.

In April, 2004, we issued to Marina Co., a nominee of partners of Morse, Zelnick, Rose & Lander LLP, our legal counsel, options expiring April 16, 2009 for the purchase of 160,000 shares of our common stock, at an exercise price of \$3.26 per share, and warrants, expiring April 16, 2009, to purchase 80,000 shares of our common stock at \$4.89 per share, as partial consideration for services rendered in connection with our February, 2004 public offering.

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In April 2004, pursuant to an agreement to purchase media placement services, we issued 1,106 shares of common stock valued at \$2,500.

In May of 2004, we issued 1,133 options for consulting services valued at \$1,548.

On May 10, 2004, our Board of Directors granted options, expiring May 10, 2009, to purchase 40,000 shares of our common stock at an exercise price of \$2.25 per share, to our investor relations consultant as consideration for the provision of consulting services. On the same date, the Board of Directors also granted options, expiring May 10, 2009, for the purchase of an aggregate number of 59,668 shares of common stock at an exercise price of \$4.92 per share, to certain vendors in payment of services.

On August 31, 2004, we issued 36,331 shares to a vendor, LC Mold, Inc., in satisfaction of \$70,410 of payables owed in connection with the manufacturing of product molds for our Safety Wand product.

In November 2004, we satisfied the \$50,000 promissory note and accrued interest at 6% of \$4,475 by issuing 58,200 shares of common stock.

In December 2004 we issued 6,060 shares having a fair value of \$10,000 to two employees and 9,091 shares to a distributor having a fair value of \$15,000.

The foregoing securities were issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended, provided in Section 4(2) thereof, as a transaction by an issuer not involving a Public Offering. The registrant reasonably believed that each purchaser had such knowledge and experience in financial and business matters to be capable of evaluating the merits and risks of the investment, each purchaser 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 or warrants. No commissions were paid in connection with such issuances.

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ITEM 6. Management's Discussion and Analysis or Plan of Operation.

You should read the following discussions of our financial condition and results of operations in conjunction with the financial statements and the notes to those statements included elsewhere in this Form 10-KSB. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under "Risk Factors" and elsewhere in this Form 10-KSB.

OVERVIEW

We began 2004 with a six point plan to penetrate the dental and medical markets with our computer controlled injection technologies as outlined below:

- o Complete the equity raise necessary to fund the business operations.
- o Develop a domestic sales organization to market and sell our products
- o Develop new product offerings to compliment the existing product lines and generate higher revenues. Secure patent protection for all new technologies.
- o Continue to invest in our core technology platform.
- o Grow our sales volume by double digit amounts over the comparable period of the previous year.
- o Manage our spending to achieve cash flow breakeven within the second quarter 2005.

Based upon the results to date, we believe that we have achieved or are in position to achieve all of the above objectives. We have developed a highly trained domestic sales organization to penetrate 31 markets in the United States. We have thus far covered 25 markets. Accordingly we have increased our spending and incurred losses, all of which were planned in line with our projections. We believe that the return on this investment has been and will continue to be increased revenues. From the second quarter 2004, revenues have increased by double digit percentages compared to the comparable quarter in the previous year.

During 2004, we developed a new consumer tooth whitening product line and entered into a manufacturing and distribution agreement with a third party. The third party has in turn entered into a marketing agreement, which provides for the sale of the products through infomercials followed by major worldwide retailers. We expect these arrangements to generate revenues for us commencing in early 2005 on a no-risk basis, as all costs, including tooling, marketing and the infomercial expenses, will be incurred by the third parties.

During 2004, we continued development of our Professional Whitening product, which is targeted to the dental office. This product also targets a very large market and offers a lower priced, safer alternative to existing whitening products. We anticipate significant margins on the whitening gels in excess of 70% while also commanding a strong margin on the equipment used to activate the gels of over 50%. The launch of this product is expected within the second quarter of 2005.

We have also developed new advanced sophisticated technology, for which we have been granted patent protection that can be used for a number of medical

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purposes, including the delivery of epidural injections. A prototype of the epidural injection device has been successfully reviewed in two clinical studies at a major university connected hospital.

Our focus on sales and marketing initiatives are reflected in the strong revenue growth in 2004. Revenues have increased both domestically and internationally, generated from increases in all product lines

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including CompuDent units, an increasing base of handpiece sales and the sales from CoolBlue products. CompuDent unit sales increased by 25% domestically and 12.8% internationally. Worldwide handpiece sales increased by 20.7% over 2003.

