

MILESTONE SCIENTIFIC INC.  
Form 424B5  
December 15, 2016  
**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-209466**

The information in this preliminary prospectus supplement is not complete and may be changed. The preliminary prospectus supplement is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS  
SUPPLEMENT  
(To the Prospectus dated May 4, 2016)**

**SUBJECT TO  
COMPLETION**

**DATED DECEMBER 15,  
2016**

MILESTONE SCIENTIFIC INC.

\_\_\_\_\_ Shares of Common Stock

Warrants to Purchase \_\_\_\_\_ Shares of Common Stock

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We are offering \_\_\_\_\_ shares of our common stock, par value \$0.001 per share (“common stock”) and warrants to purchase \_\_\_\_\_ shares of our common stock (and the shares of common stock issuable from time to time upon exercise of the warrants) pursuant to this prospectus supplement and the accompanying base prospectus. The common stock and warrants will be sold in combination with a warrant to purchase \_\_\_ shares of common stock accompanying each share of common stock sold. The combined purchase price for each common share and accompanying warrant is \$\_\_\_\_\_. The warrants may only be exercised to purchase whole shares of common stock at an exercise price of \$\_\_\_ per share and will expire on December \_\_\_, 2019. The common stock and the warrants are immediately separable and will be issued separately, but must be purchased together in this offering.

Our common stock is listed on the NYSE MKT under the symbol “MLSS.” The last reported sale price of our shares of common stock on December 14, 2016 was \$1.80 per share. There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to list the warrants on the NYSE MKT, any other national securities exchange or any other nationally recognized trading system.

One-third of the aggregate market value of the shares of our outstanding common stock held by non-affiliates, computed by reference to the highest price at which a share was last sold within the 60-day period ending on the date hereof, was \$11,671,439 based on 17,080,155 shares of our outstanding common stock held by non-affiliates. We have sold common stock having an aggregate value of \$250,080 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.

Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus and all information incorporated by reference therein. These documents contain information you should consider when making your investment decision.

*Investing in these securities involves significant risks. Please read “Risk Factors” on page S-8 of this prospectus supplement, on page 3 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement.*

*Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.*

	<b>Per Share</b>	
	<b>And</b>	<b>Total</b>
	<b>Accompanying</b>	
	<b>Warrant</b>	
Offering price	\$	\$
Underwriting discount and commissions (1)	\$	\$
Proceeds, before expenses, to us (1)	\$	\$
	There will be additional items of value paid in connection with this offering that are viewed by the Financial Industry Regulatory Authority, Inc. as	

underwriting compensation.  
See “Underwriting” beginning  
on page S-19 of this  
prospectus supplement for a  
description of the  
compensation payable to the  
underwriters.

We have granted the representative of the underwriters a 45-day option to purchase up to \_\_\_\_\_ additional shares of common stock and/or warrants to purchase up to \_\_\_\_\_ shares of common stock to cover over-allotments, if any.

We expect to deliver the common stock and warrants being offered pursuant to this prospectus supplement on or about December \_\_, 2016.

***Sole Book Running Manager***

**Maxim Group LLC**

December \_\_, 2016

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## ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the “SEC,” using a “shelf” registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the “prospectus,” we are referring to both parts combined.

All references in this prospectus supplement 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>, *SafetyWand*<sup>®</sup>, *DPS Dynamic Pressure Sensing Technology*<sup>®</sup>, and *STA Single Tooth Anesthesia System*<sup>®</sup> *Instrument* (STA Instrument, instruments and handpieces). References to our “common stock” refer to the common stock of Milestone Scientific Inc.

This prospectus supplement, and the information incorporated herein by reference, may add, update or change information in the accompanying prospectus and any free writing prospectuses. You should read both this prospectus supplement, the accompanying prospectus and any free writing prospectuses together with additional information described under the heading Where You Can Find More Information. If there is any inconsistency between the information in this prospectus supplement and the accompanying prospectus, you should rely on the information in this prospectus supplement.

You should rely only on the information contained in or incorporated by reference to this prospectus supplement, the accompanying prospectus and any free writing prospectuses. We have not authorized any other person to provide information different from that contained in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and therein and any free writing prospectuses. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information appearing in the prospectus and this prospectus supplement is accurate as of the dates on their respective covers, regardless of time of delivery of the prospectus and this prospectus supplement or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since those dates.

All references in this prospectus supplement to our consolidated financial statements include, unless the context indicates otherwise, the related notes.

The industry and market data and other statistical information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference are based on management's own estimates, independent publications, government publications, reports by market research firms or other published independent sources, and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information. None of the independent industry publications used in this prospectus supplement, the accompanying prospectus or the documents we incorporate by reference were prepared on our or our affiliates' behalf and none of the sources cited by us consented to the inclusion of any data from its reports, nor have we sought their consent.

We are not making an offer to sell the securities covered by this prospectus supplement in any jurisdiction in which an offer or solicitation is not permitted or in which the person making the offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation.

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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,” “estimate,” “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 in the 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.



## PROSPECTUS SUMMARY

*The information below is only a summary of more detailed information included elsewhere in or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary may not contain all the information that is important to you or that you should consider before making a decision to invest in our common stock and warrants. Please read this entire prospectus supplement and the accompanying prospectus, including the risk factors, as well as the information incorporated by reference in this prospectus supplement and the accompanying prospectus, carefully.*

### About Milestone Scientific Inc.

Milestone Scientific Inc. (NYSE MKT: MLSS) is 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.

Milestone Scientific remains focused on advancing efforts to achieve the following two primary objectives:

- Enhancing our global reach by partnering with distribution companies in the medical sector; and
- Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the *STA Single Tooth Anesthesia System<sup>®</sup> Instrument*.

### Our Injection Technology

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, thereby reducing their anxiety and stress, and by making it easier for the healthcare provider to administer injections.

We believe that we and our technology are widely recognized by key opinion leaders (*i.e.*, academics, anesthesiologists and practicing dentists whose opinions are widely respected), industry experts and medical and dental practitioners as a leader in the emerging, high growth, computer-controlled injection industry. We remain intent on expanding the use and application of our 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.

We have developed and commercialized proprietary, innovative, computer controlled injection instruments and related disposable, single-use handpieces for the medical and dental markets. We believe our dental instruments have set a new standard of care for dental injections. As of November 30, 2016, we have not yet obtained U.S. Food and Drug Administration (“FDA”) regulatory clearance for our new epidural anesthetic injection and intra-articular injection instruments. However, in September 2014, we received European Union (CE) clearance to market our new epidural anesthetic injection and intra-articular injection instruments in the European market. We believe our technology is proven and well established and our dental instruments have been used to administer millions of injections worldwide. Each of our instruments has a related single use disposable leading to a continuing revenue stream following sale of the instrument.

### ***CompuDent® and The Wand®***

Our first commercial product, the *CompuDent®*, and its associated disposable *The Wand®* handpiece for the dental market is intended to allow the dentist to provide virtually painless injections for all dental procedures, including routine cleanings and fillings, as well as more sophisticated implants, root canals and crowns. New injections made possible by the *CompuDent®* eliminate collateral numbness of the tongue, lips and facial muscles and often hasten the onset of anesthesia by eliminating the need for preliminary mandibular blocks. The pencil grip used with *The Wand®* handpieces provides the practitioner with enhanced tactile sense and accurate control and allows bi-directional rotation eliminating needle deflection, resulting in a greater success rate. Since *The Wand®* handpiece does not look like a typical syringe it also reduces patient anxiety and offers the possibility of curing dental phobia, which afflicts approximately 30 to 40 million Americans. (See “What is Dental Anxiety and Phobia?” Colgate (Sept. 18, 2013)).

