

MILESTONE SCIENTIFIC INC.

Form S-3/A

April 26, 2016

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As filed with the Securities and Exchange Commission on April 26, 2016

Registration No. 333-209466

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

AMENDMENT NO. 1 TO  
FORM S-3  
REGISTRATION STATEMENT  
*UNDER*  
*THE SECURITIES ACT OF 1933*

MILESTONE SCIENTIFIC INC.

(Exact name of Registrant as specified in its charter)

Delaware

3842

13-3545623

**(State or Other Jurisdiction of  
Incorporation or Organization)**

**(Primary Standard Industrial  
Classification Code Number)  
220 South Orange Avenue**

**(I.R.S. Employer  
Identification No.)**

**Livingston, New Jersey 07039**

**(973) 535-2717**

**(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)**

**Leonard Osser**

**Chief Executive Officer**

**220 South Orange Avenue**

**Livingston, New Jersey 07039**

**(973) 535-2717**

**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

*Please send copies of all communications to:*

**Stephen Zelnick, Esq.**

**Morse, Zelnick, Rose & Lander, LLP**

**825 Third Avenue**

**New York, New York 10022**

**(212) 838-8040**

**(212) 208-6809 Facsimile**

**Approximate date of commencement of proposed sale to the public:**

From time to time after the effective date of this Registration Statement as determined by market conditions.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer  Accelerated filer   
 Non-accelerated filer  (do not check if a smaller reporting company) Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered(1) Debt Securities	Amount to be registered(1)(2)(3)	Proposed	Proposed	Amount of registration fee
		maximum offering price per unit(2)(3)	maximum aggregate offering price(3)	

Preferred Stock		
Common Stock		
Warrants		
Units		
Total	\$30,000,000(4)	\$3,021(4)(5)*

\* Registration fee previously paid

- (1) This Registration Statement also covers (i) debt securities, preferred stock, common stock and units that may be issued upon exercise of warrants and (ii) such indeterminate amount of securities as may be issued upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including under any applicable anti-dilution provisions. In addition, securities registered hereunder may be sold separately or as units with other securities registered hereunder.
- (2) An indeterminate number of the securities is being registered as may at various times be issued at indeterminate prices, with an aggregate public offering price not to exceed \$30,000,000 or the equivalent thereof in one or more currencies or, if any debt securities are issued at any original issuance discount, such greater principal amount as shall result in an aggregate initial offering price of \$30,000,000.
- (3) Not specified as to each class of securities to be registered pursuant to General Instruction II.D of Form S-3 under the Securities Act.
- (4) The Registrant registering on this Registration Statement securities with an aggregate offering price of \$30,000,000 (the New Securities ), which aggregate offering price is not specified as to each class of security (see footnote (3)).
- (5) Calculated pursuant to Rule 457(o) of the rules and regulations under the Securities Act for the \$30,000,000 of New Securities being registered hereunder.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.**

**SUBJECT TO COMPLETION, DATED APRIL 26, 2016**

**\$30,000,000**

**MILESTONE SCIENTIFIC INC.**

**Common Stock**

**Preferred Stock**

**Debt Securities**

**Warrants**

**Units**

This prospectus relates to common stock, preferred stock, debt securities, warrants and units that we may sell from time to time in one or more offerings up to a total public offering price of \$30,000,000 on terms to be determined at the time of sale. We will provide specific terms of these securities in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest. This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for those securities.

Our common stock is listed on the NYSE MKTS under the symbol `MLSS`. As of April 25, 2016, the aggregate market value of our outstanding common stock held by non-affiliates was \$23,954,939 based on 21,687,164 shares of outstanding common stock, of which 12,037,658 shares are held by non-affiliates, and a per share price of \$1.99 which was the closing sale price of our common stock as quoted on the NYSE MKTS on March 22, 2016. We have not sold any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters or through a combination of these methods. See `Plan of Distribution` in this prospectus. We may also describe the plan of distribution for any particular offering of these securities in any applicable prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

**Investing in our securities involves certain risks. See Risk Factors beginning on page 4 of this prospectus and in any prospectus supplement before you make your investment decision.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**The date of this prospectus is \_\_\_\_\_, 2016.**

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**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You can inspect and copy these reports, proxy statement and other information at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D. C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The SEC also maintains a web site that contains reports, proxy and information statements and other information regarding issuers, such as Milestone Scientific Inc. ([www.sec.gov](http://www.sec.gov)). Our web site is located at [www.milestonescientific.com](http://www.milestonescientific.com). The information contained on our web site is not part of this prospectus.