The following table shows a breakdown of our revenues, domestically and internationally, by product category, and the percentage of total revenue by each product category:

| | Year Ended December 31, | | | |
|--|-------------------------|--------|-------------|--------|
| | 2004 | | 2003 | |
| | ----- | ----- | ----- | ----- |
| DOMESTIC | | | | |
| CompuDent | \$ 813,610 | 24.1% | \$ 649,156 | 23.2% |
| Handpieces | 2,334,297 | 69.1% | 1,933,052 | 69.1% |
| Other | 230,627 | 6.8% | 214,245 | 7.7% |
| | ----- | ----- | ----- | ----- |
| Total Domestic | \$3,378,534 | 100.0% | \$2,796,453 | 100.0% |
| | ----- | ----- | ----- | ----- |
| INTERNATIONAL | | | | |
| CompuDent | \$ 682,708 | 49.7% | \$ 605,378 | 51.5% |
| Handpieces | 682,968 | 49.8% | 567,302 | 48.3% |
| Other | 6,976 | 0.5% | 2,574 | 0.2% |
| | ----- | ----- | ----- | ----- |
| Total International | \$1,372,652 | 100.0% | \$1,175,254 | 100.0% |
| | ----- | ----- | ----- | ----- |
| DOMESTIC/INTERNATIONAL ANALYSIS | | | | |
| Domestic | \$3,378,534 | 71.1% | \$2,796,453 | 70.4% |
| International | 1,372,652 | 28.9% | 1,175,254 | 29.6% |
| | ----- | ----- | ----- | ----- |
| Totals | \$4,751,186 | 100.0% | \$3,971,707 | 100.0% |
| | ===== | ===== | ===== | ===== |

We have earned gross profits of 49.2% and 49.6% in the years ended December 31, 2004 and 2003, respectively. However, our revenues have not been sufficient to support our overhead, research and development expense and interest on our debt. We have therefore reported substantial losses for each of those periods. We have taken steps to cut our overhead, increase sales and reduce our interest expense.

In contrast to the cost containment measures in place through 2003, because of cash constraints, 2004 was a period of planned expansion with a focus on investing in revenue generating opportunities. The completed February 2004 public offering enabled us to execute our strategic plan of creating a domestic sales organization, expand marketing and advertising programs and invest in new product development. During 2004, our operating results reflected increased spending in the following areas:

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- o Hired and trained 3 new sales managers and 19 combined inside and outside sales representatives to penetrate the US dental market.
- o Contracted with advertising placement agencies and market research firm to maximize the effectiveness of our sales and marketing efforts.
- o Invested in research and development and patent protection on new and existing products including SafetyWand, CoolBlue and CompuFlo products.

During 2003, we took several steps to reduce our operating overhead and improve our utilization of cash. These included reconfiguring our sales force, cutting marketing expenses, closing our Illinois facility and outsourcing the receiving, shipping and storage functions previously conducted there. We also took several steps to reduce our debt burden, including cutting interest rates on some of our Notes and satisfying certain debts. We took steps intended to increase future revenues, one of which was to complete development of the SafetyWand and make it available commercially.

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Since our public offering in February 2004 we have invested heavily in the development of a national sales organization implementing the new marketing and sales plan successfully tested in 2003. This sales force is currently configured as follows:

- o Manager of Outside Sales Representatives
 - Seven outside sales representatives
- o Manager of Inside Sales
 - Seventeen inside sales representatives communicating with customers primarily by telephone, e-mail and fax
 - Four sales support representatives working in conjunction with our outside sales representatives

We anticipate eventually having 10 outside sales representatives, while we plan to increase our inside sales representatives to a total of 21. In both cases, however, we have experienced an attrition rate of approximately 35% per year.

We plan to further support our increased sales and marketing activity through an increase in trade show appearances, increased advertising to dental professionals and, perhaps, direct to consumer advertising. Since our public offering we have provided further support for our expanded activities through added investment in the following areas:

SafetyWand

- o Purchase of multi-cavity production tooling enabling the manufacture of adequate inventory levels of the SafetyWand at manageable costs. This tooling cost approximately \$291,000 and is now in use for production. Since SafetyWand can only be used with our CompuDent unit and since the Federal Needle Stick Safety Act requires the use of safety engineered sharps, we believe that SafetyWand will provide additional motivation for dentists in the United States to purchase

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CompuDent.

Tooth Whitening and Curing

- o Acquisition of inventory component parts to manufacture our CoolBlue Light System

Inventory cost of approximately \$95,000 is currently in use to manufacture our CoolBlue product for the dental market.

- o Acquisition for tooling for this product line.