## CompuFlo®

Our next significant intellectual property advancement was the development of our proprietary patented *CompuFlo*® technology for the precise delivery of anesthetics and other medicaments into various tissues and bodily cavities. The *CompuFlo*® technology has been approved by the FDA and allows the practitioner to precisely regulate and control the flow rate of the injectable material while receiving visual and audible in-tissue pressure feedback, allowing the practitioner to determine the tissue into which the injectable material is being delivered. The *CompuFlo*® technology encompasses the painless delivery benefits of the *CompuDent*® while allowing the practitioner to know which tissues have been penetrated and to inject medicaments precisely into the desired location. With *CompuFlo*®, the injection of chemotherapeutics and other toxic substances outside the targeted area can be avoided. The instruments developed using the *CompuFlo*® also provide a digital record of the time and amount of anesthetic or medicament injected.

Our first system utilizing the *CompuFlo*® technology was our STA instrument and handpieces for the dental market. The STA instrument and handpieces continue to provide all of the benefits of the *CompuDent*® system while better facilitating single tooth anesthesia (now generally performed with a high pressure spring loaded gun-like instrument) by allowing the practitioner to monitor and precisely control pressure, rate and volume. Instruments using the *CompuFlo*® technology can be used to inject a wide variety of liquid medicaments as well as anesthetics. We believe *CompuFlo*® avoids the negative side effects from the use of traditional hypodermic drug delivery injection instruments, which are well documented in dental and medical literature and include risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications. Pain and tissue damage often result from uncontrolled flow rates and pressure created during the administration of drug solutions into human tissue. While several technologies have been capable of controlling flow rate, we believe the ability to accurately and precisely control pressure was unobtainable until the development of *CompuFlo*®.

The next systems utilizing the *CompuFlo*® technology were instruments for administering epidural injections and the related disposable and an instrument for administering hyaluronic acid and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions.

Our epidural injection instrument using *CompuFlo*® pressure sensing technology provides an objective tool that we believe consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the extraligamentary tissue. In studies, the *CompuFlo*® technology has been shown to be effective in correctly identifying the epidural space. (See Ghelber O, et al. *The CompuFlo*® helps unexperienced operators identify the epidural space in a simulator model: A 941. Eur J Anaesthesiology 2006 23:242). 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, in the absence of fluoroscopy, who identify the epidural space by relying on the subjective perception of loss of resistance to saline.

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.

We believe our intra-articular injection instrument is particularly efficacious for arthritis patients who are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious because the doctor using a syringe fails to locate the intra-articular space or does not inject the appropriate volume of hyaluronic acid or other medicament into that space. The *CompuFlo*<sup>®</sup> technology has been successful in administering medicaments into a certain intra-articular space using its computer-controlled pressure sensing capabilities in an independent animal study. (See Dr. Campoy, Luis. Cornell University, College of Veterinary Medicine, Department of Clinical Sciences. *Maxillary Foramen Block Using A Novel Equipment Device By Milestone Medical*. Ithaca, NY: Cornell University, 2016).

The epidural instrument has obtained CE mark approval and may now be marketed and sold in most European countries and many other countries accepting CE approved instruments. In the United States, we have completed required testing for the epidural instrument for birthing and pain management and have submitted what we believe to be the favorable results of these tests to the FDA. We expect to receive FDA approval of our epidural instrument by the end of the second quarter of 2017; however, we can provide no assurances of when, if ever, we will receive FDA approval for our epidural instrument. We have entered into a limited number of European and Middle East distributor arrangements for our epidural instrument and plan to develop an international marketing network of independent distributors upon receipt of FDA approval.

The intra-articular instrument has obtained CE mark approval and may now be marketed and sold in most European countries and many other countries accepting CE approved instruments. We recently received notification from the FDA that our 510(k) application for marketing approval of the intra-articular instrument did not demonstrate that the device was as safe and effective as legally marketed devices. We intend, following consultation with the FDA Office of Device Evaluation, to provide additional data, including a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the intra-articular instrument. An HFV Study demonstrates the ease of use of a product. The cost to generate this incremental data is estimated to approximate \$100,000. We believe that the new 510(k) application as supported by the new HFV Study will demonstrate substantial equivalency; however we can provide no assurances of when, if ever, we will receive FDA approval for our intra-articular instrument.

At earlier stages of development are our products using our *CompuFlo*<sup>®</sup> technology for less painful injections into the eye and for the subcutaneous injection of fillers and other substances in the dermatology market. In the self-injectable market, 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, Rheumatoid Arthritis, and other diseases of the auto immune system. We believe the *CompuFlo*<sup>®</sup> 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. In addition, the ability to record the injection will allow for significantly enhanced monitoring of the patient.

### **Distribution and Marketing Arrangements**

Beginning January 1, 2016, we entered into a non-exclusive distribution agreement with Henry Schein, Inc. (“Henry Schein”). In June 2016 we established new exclusive distribution arrangements for our dental products for the United States and Canada with Henry Schein. Under these arrangements we will, for the first time, have a semi-dedicated independent sales force visiting dentists. We believe that these arrangements will be more effective than previous arrangements relying on appearances at dental shows and catalog sales.

To date, Henry Schein has endeavored to accomplish the goals laid out in the exclusive distribution agreement for *The Wand*<sup>®</sup> STA instrument and handpieces, including training of its exclusive products sales specialists. Specifically, nine exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand*<sup>®</sup> STA instrument and handpieces and are currently in the field selling the instrument. In addition, Henry Schein is expected to complete the training of an additional 16 exclusive product sales specialists before year end. Henry Schein also plans to train an additional two to three dedicated customer service representatives to support dentists across North America through its exclusive product sales customer call center.

Henry Schein’s exclusive products sales specialist team, which is comprised of 25 sales representatives and supported by over 1,000 field service representatives, will exclusively market and distribute *The Wand*<sup>®</sup> STA instrument and

handpieces, together with a select group of other devices in the United States and Canada. Our agreement with Henry Schein has minimum purchase orders to maintain exclusivity in the third through tenth years.

In China, where the dental market lags behind other health care services and has largely been neglected in the past, a CS Market Research report indicates that 50% of adults and 70% of children out of China's estimated 1.3 billion plus population have tooth decay problems and over 90% have periodontal disease. (See Shuyu Sun & Seth Pierrepont. *The Dental Equipment Market Over in China*, CS Market Research (Sept. 20, 2005) and *Opportunities Abound for Dental Care in China*, CHINA BRIEFING (February 27, 2015)). With increasing affluence and increasing attention towards personal care, the provision of dental services in China has been growing rapidly. We have established exclusive distribution arrangements with Milestone China, Ltd, a 40% owned affiliate, which has placed our dental instruments in clinics serving major cities in China. We expect this initial limited distribution of instruments will lead to both increased sales of dental instruments and our single-use handpieces. We are currently exploring strategic alternatives for our 40% ownership interest in Milestone China, Ltd.

## **Additional Applications**

### Botulinum toxin Instrument

In 2014, we established a joint venture to develop and commercialize an instrument for the pain free injection of botulinum toxin. The joint venture entity is owned 50% by us and 50% by Milestone China Ltd., a People's Republic of China corporation in which we own a 40% interest. Milestone China has contributed \$900,000 of cash to the joint venture and we provided a royalty-free license to utilize our technology to the joint venture, to develop a botulinum toxin injection instrument.

### Veterinary Instruments

In August 2016, we signed a distribution agreement with MILA International Inc. to market and distribute an anesthetic instrument using our *CompuFlo*® technology for nerve blocks in horses. The effectiveness of this instrument for such use was confirmed by a pilot study and final report completed by Cornell University, College of Veterinary Medicine. (See Dr. Campoy, Luis. Cornell University, College of Veterinary Medicine, Department of Clinical Sciences. *Maxillary Foramen Block Using A Novel Equipment Device By Milestone Medical*. Ithaca, NY: Cornell University, 2016). We expect to commence marketing and distribution of this instrument in the second quarter of 2017.