This prospectus incorporates by reference certain information that we have filed with the SEC under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This means we are disclosing important information to you by referring you to those documents. We incorporate by reference the documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until the offering is terminated:

Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed on April 6, 2016 ( "2015 Annual Report" );

Current Report on Form 8-K, filed on April 26, 2016; and

The description of Milestone's Common Stock contained in its Registration Statement on Form S-2, filed on November 10, 2003, including any further amendment or report filed hereafter for the purpose of updating such description.

You should rely only on the information incorporated by reference or provided in this prospectus. We have authorized no one to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of this document. All documents that we file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus or after the date of the registration statement of which this prospectus forms a part and prior to the termination of the offering will be deemed to be incorporated in this prospectus by reference and will be a part of this prospectus from the date of the filing of the document. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes that statement. Any statement that is modified or superseded will not constitute a part of this prospectus, except as modified or superseded.

We will provide, upon written or oral request, without charge to you, including any beneficial owner to whom this prospectus is delivered, a copy of any or all of the documents incorporated herein by reference other than the exhibits to those documents, unless the exhibits are specifically incorporated by reference into the information that this prospectus incorporates. You should direct a request for copies to us at Attention: Chief Executive Officer, Leonard Osser, Milestone Scientific Inc., 220 South Orange Avenue, Livingston New Jersey 07039 or you may call us at (973) 535-2717.



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**FORWARD-LOOKING STATEMENTS**

Certain information set forth in this prospectus or incorporated by reference in this prospectus may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ), that are intended to be covered by the safe harbor created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as believe, expect, may, will, should, would, could, seek, intend, plan, anticipate, project or other comparable terms. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties included in this prospectus under the caption Risk Factors, and those risks and uncertainties described in the documents incorporated by reference into this prospectus. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements. We further caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein or in the accompanying prospectus (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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**PROSPECTUS SUMMARY**

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC utilizing a shelf registration process. Under this shelf process, we may from time to time, sell any combination of securities described in this prospectus in one or more offerings. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of the securities being offered and risk factors specific to that offering.

We may add or modify in a prospectus supplement any of the information contained in this prospectus or in the documents that we have incorporated into this prospectus by reference. If there is any inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in that prospectus supplement. You should read both this prospectus and any applicable prospectus supplement together with additional information described above under the heading **Where You Can Find More Information**.

When acquiring any securities discussed in this prospectus, you should rely on the information provided in this prospectus and the prospectus supplement, including the information incorporated by reference. Neither we, nor any underwriters or agents, have authorized anyone to provide you with different information. We are not offering the securities in any state where such an offer is prohibited. You should not assume that the information in this prospectus, any prospectus supplement, or any document incorporated by reference, is truthful or complete at any date other than the date mentioned on the cover page of those documents. You should also carefully review the section entitled **Risk Factors**, which highlights certain risks associated with an investment in our securities, to determine whether an investment in our securities is appropriate for you.

All references in this prospectus to Milestone, us, , our, we or Milestone Scientific refer to Milestone Scientific Inc. and its wholly owned subsidiary, Wand Dental Inc., a Delaware corporation, unless the context otherwise indicates. Milestone has rights to the following trademarks: *CompuDent*<sup>®</sup>, *CompuMed*<sup>®</sup>, *CompuFlo*<sup>®</sup>, *The Wand*<sup>®</sup>, *The Wand Plus*<sup>®</sup>, *The SafetyWand*<sup>®</sup>, *Dynamic Pressure Sensing Technology*<sup>®</sup>, and *STA Single Tooth Anesthesia*, (STA Instrument, instruments and handpieces).

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**RISK FACTORS**

*Investing in our securities involves a high degree of risk. You should carefully consider risk factors described in our Annual Report on Form 10-K for our fiscal year ended December 31, 2015 (together with any material changes thereto contained in subsequently filed Quarterly Reports on Form 10-Q) and those contained in our other filings with the SEC, which are incorporated by reference in this prospectus and any accompanying prospectus supplement and all other information contained in this prospectus and in any supplementary prospectus relating to the offering of any of our securities before purchasing any of our securities. Some statements in this prospectus, constitute forward-looking statements. Please refer to the section entitled Forward-Looking Statements.*

*The prospectus supplement applicable to each type or series of securities we offer may contain a discussion of risks applicable to the particular types of securities that we are offering under that prospectus supplement. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the caption Risk Factors in the applicable prospectus supplement, together with all of the other information contained in the prospectus supplement or appearing or incorporated by reference in this prospectus. These risks could materially affect our business, results of operations or financial condition and cause the value of our securities to decline. You could lose all or part of your investment.*

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**THE COMPANY**

**Business overview**

We are a medical research and development company that designs and patents innovative injection technology. Our computer-controlled injection systems make injections precise, efficient, and virtually painless.