The cost of tooling to ensure adequate supply of the molded plastic parts was approximately \$64,000, and is currently in use

CompuFlo

- o Development of new software for the epidural clinical studies

Required additional engineering effort to make the software suitable for clinical studies

- o Research related activities to support the software development and clinical trials

Conducted a focus group in addition to other marketing and clinical research

Current Condition of Milestone

With the progress achieved in 2004, we believe that we are now positioned to seize the market opportunities that we believe are available to us through our patent protected products. We believe that our ownership of the SafetyWand technology in the light of OSHA regulations issued pursuant to recent federal and state government legislation mandating needle stick safety standards positions us to become a leading provider for dentists and other health care professionals in the administration of local anesthesia. We have used the financial resources gained in the Public Offering to build the infrastructure necessary to market our products throughout the United States. Our goal in 2005 is to carry out the plan we initiated in 2004 and grow our revenue base of CompuDent users, thereby increasing our recurring revenue stream from the sales

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of our consumable hand piece products.

New Sales Promotion Program:

One of the persistent issues that prevents dentists from purchasing the CompuDent system is the recurring cost for handpieces. Milestone has not faced pricing pressures on the drive unit, raising prices several times from a low of \$1,000 in 1998 to the \$2,495 current retail price. However, Milestone has found that once dentists begin using CompuDent in a regular way their concern with the \$1.50 cost of each handpiece disappears. Accordingly, in December 2004, Milestone piloted a program whereby the dentist would purchase a CompuDent system at full retail price and receive a one year supply of handpieces free. This program was very successful, with 31 new customers participating in this program.

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Based on the success of this program and taking into account the lack of pricing resistance on the purchase of the drive unit, Milestone has implemented a sales program in the first quarter of 2005 designed to drive revenues from the sale of the CompuDent unit. The program particulars follow:

1. After upgrading the CompuDent system, increase its retail price in the U.S. to \$2,495 from \$2,195. This will increase the gross margin on the unit to 87%.
- 2 Offer to first-time buyers of CompuDent at the retail price a free one year supply of handpieces, including our new SafetyWand handpiece.
- 3 Additional new programs have been implemented.

The premise of this program is to increase the installed base of users, eliminate the initial cost issue associated with handpieces and nurture the customer so that they will begin purchasing handpieces when they run out.

Enhanced CompuDent

- o A software enhancement to the current CompuDent will add TurboFlo(TM) , enabling a practitioner to deliver medication using a third speed. This eliminates one of the few remaining obstacles to the sale of the product, as some practitioners are concerned that the system takes longer to deliver medication than a traditional syringe.
- o The retail price of the CompuDent has been increased to \$2,495, as the enhanced feature will add significant value to the sale.

SafetyWand

This product has been launched in January 2005 in California, Chicago and the New York metropolitan areas and will be launched in the rest of the U.S. during the second quarter. Plans for the introduction of this product include advertising in professional journals, promotional activity during trade shows, website enhancement and awareness campaigns targeted to existing users.

Professional Tooth Whitening Product

There are two basic methods used to whiten teeth in the dental office. The first method, which varies in price from \$600 to \$900, utilizes a high intensity plasma arc light to illuminate a very potent gel material on the teeth. The heat from this light accelerates the whitening process. After application of the gels, the teeth are illuminated for 20 minutes and then the gels are removed. This is repeated at least twice. This method typically takes between one and two hours. The patient is given a home kit which consists of custom molded trays which the dentist must produce requiring approximately 30 minutes of time for their teeth and enough gel material to continue the treatment for several days.

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The second method, which costs between \$300 and \$500, consists of the dentist making custom molds of the patient's teeth and providing the patient with gel material which is applied for one hour per day over a period of three to five weeks.

The CoolBlue Tooth Whitening system is a professional whitening system marketed directly to dental offices. The technique used with this system is

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differentiated from the competition in the following manner.

1. It uses blue Light Emitting Diodes (LED) to accelerate the whitening process.
2. It requires a minimum amount of time in the dental chair, as the teeth are illuminated for only ten seconds which is enough to begin the whitening process.
3. The patient goes home with our proprietary whitening rinse, which does not require custom trays, again reducing the time in the dentist's office.

This method has advantages for both the dentist and patient. For the dentist, it requires less chair time, which increases the number of patients a dentist can see. It will also cost considerably less than the methods described above, and thus has the potential to increase the dentist's margin. From the patients' perspective, less chair time and lower costs are both very attractive.

We believe that the sales initiative for this product will enable us to access an expanded number of dental offices, thereby providing an opening to sell our core product - the CompuDent system. It is our intention to make the CoolBlue Tooth Whitening system available in the second quarter of 2005.