### **Competition**

We face intense competition from many companies in the medical and dental device industry, possessing substantially greater financial, marketing, personnel and other resources. In dentistry the main competition is the syringe, a product that has been in use and virtually unchanged for more than 150 years. For epidurals, we face competition from the established method of providing epidurals with the use of two medical practitioners, one to insert and place the needle and the other to inject the anesthesia and potentially from a computer controlled injection instrument that claims to be able to reliably identify the epidural space but has had limited success in the marketplace.

### **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 and our telephone number is (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.

## THE OFFERING

Issuer: Milestone Scientific Inc.

Securities \_\_\_\_\_ shares of our common stock and warrants to purchase up to an aggregate of \_\_\_\_\_ offered by us: shares of common stock.

Warrants offered by us: The warrants are immediately exercisable. However, they may only be exercised to purchase a whole share of common stock. The exercise price of the warrants is \_\_\_\_ per share. The warrants will expire on December \_\_\_\_, 2019. At our option, the warrants are mandatorily exercisable if at any time the daily average volume weighted average price ("VWAP") for any ten (10) consecutive trading days is equal to or greater than \_\_\_\_ per share. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants. For more information, see the section entitled "Description of The Securities We Are Offering — Description of Warrants" on page S-15 of this prospectus supplement.

Public offering price \$ \_\_\_\_\_ per share of common stock.

\$0.01 per warrant to purchase \_\_\_\_ shares of common stock

Shares of common stock outstanding after the offering (1): \_\_\_\_\_ shares (assuming none of the warrants issued in this offering are exercised).

Over-allotment option: We have granted the representative a 45-day option to purchase up to an additional \_\_\_\_\_ shares of common stock and warrants to purchase up to \_\_\_\_\_ shares of common stock to cover over-allotments, if any.

Use of proceeds: Any net proceeds we may receive will be used for working capital and general corporate purposes including marketing and sales of our epidural instrument and development of new products and new product uses. See "Use of Proceeds."

NYSE MKT listing: Our common stock is listed on the NYSE MKT under the symbol "MLSS." There is no established public trading market for the warrants and a market may never develop. We do not intend to list the warrants on the NYSE MKT, any other national securities exchange or other nationally recognized trading system.

Risk factors: Investing in our common stock and warrants involves a high degree of risk and purchasers of our common stock and warrants may lose their entire investment. See "Risk Factors" and the other information included and incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of risk factors you should carefully consider before



deciding to invest in our securities.

- (1) The number of shares of our common stock to be outstanding after this offering is based on 28,072,224 shares of our common stock outstanding as of November 30, 2016. The number of shares of common stock outstanding excludes 2,064,772 shares of common stock issuable upon exercise of outstanding stock options and warrants, at a weighted average price of \$1.70 per share.

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## **RISK FACTORS**

*Any investment in our common stock and warrants involves a high degree of risk. You should carefully consider the risks and uncertainties described below and all of the information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus before deciding whether to purchase our common stock and warrants, including the risk factors contained herein and in the accompanying prospectus, as well as those in our periodic reports filed with the Securities and Exchange Commission incorporated by reference in this prospectus supplement and the accompanying prospectus. If any of these risks actually occurs, our business, financial condition, liquidity and results of operations would suffer. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See the information under the heading “Forward-Looking Statements” in this prospectus supplement.*

## **RISKS RELATING TO THIS OFFERING AND OUR COMMON STOCK**

**Management has broad discretion over the use of the proceeds from this offering. We may use the proceeds of this offering in ways that do not improve our operating results or the market value of our common stock.**

We will have broad discretion in determining the specific uses of the net proceeds from the sale of the common stock and warrants. Our allocations may change in response to a variety of unanticipated events, such as differences between our expected and actual revenues from operations or availability of commercial financing opportunities, unexpected expenses or expense overruns or unanticipated opportunities requiring cash expenditures. We will also have significant flexibility as to the timing and use of the net proceeds. As a result, investors will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the net proceeds. You will rely on the judgment of our management with only limited information about their specific intentions regarding the use of proceeds. We may spend most of the net proceeds of this offering in ways which you may not agree with. If we fail to apply these funds effectively, our business, results of operations and financial condition may be materially and adversely affected.

**There is no public market for the warrants to purchase common stock being offered in this offering.**

There is no established public trading market for the warrants being offered in this offering and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or

other nationally recognized trading system, including the NYSE MKT. Without an active market, the liquidity of the warrants will be limited.

**We may require additional financing, which may in turn require the issuance of additional shares of common stock, preferred stock or other debt or equity securities (including convertible securities), that may dilute the ownership held by our stockholders.**

We may need to raise additional funds through either debt or the sale of our shares of capital stock in order to achieve our business goals. Any additional shares issued would further dilute the percentage ownership held by the stockholders. Furthermore, if we raise funds in equity transactions through the issuance of convertible securities which are convertible at the time of conversion at a discount to the prevailing market price, substantial dilution is likely to occur, which may result in a material decline in the price of your shares.

**We may require additional financing in the future, which may not be available or, if available, may be on terms that cause a decline in the value of the securities purchased in this offering.**

If we raise capital in the future by issuing additional securities, investors may experience a decline in the value of the securities purchased in this offering. In addition, such securities may have rights senior to the rights of the securities purchased in this offering.

**There is no intention to pay dividends at the present time.**

We have never paid dividends or made other cash distributions on our common stock and do not expect to declare or pay any dividends in the foreseeable future. We intend to retain future earnings, if any, for working capital and to finance current operations and expansion of our business. Investors should not count on dividends in evaluating an investment in our common stock.

## **RISKS RELATING TO OUR BUSINESS AND INDUSTRY**

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

For the nine months ended September 30, 2016, our revenue was approximately \$8.9 million and we had a net loss of approximately \$5.3 million. For the years ended December 31, 2015 and 2014, our revenues were approximately \$9.4 million and \$10.3 million, respectively, and we had net losses of approximately \$5.4 million and \$1.7 million, respectively. In addition, with the exception of 2013, we have had losses for each year since the commencement of operations. At September 30, 2016 and December 31, 2015, we had (i) an accumulated deficit of approximately \$71.6 million and \$67.4 million, respectively; (ii) cash and cash equivalents approximately \$2.3 million and \$4.2 million, respectively; and (iii) working capital of approximately \$6.3 million and \$8.2 million, respectively. The working capital for the nine months ended September 30, 2016 decreased by approximately \$1.9 million from December 31, 2015. The change in working capital is primarily due to the use of cash for operations and the consolidation of Milestone Medical in 2015. As of September 30, 2016, we believe that our dental revenues are projected to improve due to the new exclusive distribution arrangements for our dental products for the United States and Canada with Henry Schein. To further reduce our expenditures, Milestone Medical expenses related to USA FDA clearance for the epidural and intra-articular instruments can be controlled as required to meet our budget. By limiting the FDA related expenses and increasing the dental instrument revenue through the Henry Schein distribution agreement, management believes that we will have sufficient cash reserves to meet all of its anticipated obligations over the next twelve months.

Our management continues to examine all areas of the business to manage our cash flow, however, continuing losses could negatively impact our results of operations and could impact our ability to continue operations.

**Excessive returns under the June 2016 Exclusive Distribution and Supply Agreement with Henry Schein, Inc. could have a material adverse effect on our results of operations and liquidity.**

In June 2016, we entered into a new exclusive distribution and supply agreement with Henry Schein, Inc. pursuant to which they were appointed as the exclusive distributor for our dental products in the United States and Canada. Under that agreement, Henry Schein, Inc. has a right to return our products for full credit against the purchase price paid by them under limited circumstances in accordance with such agreement, including but not limited to, returns due to shipment error by us or factory defect. Excessive returns during any calendar year could have a material adverse effect on our results of operations and liquidity.