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

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

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

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

In 2007, Milestone received U.S. Food and Drug Administration (FDA) pre-market clearance for marketing and sale of the *STA* instruments (dental instrument) under section 510(k). Milestone introduced the instrument to the market in February 2007 and this instrument is currently being marketed throughout the world.

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

The *CompuFlo* technology consists of two critical elements. One element is the ability to determine exit pressure *In Situ* (in the injection site tissue) at the tip of the needle in real time. This minimizes tissue damage (and eliminates the pain of the injection) because the flow rate and pressure of the injection are controlled. The other critical element of the technology is an integrated injection database of algorithms that have been defined which allow for the measurement of the exit pressure. This database of algorithms contains the critical

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components of specific drugs, parameters of needles, tubing and syringes and all other pertinent components for the safe and efficacious delivery of medications for all procedures.

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

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

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

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

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

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

Initial market response to the *STA Instrument* following its commercial debut in February 2007 proved to be less than robust. Moreover, at that time, Milestone had granted exclusive U.S. and Canadian distribution and marketing rights

for the *STA Instrument* to Henry Schein, Inc., the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets. Following several months of lackluster sales and after making critical senior management changes, Milestone initiated an in-depth

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market study to reassess its positioning and marketing strategies for the *STA Instrument*. The insight gained from this study led management to redefine and implement a new messaging platform, created to emphasize key benefits that Milestone discovered are of most value to dental professionals. This new product messaging was launched in January 2008 and has remained in constant review.

In the spring of 2009, Milestone signed an Exclusive Distribution and Marketing Agreement with China National Medicines Corporation, dba Sinopharm, which is China's largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and the country's largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone a blanket purchase order for 12,000 *STA instruments* and related handpieces to be delivered over 36 months, thereby marking Milestone's initial penetration into China's emerging dental market. The agreement was terminated in September 2014 and a new distributor, Milestone China Ltd., a Hong Kong corporation, owned forty (40) percent by Milestone, became the distributor for the *STA Instruments* and handpieces in China.

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

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

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

In November 2012, Milestone signed an exclusive distributor and marketing agreement with a well-known US domestic manufacturer and distributor, for the sale and distribution of the *STA instrument* and handpieces in the United States and Canada. The marketing initiative will include participation in U.S. and Canadian dental shows, as well as pediatric dental shows; an active advertising initiative targeting major dental publications; and direct mailing campaigns to over 150,000 dentists across the U.S. and Canada. This agreement was amended in December 2015 to a non-exclusive distributor arrangement, which is scheduled to terminate in March 2016.

On January 1, 2016, Henry Schein accepted an arrangement to become a non-exclusive distributor for the *STA Instruments* and handpieces in the USA and Canada. In addition, in August 2013, Milestone appointed Henry Schein as its exclusive distributor in the USA and Canada for the *CompuDent* handpieces.

### ***CompuFlo*® Advanced Injection Technology Core Technology**

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

parts of the world who are using the *STA Instrument* in their practices.

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

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

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

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

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

There are a number of injectable drugs routinely self-administered in a home or office setting using spring loaded automatic injection devices by people who suffer from long term chronic conditions such as Multiple Sclerosis diseases of the auto immune system and Rheumatoid Arthritis. The *CompuFlo* technology, using pressure sensing capabilities, can serve as a painless subcutaneous injection method for these self-administered drugs. A significant reduction in pain during delivery should have a positive impact on compliance, which is a major consideration when physicians are treating patients.

## **Product Platform**

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

### ***STA Single Tooth Anesthesia Instrument (Wand STA Instrument)***

The *STA Single Tooth Anesthesia Instrument (STA Instrument)* is a patented, computer-controlled local anesthesia delivery instrument that incorporates the pressure feedback elements of Milestone's patented *CompuFlo* technology, thereby allowing dentists to administer injections accurately into the periodontal ligament space, effectively

anesthetizing a single tooth. While the periodontal ligament injection has been available for some time, there has been no effective technology that allows dentists to easily perform the procedure painlessly, safely and predictably until now. With this unique procedure dentists can easily and predictably anesthetize a single tooth root in one minute as the primary and sole injection, as compared to a general blocking injection and

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

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

***CompuDent*<sup>®</sup>**

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

*CompuDent* minimizes the pain associated with palatal, mandibular block and all other injections, resulting in a more comfortable injection experience for the patient;

the pencil grip used with *The Wand* handpieces allows unprecedented tactile sense and accurate control;

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

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

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

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

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

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used today by thousands of dentists around the world, many of whom have long since abandoned the over 150-year old syringe.