Consumer Tooth Whitening Product

Ionic White(TM) Tooth Whitening system is a consumer product designed to whiten and brighten teeth. This product uses a proprietary formulation of whitening gels in conjunction with an intra-oral mouthpiece which contains a series of blue LEDs used to accelerate the whitening process. There are patents pending in the US and internationally on both the design and method of this product

What differentiates this product from other over the counter (OTC) consumer products can be summed up in the following points:

- o The formulation of the whitening gels uses micropore gel, which is 1/10th the size of the typical molecules used in tooth whitening products. This allows the gels to enter the dentin tubules for superior whitening.
- o The unique construction of the intra-oral mouthpiece allows the gels to migrate to the top and bottom of the teeth as well as the front and back. OTC products, including whitening strips, typically whiten only the front of the teeth. As teeth are translucent, if the back of the teeth are stained, the teeth will not look white.
- o The initial process takes only 21 minutes. There will be a noticeable difference in the brightness of the teeth after just 21 minutes, and once the customer begins using the whitening rinse on a regular basis, their teeth will continue to whiten.
- o Following any whitening procedure, teeth will continue to stain, primarily due to coffee, tea and other items that cause chromagenic stain. The Ionic White system also uses a proprietary whitening rinse, which when used with the intra-oral mouthpiece, maintains white, bright teeth.

There will be two products marketed. The first is the starter kit which will contain 3 applications of the whitening gels, the intra-oral mouthpiece as well as a 30 day supply of the whitening rinse. The second kit will include 3 applications of the whitening gels and another 30 - 60 day supply of the

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whitening rinse. The recurring revenue will come from customer who begin using the starter kit and want to maintain white, bright teeth.

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Milestone has reached an agreement with United Systems, a specialty manufacturer, to produce the Ionic White as well as to distribute the product on an exclusive, world wide basis. The agreement with United Systems calls for a minimum of one million starter kits over the first four years of the initial twenty-year contract period. United Systems in turn has entered into a distribution agreement with a major marketing company that specializes in television infomercials. This agreement calls for a minimum of two million starter kits over the four year term of the agreement. The marketing company also has access to retail slots with the major retailers in the US for products. The marketing company's goal is to begin placing the product into the retail outlets once the product has received adequate exposure via infomercials.

Ionic White was launched via television infomercials in March 2005.

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

The technology underlying our CoolBlue Professional Whitening and Ionic White Consumer Whitening Products was acquired from DaVinci Systems. We will pay a 7% royalty to Da Vinci Systems on the amounts paid to us by our joint venture partner as a result of its sale of the consumer whitening product.

We will also pay a 5% fee to Strider Inc. on the amounts paid to us by our joint venture partner as a result of its sale of the consumer whitening product. Strider assisted in bringing the CoolBlue and Ionic White product lines to Milestone.

Summary of Significant Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated 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, we evaluate our estimates, including those related to accounts receivable, inventories, stock based compensation and contingencies. We base our 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.

Inventory

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Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market.

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered.

Revenue Recognition

Revenue is recognized when title passes at the time of shipment and collectibility is reasonably assured.

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Results of Operations

The consolidated results of operations for the year ended December 31, 2004 compared to 2003 reflect our focus on the development and implementation of our strategic sales and marketing initiatives in the United States. During 2004 we recruited and trained 22 sales personnel including three new sales managers and 19 inside and outside sales representatives. Our spending on marketing also increased through more aggressive advertising and greater attendance at industry tradeshows. Increased expenses associated with this expansion are in line with management's expectations and contribute to a greater loss compared to 2003.

The following table sets forth for the periods presented, statement of operations data as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results.

| | Year Ended December 31, | | | |
|--|-------------------------|--------|--------------|--------|
| | 2004 | | 2003 | |
| Net sales | \$ 4,751,186 | 100.0% | \$ 3,971,707 | 100.0% |
| Cost of Sales | 2,415,826 | 50.8% | 2,003,139 | 50.4% |
| Gross Profit | 2,335,360 | 49.2% | 1,968,568 | 49.6% |
| Selling, general and administration expenses | 5,155,569 | 108.5% | 3,483,439 | 87.7% |
| Closing of Deerfield facility | -- | 0.0% | 86,165 | 2.2% |
| Research & development | 187,992 | 4.0% | 131,015 | 3.3% |
| Loss from operations | (3,008,201) | -63.3% | (1,732,051) | -43.6% |

Fiscal Year ended December 31, 2004 compared to year ended December 31, 2003

Net sales for the years ended December 31, 2004 and 2003 were \$4,751,186 and \$3,971,707, respectively. The \$779,479 or 19.6% increase is primarily related to a \$164,454 or 25.3% increase in domestic sales of CompuDent and CompuMed, an increase of \$77,330 or 12.8% in international CompuDent and CompuMed sales and a \$516,910 or 20.7% increase in worldwide sales of the Wand handpieces. Total domestic sales, including CompuDent, CompuMed, handpieces, and our new CoolBlue products increased 20.8%, while total international sales increased by 16.8% in 2004.