**Our near-term prospects are dependent on the marketing success of our epidural anesthetic injections and intra-articular injection instruments in the EU community. If we fail to successfully commercialize these instruments in the EU, our business and prospects would be harmed significantly.**

Our near-term prospects are dependent upon our success in marketing our epidural anesthetic injections and intra-articular injection instruments in the EU community where we have previously received CE approval. There can be no assurance that we will be able to successfully commercialize these products in the EU. If we fail to successfully commercialize these products in the EU, our business and prospects would be harmed significantly.

**Our prospects are dependent on FDA approval of our epidural anesthetic injections instrument to permit marketing in the U.S. If we fail to obtain the regulatory approvals necessary to sell this instrument in the U.S., or upon approval, fail to successfully commercialize this instrument in the U.S., our business and prospects would be harmed significantly.**

Our prospects are dependent upon our receipt of FDA approval of our epidural anesthetic injections instrument. We have filed a 510(k) application with respect to this instrument with the FDA and approval, which will permit us to commence marketing of the instruments in the U.S., is pending. There can be no assurance that we will obtain the FDA approvals necessary to sell our epidural anesthetic injections instrument in the U.S. In addition, even if we obtain such regulatory approvals, there can be no assurance that we will be able to successfully commercialize this product in the U.S. If we fail to obtain the regulatory approvals necessary to sell this instrument or fail to successfully commercialize this product in the U.S., our business and prospects would be harmed significantly.

**Changes in laws and regulations over which we have no control can significantly affect our business and results of operations.**

Any governmental entity that regulates our operations in the country in which they are located may enact new legislation or adopt new laws and regulations or policies at any time, and new judicial decisions may change the interpretation of existing legislation or regulations at any time in any of the countries in which our operations or projects are located. We have no control over any such changes. Any new laws or regulations governing our operations could have an adverse impact on our business, results of operations and prospects.

**Our planned operations in the developing world could cause us to incur additional costs and risks associated with doing business in developing markets.**

We are seeking to operate in the developing world (e.g., China), which would make us vulnerable to political, economic and social instability in such areas. Many areas of the developing world have experienced political, economic and social uncertainty in recent years, including an economic crisis characterized in some cases by

increased inflation, high domestic interest rates, negative economic growth, reduced consumer purchasing power and high unemployment. Political, economic and social instability in these countries may have an adverse effect on our business, financial condition and results of operations.

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**We participate in a highly competitive environment.**

The medical device industry is characterized by rapid technological change, changing customer needs and frequent new product introductions. Our products may be rendered obsolete as a result of future innovations. We face intense competition from other manufacturers. Some of our competitors may be larger than we are and may have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe that price competition will continue among products developed in our markets. Our competitors may develop or market technologies and products that are more effective or commercially attractive than any we are developing or marketing. Our competitors may succeed in obtaining regulatory approval and introducing or commercializing products before we do. Such developments could have a significant negative effect on our business, financial condition and results of operations. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

**Our success depends upon the development of new products and product enhancements, which entails considerable time and expense.**

We place a high priority on the development of new products to add to our product portfolio, as well as on the development of enhancements to our existing products. Product development involves substantial expense and we cannot be certain that a completed product will generate sufficient revenue for our business to justify the resources that we devote to research and development related to such product. The time and expense required to develop new products and product enhancements is difficult to predict and we cannot guarantee that we will succeed in developing, introducing and marketing new products and product enhancements. Our inability to successfully develop and introduce new or enhanced products on a timely basis or at all, or to achieve market acceptance of such products, could materially impair our business.

**We are dependent on adequate protection of our patent and proprietary rights.**

We rely on patents, trade secrets, trademarks, copyrights, know-how, license agreements and contractual provisions to establish and protect our intellectual property rights. However, these legal means afford us only limited protection and may not adequately protect our rights or remedies to gain or keep any advantages we may have over our competitors. We cannot guarantee that others may not independently develop the same or similar technologies or otherwise obtain access to our technology and trade secrets. Our competitors, many of which have substantial resources and may make substantial investments in competing technologies, may apply for and obtain patents that will prevent, limit, or interfere with our ability to manufacture or market our products. Further, while we do not believe that any of our products or processes interfere with the rights of others, third parties may nonetheless assert patent infringement claims against us in the future.

Costly litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how we own, to defend us against claimed infringement of the rights of others or to determine the ownership, scope, or validity of our proprietary rights and the rights of others. Any claims of infringement against us may involve significant liabilities to third parties, could require us to seek licenses from third parties and could prevent or delay us from manufacturing, selling or using our products. The occurrence of such litigation or the effect of an adverse determination in any of this type of litigation could have a material adverse effect on our business, financial condition and results of operations.

**We are subject to substantial domestic and international government regulation, including regulatory quality standards applicable to our manufacturing and quality processes. Failure by us to comply with these standards could have an adverse effect on our business, financial condition or results of operations.**

The FDA regulates the approval, manufacturing and sales and marketing of many of our products in the United States. Significant government regulation also exists in other countries in which we conduct business. As a device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European community, we are required to maintain certain ISO certifications to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Failure to comply with current governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages or delays in product manufacturing. Efficacy or safety concerns, an increase in trends of adverse events in the marketplace, and/or manufacturing quality issues with respect to our products could lead to product recalls or related field actions, withdrawals, and/or declining sales.



**We may be subject, directly or indirectly, to U.S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.**

Our operations are and will continue to be directly, or indirectly through our customers and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, and the Foreign Corrupt Practice Act of 1977 (“FCPA”). These laws may impact, among other things, our proposed sales, and marketing and education programs. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as the federal False Claims Act. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government and such individuals, commonly known as “relators” or “whistleblowers,” may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and health care companies to have to defend False Claim Act actions. The Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been previously dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws with qui tam provisions. States had until March 31, 2013 to enact or amend their false claims laws modeled after the federal False Claims Act for review and approval to receive a greater portion of any recovery.

The Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals beginning in August 2013 and to report to the Centers for Medicare and Medicaid Services starting in 2014 for subsequent public disclosure. Manufacturers

must also disclose investment interests held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to \$1 million per year for knowing violations and may result in liability under other federal laws or regulations. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states, such as Massachusetts and Vermont, impose an outright ban on certain gifts to physicians. If we receive FDA clearance to market our epidural anesthetic injections and/or our intra-articular injection instruments in the United States, these laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our system. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us.

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We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, or an administrative action of suspension or exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations.

In addition, we are subject to the FCPA and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business.

Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, results of operations and financial condition.

## USE OF PROCEEDS

We estimate the net proceeds from this offering will be approximately \$\_\_\_\_\_, after deducting estimated offering expenses payable by us. We intend to use the net proceeds from this offering, and any proceeds from the exercise of warrants, for general corporate and working capital purposes, including marketing and sales of our epidural instrument and the development of new products and new product uses.

## DILUTION

If you purchase securities in this offering, your interest will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our common stock and accompanying warrant, assuming \$0.01 of the public offering price is attributable to each warrant to purchase \_\_\_\_ shares of common stock, and the as adjusted net tangible book value per share of our common stock after giving effect to this offering.