### ***CompuMed***<sup>®</sup>

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

### ***The Wand***<sup>®</sup>

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

## **Competition**

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

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

Milestone faces intense competition from many companies in the medical and dental device industry, possessing substantially greater financial, marketing, personnel, and other resources. Most competitors have established reputations, stemming from their success in the development, sale, and service of competing dental products. Further, rapid technological change and research may affect the products. Current or new competitors could, at any time, introduce new or enhanced products with features that render the products less marketable or even obsolete. Therefore, Milestone must devote substantial efforts and financial resources to improve existing products, bring products to market quickly, and develop new products for related markets. In addition, the ability to compete

successfully requires that Milestone establish an effective distribution network with a strong marketing plan. Historically, Milestone has been unsuccessful in executing the marketing plans for the products, primarily due to resource constraints. New products must be approved by regulatory authorities before they may

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be marketed. Milestone cannot assure you that it can compete successfully; that competitors will not develop technologies or products that render the products less marketable or obsolete; or, that Milestone will succeed in improving the existing products, effectively develop new products, or obtain required regulatory approval for those products.

**Patents and Intellectual Property**

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

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

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

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

**Government Regulation**

The FDA cleared the *CompuDent* instrument and its disposable handpieces for marketing in the U.S. for dental applications in July 1996; the *CompuMed* instrument for marketing in the U.S. for medical applications in May 2001; and, the *Safety Wand* for marketing in the U.S. for dental applications in September 2003. For us to

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commercialize the other products in the U.S., Milestone will have to submit additional 510(k) applications with the FDA. Milestone received FDA 510 (k) approval for the *STA Instrument* in August 2006.

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

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

Though the *STA Instrument*, *CompuDent*, the *Safety Wand* and *CompuMed* have received FDA marketing clearance, there can be no assurance that any of the other products under development will obtain the required regulatory clearance in a timely manner, or at all. If regulatory clearance of a product is granted, such clearance may entail limitations on the indicated uses for which the product may be marketed. In addition, modifications may be made to

the products to incorporate and enhance their functionality and performance based upon new data and design review. There can be no assurance that the FDA will not request additional information relating

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to product improvements; that any such improvements would not require further regulatory review, thereby delaying the testing, approval and commercialization of product improvements; or, that ultimately any such improvements will receive FDA clearance.

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

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

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

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

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

## **Product Liability**

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

## **Corporate Information**

We were organized in August 1989 under the laws of the State of Delaware. Our principal executive office is located at 220 South Orange Avenue, Livingston, New Jersey 07039, telephone number (973) 535-2717. Our web address is [www.milestonescientific.com](http://www.milestonescientific.com). None of the information on our website is part of this prospectus.

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**USE OF PROCEEDS**

We currently intend to use the estimated net proceeds from the sale of these securities for general corporate and working capital purposes, including the funding of strategic initiatives that we may undertake from time to time. We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities. Our plans to use the estimated net proceeds from the sale of these securities may change, and if they do, we will update this information in a prospectus supplement.

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**DESCRIPTION OF COMMON STOCK WE MAY OFFER**

*The following description of our common stock is only a summary. This description and the description contained in any prospectus supplement is subject to, and qualified in its entirety by reference to, our restated certificate of incorporation and bylaws, each as amended, each of which has previously been filed with the SEC and the Delaware General Corporation Law ( DCGL ).*

**Common Stock**

Our authorized capital stock includes 50,000,000 shares of common stock, par value \$0.001 per share. As of the date of this prospectus, there are 21,720,497 shares of common stock issued, of which 21,687,164 were outstanding and 33,333 shares were held in the treasury.

Subject to preferences that may apply to preferred shares outstanding at the time, the holders of outstanding common stock are entitled to receive dividends out of assets legally available therefor at such times and in such amounts as the board of directors may from time to time determine. Each stockholder is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Directors are elected by plurality vote. Therefore, the holders of a majority of the common stock voted can elect all of the directors then standing for election. The common stock is not entitled to preemptive rights and are not subject to conversion. If we are liquidated or dissolved or our business is otherwise wound up, the holders of common stock would be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities and the payment of the liquidation preference of any outstanding preferred shares. Each outstanding share of common stock is, and all shares of common stock to be outstanding upon completion of any offering under the registration statement of which this prospectus forms a part, will be, fully paid and nonassessable.

**Authorized but Unissued Common Stock**

The DCGL does not require stockholder approval for any issuance of authorized shares, except in certain limited circumstances. However, the listing requirements of the NYSE MKTS, which would apply for so long as our common stock are listed on the NYSE MKTS, require stockholder approval of certain issuances (other than a public offering) equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock, as well as for certain issuances of stock in compensatory transactions. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions. One of the effects of the existence of unissued and unreserved shares of common stock may be to enable our board of directors to sell shares to persons friendly to current management, for such consideration, in form and amount, as is acceptable to the board, which issuance could render more difficult or discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive stockholders of opportunities to sell their common stock at prices higher than prevailing market prices.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