Cost of sales for the years ended December 31, 2004 and 2003 were \$2,415,826 and \$2,003,139, respectively. The \$412,687 increase is primarily

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attributable to the additional cost of goods sold for the higher revenues previously discussed.

For the year ended December 31, 2004, Milestone generated a gross profit of \$2,335,360 or 49.2% as compared to a gross profit of \$1,968,568 or 49.6% for the year ended December 31, 2003. The increase in total gross profit is related to the 19.6% increase in revenues. The slight decrease in gross profit percentage is the net result of improved margins from increased domestic sales as a percentage of total sales, offset by lower margins associated with bundled pricing offerings. Sales to foreign distributors are of higher volume but at a reduced margin.

Selling, general and administrative expenses for the years ended December 31, 2004 and 2003 were \$5,155,569 and \$3,483,439, respectively. The \$1,672,130 or 48.0% increase is primarily attributable to Milestone's continued execution of its strategy to develop our domestic sales force and distribution capacity. Sales headcount increased from 1 manager, 3 sales representatives and 10 independent contractors in 2003 to 4 sales managers, 19 inside sales representatives and 14 independent contractors. Accordingly, hiring and related employee expenses increased by \$674,000, a 46.1% increase over the prior period. Legal and professional fees increased by \$369,000 or 74.5% for legal fees relating to divisional patent protection for CompuFlo and SafetyWand products, advertising and marketing initiatives and investor relations expenses. The increases in these expenses were anticipated and in line with management's strategy of investing in revenue generating areas of the business.

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Research and development expenses for the years ended December 31, 2004 and 2003 were \$187,992 and \$131,015 respectively. These costs are associated with the development of Milestone's SafetyWand, CoolBlue and CompuFlo products.

The loss from operations for the years ended December 31, 2004 and 2003 was \$3,008,201 and \$1,732,051, respectively. The \$1,276,150 increase in loss from operations is explained above.

Interest income of \$80,867 was earned through December 31, 2004 compared with no interest income for the prior year. This difference was due to the change in cash balances related to the February equity placement.

Interest expense of \$69,530 was incurred for the year ended December 31, 2004 as compared to \$680,857 for the year ended December 31, 2003. The decrease is mainly attributable to a \$5 million debt to equity conversion on September 30, 2003 and a \$1.4 million retirement of debt in the first quarter of 2004.

The net loss for the year ended December 31, 2004 was \$2,996,864 as compared to a net loss of \$2,412,908 for the year ended December 31, 2003. The \$583,956 increase in net loss is the result of planned increases in operating expenses explained above offset by lower debt service costs.

Liquidity and Capital Resources

Public Offering. On February 17, 2004, we significantly improved our liquidity position by completing a \$9.4 million public offering (\$7.6 million after underwriter discount, underwriter non accountable expense allowance and other expenses). Overall, for the year ended December 31, 2004, we generated \$7,818,919 from financing activities. This amount consisted of \$7,868,919 of proceeds from the public offering, reduced by a \$50,000 payment of notes payable. Additional costs of \$248,815 related to the Public Offering were paid in 2003. The public offering consisted of the sale of 1,440,000 units at a price

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of \$6.52 per unit. Each unit consisted of two shares of common stock and one warrant. The warrants included in the units are exercisable at any time after they become separately tradable until their expiration date, five years after the date of the closing of the public offering at an exercise price equal to \$4.89. Some or all of the warrants may be redeemed by us at a price of \$0.01 per warrant, by giving not less than 30 days notice to the holders of the warrants, which we may do at any time, beginning 6 months from the effective date of the offering after the closing price for our common stock on the principal exchange on which it trades (i.e. AMEX) has equaled or exceeded 200% of the price of our common stock on the effective date of the offering.