Our net tangible book value as of September 30, 2016 was approximately \$6,543,500 or approximately \$0.23 per share of common stock. Our net tangible book value per share of common stock represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding at September 30, 2016. After giving effect to the sale of the shares of common stock and accompanying warrants in this offering at the public offering price of \$\_\_\_\_ per share and after deducting underwriter discounts and commissions and other estimated offering expenses payable by us and excluding the proceeds attributable to sale of the warrants and the proceeds, if any, from the exercise of the warrants issued pursuant to this offering, our pro forma as adjusted net tangible book value at September 30, 2016 would have been approximately \$\_\_\_\_\_ million or \$\_\_\_\_ per share. This represents an immediate increase in net tangible book value of approximately \$\_\_\_\_ per share to our existing stockholders, and an immediate dilution of \$\_\_\_\_ per share to investors purchasing shares in the offering.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of our common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

The following table illustrates the per share dilution to investors purchasing securities in the offering:

Public offering price per share of common stock, not including \$0.01 of the offering price per share attributable to each warrant for ____ shares of common stock	\$
Net tangible book value per share as of September 30, 2016	\$0.23

Increase in net tangible book value per share attributable to this offering	\$
Adjusted net tangible book value per share after this offering	\$
Amount of dilution in net tangible book value per share to new investors in this offering	\$

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the as adjusted net tangible book value (not including amounts attributable to the warrants) will increase to \$\_\_\_\_ per share, representing an immediate increase to existing stockholders of \$\_\_\_\_ per share and an immediate dilution of \$\_\_\_\_ per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

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**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization, as of September 30, 2016:

- on an actual basis; and
- on a pro forma basis, based on an offering price of \$\_\_\_\_\_ per share of common stock and a warrant to purchase \_\_\_ shares of common stock, to give effect to the sale of \_\_\_\_\_ shares of common stock and warrants to purchase \_\_\_\_\_ shares of common stock, after deducting the estimated underwriter discounts and commissions and estimated offering expenses payable by us.

You should consider this table in conjunction with “Use of Proceeds” above as well as our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the notes to those financial statements incorporated by reference in this prospectus.

	<b>As of September 30, 2016</b>	
	<b>Unaudited, Actual</b>	<b>Unaudited, Pro forma</b>
Cash and cash equivalents	\$2,322,705	
Stockholders’ Equity:		
Series A Preferred stock	7	
Common stock,	29,213	
Additional paid-in capital	79,477,418	
Accumulated deficit	(71,642,654)	
Treasury stock, at cost, 33,333 shares	(911,516 )	
Noncontrolling interest	269,171	
Total Stockholders’ Equity	\$7,221,639	

## **DESCRIPTION OF THE SECURITIES WE ARE OFFERING**

In this offering, we are offering \_\_\_\_\_ shares of common stock and warrants to purchase up to \_\_\_\_\_ shares of common stock. The warrants may only be exercised to purchase whole shares of common stock. The exercise price of the warrants is \$\_\_\_\_ per share of common stock. No fractional shares will be issued. The common stock and the warrants are immediately separable and will be issued separately. This prospectus supplement also relates to the offering of the common stock issuable upon exercise of the offered warrants.

## **DESCRIPTION OF COMMON STOCK**

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

### **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 28,105,557 shares of common stock issued, of which 28,072,224 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 MKT, which apply for so long as our common stock is listed on the NYSE MKT, 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 us 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.

## **DESCRIPTION OF WARRANTS**

*The following summary of certain terms and provisions of the warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the warrant, the form of which will be filed with the SEC by us as an exhibit to a Current Report on Form 8-K in connection with this offering. Prospective investors should carefully review the terms and provisions of the form of the warrant for a complete description of the terms and conditions of the warrants.*



## Warrants

*Duration and Exercise Price.* In connection with this offering, we will issue warrants to purchase \_\_\_\_\_ shares of our common stock. For every share of common stock sold in this offering, we will issue a warrant to purchase \_\_\_\_ shares of common stock. The warrants may only be exercised to purchase whole shares of common stock. At the Company's election, fractional shares will be paid in cash or rounded up to the next whole share. The exercise price of the warrants is \_\_\_\_ per share of common stock, subject to adjustment as discussed below, at any time commencing upon consummation of this offering and terminating at 5:00 p.m., New York City time, on December \_\_, 2019. After the exercise period, holders of the warrants will have no further rights to purchase the common stock underlying the warrants.

*Exercisability.* The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder may not exercise any portion of the warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of the outstanding shares of common stock after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding shares after exercising the holder's warrants up to 9.99% of the number of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

*Cashless Exercise.* If, at the time a holder exercises its warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

*Mandatory Exercise.* If at any time the VWAP for any ten (10) consecutive trading days is equal to or greater than \_\_\_\_ per share (as adjusted for stock splits, stock combinations and the like), then we will have the right to require all warrant holders to exercise all, but not less than all, of their warrant for all of the then-remaining shares of common stock. We may exercise our right to require exercise on one occasion by delivering an irrevocable mandatory exercise notice to the holder; provided, however, if any shares of common stock trade for a price less than \_\_\_\_ on any day during the period commencing on the date on which such notice is delivered to the holder and ending on the trading day immediately preceding the date the holder is required to exercise its warrant pursuant to such notice, then the notice delivered to the holder shall be null and void ab initio and we will be permitted to submit an additional irrevocable mandatory exercise notice at a future date.

*Fundamental Transactions.* In the event of any fundamental transaction, as described in the warrants and generally including any merger with or into another entity, sale, lease, license or other disposition of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the warrant is exercisable immediately prior to such event. In addition, in the event of a fundamental transaction, we or any successor entity shall purchase such warrants from the holders for an amount of cash equal to the value of the warrant as determined in accordance with the Black Scholes option pricing model described in the warrants.

*Adjustments.* If we, at any time while the warrant is outstanding: (i) pay a stock dividend or otherwise makes a distribution or distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock (not include any shares of common stock issued by us upon exercise of the warrant), (ii) subdivides outstanding shares of common stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of common stock into a smaller number of shares, or (iv) issues by reclassification of shares of common stock any shares of our capital stock, then in each case the exercise price of the warrant and the number of shares of common stock issuable upon exercise of the warrant will be proportionately adjusted such that the aggregate exercise price will remain unchanged.

*Transferability.* Subject to applicable laws and the restriction on transfer set forth in the warrant, the warrants may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

*Listing.* We do not intend to list the warrants on the NYSE MKT, any other national securities exchange or any other nationally recognized trading system.

*Right as a Stockholder.* Holders of the warrants will not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants, with exceptions for participation in rights offerings or extraordinary distributions.

## **Anti-Takeover Provisions**

### *Delaware Law*

We are subject to Section 203 of the DGCL. This provision generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of voting shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or



- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of us. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders.

*Certificate of Incorporation and Bylaw Provisions*

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, the certificate of incorporation and bylaws, as applicable, among other things:

- provide our board of directors with the ability to alter its bylaws without stockholder approval; and
- provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third-party from acquiring us, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of us. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms. However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

Our certificate of incorporation provides that no director is personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty by such director as a director. Nonetheless, a director is liable to the extent provided by applicable law, (i) for breach of the director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL (relating to unlawful payment of dividend or unlawful stock purchase or redemption) or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is amended to authorize the further elimination or limitation of the liability of directors, then the liability of one of our directors, in addition to the limitation on personal liability provided in our certificate of incorporation, will be limited to the fullest extent permitted by the amended DGCL. No amendment to or repeal of the relevant article of our certificate of incorporation will apply to or have any effect on the liability or alleged liability of any of our directors for or with respect to any acts or omissions of such director occurring prior to such amendment.

Our certificate of incorporation furthermore states that we shall indemnify, to the fullest extent permitted by Section 145 of the DGCL, as amended from time to time, each person that such section grants us the power to indemnify. Insofar as indemnification for liability under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

## **Dividends**

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

## **Transfer Agent and Registrar**

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





## UNDERWRITING

We have entered into an underwriting agreement with Maxim Group LLC acting as the sole book-running manager and sole representative for the underwriters named below. Subject to the terms and conditions of the underwriting agreement, the underwriters named below have agreed to purchase, and we have agreed to sell to them, the number of shares of common stock and warrants to purchase common stock at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus supplement and as indicated below:

<b>Underwriters</b>	<b>Number of Shares</b>	<b>Number of Warrants</b>
Maxim Group LLC		

Total

The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the shares of common stock and warrants to purchase common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares and warrants offered by this prospectus supplement if any such shares and warrants are taken, other than those shares and warrants covered by the over-allotment option described below.