Restructuring and additional financing. We also improved our liquidity position in 2004 by continuing the process, begun in 2003, of satisfying debt and paying liabilities through issuance of equity securities. We reached agreements with a major investor and our CEO and a principal vendor to satisfy approximately \$2,541,000 of promissory notes, accrued interest, trade payables and deferred compensation through the issuance of common stock and proceeds from the public offering. In February 2004, to satisfy \$640,000 of deferred compensation to the Company's CEO, approximately \$1,700,000 in promissory notes and \$200,000 of accounts payable, we issued 335,614 units at a price of \$6.52 per unit and paid approximately \$353,000 from the net proceeds received from the Public Offering. In April of 2004 we issued 1,106 shares of our common stock having a fair value of \$2,500 to principal vendors in payment of trade payables. In August of 2004 we issued 36,331 shares of our common stock having a fair value of \$70,411 to a principal vendor as partial payment for equipment. In May 2004 we paid out \$52,033 in connection with the satisfaction of a 6% short term note payable of \$50,000 plus accrued interest. In November 2004 we issued 58,200 shares of our common stock in satisfaction of a 6% short term note payable of \$50,000 plus accrued interest. Lastly, in December 2004 we issued 15,151 shares of common stock having a fair value of \$25,000 to two key employees and a principal vendor in recognition of contributions made during 2004.

Use of proceeds of public offering; sales expansion efforts. The completed February 2004 public offering enabled us to execute our strategic plan of creating a domestic sales organization, expand marketing and advertising programs and invest in new product development. Some of the net proceeds of the offering

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were used to pay down promissory notes, the credit facilities, interest and deferred compensation as discussed above. The remainder of the proceeds are being used primarily to expand and support our domestic sales and marketing efforts for CompuDent and professional CoolBlue products, including a market focused sales organization penetrating the top 31 dental markets in the United States, new marketing and advertising campaigns, support the launch of the recently announced SafetyWand product line, expand international sales efforts and develop commercial models of products using other new subcutaneous injection technologies.

The costs incurred in connection with execution of our sales expansion plan had near term negative effects on our liquidity. In contrast to the cost containment measures implemented in 2003, in 2004 our operating results reflect increased spending in the following areas:

- o Hired and trained 3 new sales managers and 19 combined inside and outside sales representatives to penetrate US dental market.
- o Contracted with advertising placement agencies and market

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research firm to maximize the effectiveness of our sales and marketing efforts.

- o Invested in research and development and patent protection on new and existing products including SafetyWand, CoolBlue and CompuFlo products.

Operating overhead and cash flow results for 2004. As shown in the accompanying consolidated financial statements, we incurred a net loss of approximately \$2,997,000 and a negative cash flow from operating activities of approximately \$4,285,000 during the year ended December 31, 2004, both representing increases against 2003. Facilitated by the increased liquidity resulting from the proceeds of our February 2004 public offering, our selling, general and administrative expense for 2004 of \$5,155,569 represents an increase in spending of \$1,672,130 or 48%. As a percentage of revenue, selling, general and administrative expense grew from 88% in 2003 to 1.09% in 2004. As of December 31, 2004, we had cash and cash equivalents of \$3,041,306. For the year ended December 31, 2004, our net cash used in operating activities was \$4,284,869. This was attributable primarily to a net loss of \$2,996,864 adjusted for noncash items of \$135,264 and a change in operating assets and liabilities amounting to \$1,423,269.

For the year ended December 31, 2004, we used \$496,021 in investing activities. These expenditures included a \$350,529 purchase of fixed assets, a \$75,536 payment to Spintech's shareholders, a subsidiary company of Milestone, to acquire Spintech's patent rights, and a \$69,956 payment for the investment in a German based distributor.

Need for additional capital. Although at December 31, 2004 our total stockholders' equity was \$4,520,707, we need a net worth of \$6,000,000 at June 30, 2005 to remain in compliance with continued listing requirements of the American Stock Exchange. Accordingly, during 2005, we intend to seek new sources of equity funding. However, we can give no assurance that we will be able to find new sources of funding on acceptable terms. The issuance of additional equity securities may impair the value of our stock. Further, if we fail to satisfy the American Stock Exchange's listing requirements with respect to stockholder equity, we could be delisted from the Exchange after June 30, 2005 or earlier if we fail to make progress consistent with the plan of recovery that we submitted to the Exchange. Any delisting would, in turn, make it more difficult for us to raise capital in the public markets.

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 46, Consolidation of Variable Interest Entities—an Interpretation of ARB No. 51 ("FIN 46"), which addresses consolidation of variable interest entities. FIN 46 expands the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, special purpose entities, or SPEs) to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. On October 9, 2003, the FASB issued Staff Position No. 46-6 which deferred the effective date for applying the provisions of FIN 46 for interests held by public entities in variable interest entities or potential variable interest entities created before February 1, 2003. On December 24, 2003, the FASB issued

a revision to FIN 46. Under the revised interpretation, the effective date was

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delayed to periods ending after March 15, 2004 for all variable interest entities, other than SPEs. The adoption of FIN 46 did not have an impact on our financial condition, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Shared-Based Payment ("FAS 123R"), which replace FAS 123 and supercedes APB No. 25. FAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under FAS 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt FAS 123R beginning July 1, 2005. Under FAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. The Company is currently assessing the impact that FAS 123R will have on our results of operations.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4 ("FAS 151"). FAS 151 amends Accounting Research Bulletin no. 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage) should be recognized as current-period charges. In addition, FAS No 151 requires that allocation of fixed production overhead to inventory be based on the normal capacity of the production facilities. FAS 151 is effective for periods beginning January 1, 2006 and is not expected to have a significant impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, Exchange of Nonmonetary Assets, an amendment of APB No. 29, Accounting for Nonmonetary Transactions ("FAS 153"). FAS 153 amends APB No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. Adoption of FAS 153 is required on a prospective basis, for nonmonetary exchanges beginning after June 15, 2005. We do not expect this standard to have any impact on the Company's results of operations or financial position.

Item 7. Consolidated Financial Statements

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

Item 8. Change in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 8A. Controls and Procedures

A) Evaluation of Disclosure Controls and Procedures. Milestone's management, with the participation of the chief executive officer and the chief financial officer, carried out an evaluation of the effectiveness of Milestone's "disclosure controls and procedures" (as defined in the Securities Exchange Act, Rule 13a-14a. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that Milestone's disclosure controls and procedures were effective, as of the date of their evaluation, for purposes of recording, processing, summarizing and timely reporting

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material information required to be disclosed in reports filed by Milestone under the Securities Exchange Act of 1934. There were no changes in our internal control over financial reporting that occurred during Milestone's most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, Milestone's internal control over fiscal reporting.

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PART III

Item 9. Directors and Executive Officers of the Registrant

The current executive officers, directors and key personnel of Milestone and their respective ages as of March 30, 2005 are as follows:

| NAME | AGE | POSITION | DIRECTOR |
|--------------------------------|-----|--|----------|
| Leonard A. Osser..... | 57 | Chairman and Chief Executive Officer | 19 |
| Stuart J. Wildhorn..... | 47 | President | |
| Kevin T. Lusardi..... | 48 | Vice President and Chief Financial Officer | |
| Mark Hochman, D.D.S..... | 47 | Director of Clinical Affairs | |
| Eugene Casagrande, D.D.S..... | 61 | Director of Professional Relations | |
| Paul Gregory(2)..... | 70 | Director | 19 |
| Leonard M. Schiller(1)(2)..... | 63 | Director | 19 |
| Jeffrey Fuller(1) | 59 | Director | 20 |
| Leslie Bernhard(1)..... | 60 | Director | 20 |

 (1) Member of the Audit Committee

(2) Member of the Compensation Committee

Leonard A. Osser has been our Chairman and Chief Executive Officer since July 1991. From 1980 until the consummation of Milestone's Public Offering in November 1995, he was engaged primarily as the principal owner and Chief Executive of U.S. Asian Consulting Group, Inc., a New Jersey based provider of consulting services in "work-out" and "turnaround" situations for publicly and privately owned companies in financial difficulty.

Stuart J. Wildhorn has been our President since September 2003 and prior to that he had been our Senior Vice President since April 2001. From 1990 until April 2001, Mr. Wildhorn held progressive senior management positions with Datex-Ohmeda, a leading manufacturer of anesthesia and patient monitoring products.

Kevin T. Lusardi has been our Vice President and Chief Financial Officer since June 2004. Mr. Lusardi is a CPA and holds a BA degree in Business Administration from Muhlenberg College. From 1986 until May 2004, Mr. Lusardi worked in the telecommunications industry spending 14 years with Verizon Wireless where he held progressive senior financial management positions and two years with Everest Broadband Networks as the Corporate Controller.

Dr. Mark Hochman has been a clinical consultant to Milestone since 1997 and has served as the 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

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University College 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. Dr. Hochman is a recognized world authority on advanced drug delivery systems, has published numerous articles in this area and is personally responsible for inventing much of the technology currently available from Milestone.

Dr. Eugene Casagrande has been the Director of Professional Relations for Milestone since September 1998. In his capacity, Dr. Casagrande represents Milestone in a variety of clinical and industry related opportunities. Dr. Casagrande is the President and founder of Casagrande Consulting Services, an entity devoted to quality management to the dental industry.

Paul Gregory has been a director of Milestone since April 1997. Mr. Gregory has been a business

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and insurance consultant at Innovative Programs Associates Inc. and Paul Gregory Associates Inc. since January 1995 and January 1986, respectively, where he services, among other entities, foreign and domestic insurance groups, law and accounting firms and international corporations.