### Over-Allotment Option

We have granted to the underwriters an option, exercisable not later than 45 days after the effective date of the underwriting agreement, to purchase up to \_\_\_\_\_ additional shares of common stock and/or additional warrants to purchase up to \_\_\_\_\_ shares of common stock at the public offering price less the underwriting discounts and commissions set forth on the cover of this prospectus supplement. The underwriters may exercise this option only to cover over-allotments made in connection with this offering. To the extent that the underwriters exercise this option, each of the underwriters will become obligated, subject to conditions, to purchase approximately the same percentage of these additional shares and additional warrants as the number of shares and warrants to be purchased by it in the above table bears to the total number of shares and warrants offered by this prospectus supplement. We will be obligated, pursuant to the option, to sell these additional shares and additional warrants to the underwriters to the extent the option is exercised. If any additional shares and additional warrants are purchased, the underwriters will offer the additional shares and additional warrants on the same terms as those on which the other shares and warrants are being offered hereunder.

## Commissions

We have agreed to pay the underwriters a cash fee equal to 7% of the gross proceeds raised in this offering. The representative has advised us that the underwriters propose to offer the shares and accompanying warrants directly to the public at the public offering price set forth on the cover of this prospectus supplement. In addition, the representative may offer some of the shares and warrants to other securities dealers at such price less a concession of up to \$\_\_\_\_\_ per share and \$\_\_\_ per warrant. After the offering to the public, the offering price and other selling terms may be changed by the representative without changing the proceeds we will receive from the underwriters.

The following table summarizes the public offering price, underwriting commissions and proceeds before expenses to us assuming both no exercise and full exercise of the underwriters' option to purchase additional shares and warrants. The underwriting commissions are equal to the public offering price per share and accompanying warrant less the amount per share and accompanying warrant the underwriters pay us for the shares and accompanying warrant.

	Per Share and Accompanying Warrant	Total Without Over- Allotment	Total With Over- Allotment
Public offering price	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately \$\_\_\_\_\_, all of which are payable by us.

## **Lock-Up Agreements**

We and each of our officers and directors and Innovest S.p.A. have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of ninety (90) days after the effective date of the registration statement of which this prospectus is a part without the prior written consent of Maxim Group LLC.

Maxim Group LLC may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the representative will consider, among other factors, the security holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

## **Price Stabilization, Short Positions and Penalty Bids**

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares than are set forth on the cover page of this prospectus supplement. This creates a short position in our common stock for the underwriters' own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares of common stock over-allotted by the underwriters is not greater than the number of shares of common stock that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares of common stock in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock or reduce any short position by bidding for, and purchasing, common stock in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on NYSE MKT, in the over-the-counter market, or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our common stock immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;

net purchases by a passive market maker on each day are limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and

passive market making bids must be identified as such.

## **Other Terms**

In addition, we have agreed to reimburse the underwriters for all reasonable out-of-pocket expenses actually incurred up to \$30,000, including but not limited to reasonable legal fees, incurred by the underwriters in connection with the offering. We will reimburse the underwriters for all such expenses regardless of whether the offering is consummated.

## **Our Relationships with the Underwriters**

The underwriters and their affiliates have engaged, and may in the future engage, in investment banking transactions and other commercial dealings in the ordinary course of business with us or our affiliates. It has received, or may in the future receive, customary fees and commissions for these transactions. Specifically, in the past 180 days we have paid Maxim Group LLC \$30,000 in advisory fees and \$15,000 to reimburse Maxim Group LLC for expenses it incurred in connection with a securities offering we elected not to pursue.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **Indemnification**

We have agreed to indemnify the underwriters against liabilities relating to the offering arising under the Securities Act and the Exchange Act, liabilities arising from breaches of some or all of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

## **Electronic Distribution**

A prospectus supplement and accompanying base prospectus in electronic format may be made available on a website maintained by the representative of the underwriters and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives of the underwriters to underwriters that may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriters or syndicate members may distribute prospectus supplements and accompanying base prospectuses electronically. No forms of electronic prospectus other than prospectus supplements and accompanying base prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of shares offered by this prospectus supplement to accounts over which they exercise discretionary authority.

Other than the prospectus supplement in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus supplement or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

### **Foreign Regulatory Restrictions on Purchase of Securities Offered Hereby Generally**

No action has been or will be taken in any jurisdiction (except in the United States) that would permit a public offering of the securities offered by this prospectus supplement and accompanying base prospectus, or the possession, circulation or distribution of this prospectus supplement and accompanying base prospectus or any other material relating to us or the securities offered hereby in any jurisdiction where action for that purpose is required. Accordingly, the securities offered hereby may not be offered or sold, directly or indirectly, and neither of this prospectus supplement and accompanying base prospectus nor any other offering material or advertisements in connection with the securities offered hereby may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

Each of the underwriters may arrange to sell securities offered by this prospectus supplement and accompanying base prospectus in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so.

### **Listing**

Our common stock is listed on the NYSE MKT under the symbol “MLSS.”

### **Selling Restrictions**

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of our common stock and warrants, or the possession, circulation or distribution of this prospectus supplement, the accompanying prospectus or any other material relating to us or our common stock and warrants in any jurisdiction where action for that purpose is required. Accordingly, our common stock and warrants may not be offered or sold, directly or indirectly, and none of this prospectus supplement, the accompanying prospectus or any other offering material or advertisements in connection with our common stock and warrants may be distributed or published, in or from any country or jurisdiction, except in compliance with any applicable rules and regulations of any such country or jurisdiction.

## **INTERESTS OF NAMED EXPERTS AND COUNSEL**

The validity of the securities being offered by this prospectus will be passed upon for us by Morse, Zelnick, Rose & Lander, LLP, 825 Third Avenue, New York, NY 10022.

Harter Secrest & Emery LLP is acting as counsel for the representative of the underwriters in the offering.

Baker Tilly Virchow Krause, LLP, an independent registered public accounting firm, has audited our consolidated financial statements for 2014 and 2015 included in our 2015 Annual Report, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our consolidated financial statements for 2014 and 2015 are incorporated by reference in reliance on Baker Tilly Virchow Krause, LLP's report, given on their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and special reports, proxy statements and other information with 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.

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.



## INFORMATION INCORPORATED BY REFERENCE

This prospectus “incorporates by reference” certain information that we have filed with the SEC under 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”);  
Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed on May 16, 2016;  
Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, as filed on August 11, 2016;  
Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, as filed on November 9, 2016;  
Current Reports on Form 8-K, filed on April 26, 2016, June 1, 2016, June 30, 2016, July 21, 2016, August 26, 2016 and December 2, 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 not authorized anyone 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, except in case the information contained in such document to the extent “furnished” and not “filed” 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.

\$30,000,000

MILESTONE SCIENTIFIC INC.

Common Stock

Preferred Stock

Debt Securities

Warrants

Units

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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 16,633,292 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 3 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 May 4, 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,” “estimate,” “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.

## **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*®, *CompuMed*®, *CompuFlo*®, *The Wand*®, *The Wand Plus*®, *The SafetyWand*®, *Dynamic Pressure Sensing Technology*®, and *STA Single Tooth Anesthesia*™, (STA Instrument, instruments and handpieces).



## **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.*

## **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 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 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*<sup>®</sup> Advanced Injection Technology – Core Technology**

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

*CompuFlo* is a 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 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®***

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

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

Despite *CompuDent'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 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 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:

	<b>U.S. NUMBER</b>	<b>DATE OF ISSUE</b>
<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 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 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.