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.

All directors hold office until the next annual meeting of stockholders and until their successors are duly elected and qualified. Officers are elected to serve, subject to the discretion of the Board of Directors, until their successors are appointed.

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 majority of which is made up of 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 401 (e) of regulations S-B. Mr. Fuller is independent, as that term is used in Item 7 (d)

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(3) (iv) of schedule 14A under the Exchange Act.

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 2004.

Code of Ethics

Milestone has adopted a code of ethics that applies to Milestone's principal executive officer, principal financial officer and other persons performing similar functions. This code of ethics is posted on Milestone's web site at www.milesci.com.

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Item 10. Executive Compensation.

The following Summary Compensation Table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2004, 2003, and 2002 by (i) Milestone's Chief Executive Officer and (ii) the most highly compensated executive officers, other than the CEO, who were serving as executive officers at the end of the 2004 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 Executives") and may be provided to any person, without charge, upon a written request, made to Milestone's Chief Financial Officer.

SUMMARY OF COMPENSATION TABLE

| NAME AND PRINCIPAL POSITION | YEAR | ANNUAL COMPENSATION SALARY \$ | COMMON STOCK AWARD # | COMMON STOCK UNDERLYING OPTIONS # |
|---|------|--|-------------------------------|--|
| Leonard A. Osser | 2004 | 300,000 (1) | | |
| Chief Executive Officer | 2003 | 351,770 (2) | | 16,667 |
| and Chairman | 2002 | 351,800 (3) | | 16,667 |
| Stuart J. Wildhorn | 2004 | 180,740 | 3,030 (4) | |
| President | 2003 | 163,207 | | |
| | 2002 | 155,400 | | 2,333 |
| Kevin T. Lusardi | 2004 | 81,599 | | 30,000 |
| Chief Financial Officer and Vice President | | | | |
| Thomas A. Stuckey | 2004 | 145,385 | | |
| Chief Financial Officer and | 2003 | 144,835 | | |

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Vice President (6) 2002 136,267(5) 2,333

(1) Includes \$150,000 in deferred compensation in accordance with his employment agreement to be paid in common stock and not paid until the termination of the agreement in 2010. Excludes \$25,773 paid by Milestone to Marilyn Elson, a certified public accountant, in payment of tax services. Ms. Elson is the wife of Mr. Osser.

(2) Includes \$320,000 in deferred compensation but excludes \$51,928 paid by Milestone to Marilyn Elson, a certified public accountant, in payment of tax services and assistance with preparation of the recently completed registration statement.

(3) Includes \$320,000 in deferred compensation but excludes \$19,049 paid by Milestone to Marilyn Elson, Mr. Osser's wife, in payment of professional tax services.

(4) On December 16, 2004, the Board of Directors approved a grant of 3,030 shares of restricted stock to Mr. Wildhorn. The dollar value of the grant reflected in the Summary Compensation Table is calculated by multiplying the shares by \$1.65, the closing price of Milestone stock on the date of grant. Dividends are not paid on restricted stock. The value of these shares was \$5,393 on December 31, 2004 based on a closing price of \$1.78.

(5) Includes a \$20,000 bonus paid in 2002.

(6) Mr. Stuckey was CFO until his resignation on June 9, 2004. Mr. Stuckey was paid a severance package through December 31, 2004

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STOCK OPTIONS

The following tables show certain information with respect to incentive and non-qualified stock options granted in 2004 to Named Executives under Milestone's 1997 Stock Option Plan and the aggregate value at December 31, 2004 of such options. In general, the per share exercise price of all options is equal to the fair market value of a share of Common Stock on the date of grant.

Option Grants In 2004 Individual Grants Of Options

| NAME | NUMBER OF SHARES OF COMMON STOCK UNDERLYING OPTIONS | PERCENT OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN 2004 | EXERCISE PRICE (\$/SH) | EXPIRATION DATE |
|-------------------------|--|--|---------------------------|-----------------|
| ---- | ----- | ----- | ----- | ----- |
| Stuart J. Wildhorn..... | 16,667(1) | 20% | \$4.92 | 05-09-09 |
| Kevin T. Lusardi..... | 30,000(1) | 37% | \$2.00 | 12-21-09 |

(1) Options vest ratably one third on each anniversary date of the grant date

Aggregated 2004 Year End Options Values
For Options Granted Prior To And During 2004

Number of Shares of

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| Common Stock Underlying Unexercised Options At 12-31-2004 | Value of Unexercised In-The-Money Options At 12 |
|--|---|
| | |