## 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.

## 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 us 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.

### **DESCRIPTION OF PREFERRED STOCK AND PREFERRED STOCK WE MAY OFFER**

*The following description of the terms of our preferred 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 DGCL. In addition, the specific terms of any series of preferred shares will be described in the applicable prospectus supplement.*

Our restated certificate of incorporation authorizes us to issue up to 5,000,000 shares of undesignated preferred stock, par value \$0.001 per share. We may issue preferred stock from time to time in one or more series, without shareholder approval, when authorized by our board of directors. As of May 14, 2014, our board of directors had authorized 7,000

shares of Series A Stock (described below) all of which are issued and outstanding. No other shares of preferred stock were issued or are outstanding.

This section describes the general terms and provisions of the preferred stock we may offer as well as the terms of our Series A Stock which may affect other securities that we may offer by this prospectus. This information may not be complete in all respects and is qualified entirely by reference to our certificate of incorporation, with respect to each series of preferred stock, including the Series A Stock.

The specific terms of any series of preferred stock will be described in a prospectus supplement. Those terms may differ from the terms discussed below. Any series of preferred stock we issue will be governed by our certificate of incorporation and by the certificate of designations relating to that series. We will file the certificate of designations with the SEC and incorporate it by reference as an exhibit to our registration statement at or before the time we issue any preferred stock of that series.

### **Series A Convertible Preferred Stock**

In May 2014, Milestone issued 7,000 shares of Series A Convertible Preferred Stock (the “Series A Stock”), with a stated value of \$1,000 per share to an accredited investor for \$7 million in a Rule 506, Regulation D offering. The Series A Stock votes together with the common stock on an as converted basis and as a single class, except that such shares have class voting rights as to amendments to the certificate of incorporation adversely affecting the Series A Stock, increases in the number of authorized shares of Series A Stock, issuance of additional shares of Series A Stock, increases in the size of the board prior to the time the holders of the Series A Stock no longer have a right to nominate a designee for election to the board or issuance of “senior stock” or “parity stock.” The Series A Stock is also entitled to a liquidation preference equal to the greater of 100% of its \$1,000 per share stated value or the amount the Series A Stock would receive on conversion into common stock and is convertible into common stock at \$2.545 per share at the option of the holder or mandatorily convertible at this price on May 14, 2019, unless certain “threshold” prices have not been achieved prior to that date.

### **Future Classes or Series of Preferred Stock**

Our board of directors is authorized, without shareholder approval, to issue additional series of preferred stock with conversion and other rights, may adversely affect the rights of holders of our common stock or other series of preferred stock that may be outstanding.

Upon issuance of a new series of preferred stock, our board of directors is authorized, to specify:

- the number of shares to be included in the series;
- the annual dividend rate for the series, if any, and any restrictions or conditions on the payment of dividends;
- the redemption price, if any, and the terms and conditions of redemption;
- any sinking fund provisions for the purchase or redemption of the series;
- if the series is convertible, the terms and conditions of conversion;
- the amounts payable to holders upon our liquidation, dissolution or winding up; and
- any other rights, preferences and limitations relating to the series, including voting rights.

### ***Specific Terms of a Series of Preferred Stock***

The new preferred stock we may offer will be issued in one or more series. The preferred stock will have the dividend, liquidation, redemption and voting rights discussed below, unless otherwise described in a prospectus supplement relating to a particular series. A prospectus supplement will discuss the following features of the series of preferred stock to which it relates:

- the designations and stated value per share;
- the number of shares offered;
- the amount of liquidation preference per share;
- the public offering price at which the preferred stock will be issued;
- the dividend rate, the method of its calculation, the dates on which dividends would be paid and the dates, if any, from which dividends would cumulate;
- any redemption or sinking fund provisions;
- any conversion or exchange rights; and
- any additional voting, dividend, liquidation, redemption, sinking fund and other rights, preferences, privileges, limitations and restrictions.



***Rank***

Unless otherwise stated in the prospectus supplement, the new preferred stock will have priority over our common stock with respect to dividends and distribution of assets, but will rank junior to all our outstanding indebtedness for borrowed money. Any series of preferred stock could rank senior, equal or junior to our other capital stock, as may be specified in a prospectus supplement, as long as our certificate of incorporation so permit.

***Dividends***

Holders of each series of newly issued preferred stock shall be entitled to receive cash dividends to the extent specified in the prospectus supplement when, as and if declared by our board of directors, from funds legally available for the payment of dividends. The rates and dates of payment of dividends of each series of preferred stock will be stated in the prospectus supplement. Dividends will be payable to the holders of record of preferred stock as they appear on our books on the record dates fixed by our board of directors. Dividends on any series of preferred stock may be cumulative or non-cumulative, as discussed in the applicable prospectus supplement.

***Convertibility***

Shares of a new series of preferred stock may be exchangeable or convertible into shares of our common stock, another series of preferred stock or other securities or property. The conversion or exchange may be mandatory or optional. The prospectus supplement will specify whether the preferred stock being offered has any conversion or exchange features, and will describe all the related terms and conditions.

***Redemption***

The terms, if any, on which shares of preferred stock of a new series may be redeemed will be discussed in the applicable prospectus supplement.

***Liquidation***

Upon any voluntary or involuntary liquidation, dissolution or winding up of the affairs of Milestone, holders of each series of newly issued preferred stock will be entitled to receive distributions upon liquidation in the amount described in the related prospectus supplement. These distributions will be made before any distribution is made on any securities ranking junior to the preferred stock with respect to liquidation, including our common stock. If the liquidation amounts payable relating to the preferred stock of any series and any other securities ranking on a parity regarding liquidation rights are not paid in full, the holders of the preferred stock of that series will share ratably in proportion to the full liquidation preferences of each security. Holders of our preferred stock will not be entitled to any other amounts from us after they have received their full liquidation preference.

### *Voting*

The holders of preferred stock of each new series will have no voting rights, except as required by law and as described below or in a prospectus supplement. Our board of directors may, upon issuance of a series of preferred stock, grant voting rights to the holders of that series to elect additional board members if we fail to pay dividends in a timely fashion.

Without the affirmative vote of a majority of the shares of preferred stock of any series then outstanding, we may not:

- increase or decrease the aggregate number of authorized shares of that series;
- increase or decrease the par value of the shares of that series; or
- alter or change the powers, preferences or special rights of the shares of that series so as to affect them adversely.

***No Other Rights***

The shares of a new series of preferred stock will not have any preferences, voting powers or relative, participating, optional or other special rights except:

as discussed above or in the prospectus supplement;  
as provided in our certificate of incorporation and in the certificate of designations; and  
as otherwise required by law.

**DESCRIPTION OF WARRANTS WE MAY OFFER**

*The following description of warrants is only a summary. This description is subject to, and qualified in its entirety by reference to, the provisions of the applicable warrant agreement.*

We may issue warrants for the purchase of debt securities, preferred stock, common stock or units. Warrants may be issued independently or together with debt securities, preferred stock, common stock or units and may be attached to or separate from any offered securities. Any issue of warrants will be governed by the terms of the applicable form of warrant and any related warrant agreement which we will file as an exhibit to our registration statement at or before the time we issue any warrants.

The particular terms of any issue of warrants will be described in the prospectus supplement relating to the issue. Those terms may include:

the title of such warrants;  
the aggregate number of such warrants;  
the price or prices at which such warrants will be issued;  
the currency or currencies (including composite currencies) in which the price of such warrants may be payable;  
the terms of the securities purchasable upon exercise of such warrants and the procedures and conditions relating to the exercise of such warrants;  
the price at which the securities purchasable upon exercise of such warrants may be purchased;  
the date on which the right to exercise such warrants will commence and the date on which such right shall expire;  
any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;  
if applicable, the minimum or maximum amount of such warrants that may be exercised at any one time;

if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security;  
if applicable, the date on and after which such warrants and the related securities will be separately transferable;  
information with respect to book-entry procedures, if any; and  
any other terms of such warrants, including terms, procedures and limitations relating to the exchange or exercise of such warrants.

The prospectus supplement relating to any warrants to purchase equity securities may also include, if applicable, a discussion of certain U.S. federal income tax and ERISA considerations.

Warrants for the purchase of preferred stock and common stock will be offered and exercisable for U.S. dollars only.

Each warrant will entitle its holder to purchase the principal amount of debt securities or the number of shares of preferred stock, common stock or units at the exercise price set forth in, or calculable as set forth in, the applicable prospectus supplement.

After the close of business on the expiration date, unexercised warrants will become void. We will specify the place or places where, and the manner in which, warrants may be exercised in the applicable prospectus supplement.

Prior to the exercise of any warrants to purchase debt securities, preferred stock, common stock or units, holders of the warrants will not have any of the rights of holders of the debt securities, preferred stock, common stock or units purchasable upon exercise.

## **DESCRIPTION OF DEBT SECURITIES WE MAY OFFER**

*The following description of the terms of debt securities that we may issue and the related indenture, if any, is only a summary. This description and the description contained in any prospectus supplement are subject to and qualified in their entirety by reference to the applicable indentures, which will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part.*

We may offer secured or unsecured debt securities in one or more series which may be senior, subordinated or junior subordinated, and which may be convertible or exchangeable into another security. Unless otherwise specified in the applicable prospectus supplement, our debt securities will be issued in one or more series under an indenture to be entered into by us and a bank or trust company. As of the date of this prospectus, we have not entered into any indenture agreements.

The following description briefly sets forth certain general terms and provisions of the debt securities. The particular terms of the debt securities offered by any prospectus supplement and the extent, if any, to which these general provisions may apply to the debt securities, will be described in the applicable prospectus supplement.

The terms of the debt securities will include those set forth in the applicable indenture and those made a part of the applicable indenture by the Trust Indenture Act of 1939, or TIA, if any. You should read this summary, the applicable prospectus supplement and the provisions of the applicable indenture or supplemental indenture, if any, in their entirety before investing in our debt securities.

The aggregate principal amount of debt securities that may be issued under the respective indentures may be unlimited. The prospectus supplement relating to any series of debt securities that we may offer will contain the specific terms of the debt securities. These terms may include the following:

the issuer or co-obligors of such debt securities;

the guarantors of each series, if any, and the terms of the guarantees (including provisions relating to seniority, subordination and release of the guarantees), if any;  
the title and aggregate principal amount of the debt securities and any limit on the aggregate principal amount;  
whether the debt securities will be senior, subordinated or junior subordinated;  
whether the debt securities will be secured or unsecured;  
any applicable subordination provisions;  
the maturity date(s) or method for determining same;  
the interest rate(s) or the method for determining same;  
the dates on which interest will accrue or the method for determining dates on which interest will accrue and dates on which interest will be payable and whether interest shall be payable in cash or additional securities;  
whether the debt securities are convertible or exchangeable into other securities and any related terms and conditions;  
redemption or early repayment provisions;  
authorized denominations;  
form;  
if other than the principal amount, the principal amount of debt securities payable upon acceleration;

place(s) where payment of principal and interest may be made, where debt securities may be presented and where notices or demands upon the company may be made;

whether such debt securities will be issued in whole or in part in the form of one or more global securities and the date as of which the securities are dated if other than the date of original issuance;

amount of discount or premium, if any, with which such debt securities will be issued;

any covenants applicable to the particular debt securities being issued;

any defaults and events of default applicable to the particular debt securities being issued;

the currency, currencies or currency units in which the purchase price for, the principal of and any premium and any interest on, such debt securities will be payable;

the time period within which, the manner in which and the terms and conditions upon which the holders of the debt securities or the issuer or co-obligors, as the case may be, can select the payment currency;

our obligation or right to redeem, purchase or repay debt securities under a sinking fund, amortization or analogous provision;

any restriction or conditions on the transferability of the debt securities;

the securities exchange(s) on which the debt securities will be listed, if any;

whether any underwriter(s) will act as a market maker(s) for the debt securities;

the extent to which a secondary market for the debt securities is expected to develop;

provisions granting special rights to holders of the debt securities upon occurrence of specified events;

compensation payable to and/or reimbursement of expenses of the trustee of the series of debt securities;

provisions for the defeasance of the debt securities or related to satisfaction and discharge of the indenture;

provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture and the execution of supplemental indentures for such series; and

any other terms of the debt securities (which terms shall not be inconsistent with the provisions of the TIA, but may modify, amend, supplement or delete any of the terms of the indenture with respect to such series debt securities).

## **General**

We may sell the debt securities, including original issue discount securities, at par or at a substantial discount below their stated principal amount. Unless we inform you otherwise in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series or any other series outstanding at the time of issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of securities under the applicable indenture.

We will describe in the applicable prospectus supplement any other special considerations for any debt securities we sell which are denominated in a currency or currency unit other than U.S. dollars. In addition, debt securities may be issued where the amount of principal and/or interest payable is determined by reference to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such securities may receive a principal amount or a payment of interest that is greater than or less than the amount of principal or interest otherwise payable on such dates, depending upon the value of the applicable currencies, commodities, equity indices or other factors. Information as to the methods for determining the amount of principal or interest, if any, payable on any date, the currencies, commodities, equity indices or other factors to which the amount payable on such date is linked.

United States federal income tax consequences and special considerations, if any, applicable to any such series will be described in the applicable prospectus supplement. Unless we inform you otherwise in the applicable prospectus supplement, the debt securities will not be listed on any securities exchange.



We expect most debt securities to be issued in fully registered form without coupons and in denominations of U.S. \$2,000 and any integral multiples of \$1,000 in excess thereof. Subject to the limitations provided in the applicable indenture and in the prospectus supplement, debt securities that are issued in registered form may be transferred or exchanged at the designated corporate trust office of the trustee, without the payment of any service charge, other than any tax or other governmental charge payable in connection therewith.

### **Global Securities**

Unless we inform you otherwise in the applicable prospectus supplement, the debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with, or on behalf of, a depositary identified in the applicable prospectus supplement. Global securities will be issued in registered form and in either temporary or definitive form. Unless and until it is exchanged in whole or in part for the individual debt securities, a global security may not be transferred except as a whole by the depositary for such global security to a nominee of such depositary or by a nominee of such depositary to such depositary or another nominee of such depositary or by such depositary or any such nominee to a successor of such depositary or a nominee of such successor. The specific terms of the depositary arrangement with respect to any debt securities of a series and the rights of and limitations upon owners of beneficial interests in a global security will be described in the applicable prospectus supplement.

### **Governing Law**

The indentures and the corresponding debt securities shall be construed in accordance with and governed by the laws of the State of Delaware.

### **DESCRIPTION OF UNITS WE MAY OFFER**

We may issue units consisting of a combination of two or more of any offered securities, at a single price or at a separate price for each security included in the unit. The securities offered may be issued separately or may be evidenced by a separate unit certificate, which may or may not trade separately. The terms and conditions governing the issuance of any units, including the form and content of any certificate evidencing the units, will be described in detail in the prospectus supplement to be filed in connection with the offering of such units.

## **PLAN OF DISTRIBUTION**

We may sell the securities offered by this prospectus to one or more underwriters or dealers for public offering, through agents, directly to purchasers or through a combination of any such methods of sale. The name of any such underwriters, dealers or agents involved in the offer and sale of the securities, the amounts underwritten and the nature of its obligation to take the securities will be specified in the applicable prospectus supplement. We have reserved the right to sell the securities directly to investors on our own behalf in those jurisdictions where we are authorized to do so. The sale of the securities may be effected in transactions (a) on any national or international securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, (b) in the over-the-counter market, (c) in transactions otherwise than on such exchanges or in the over-the-counter market or (d) through the writing of options.

We and our agents and underwriters, may offer and sell the securities at a fixed price or prices that may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. The securities may be offered on an exchange, which will be disclosed in the applicable prospectus supplement. We may, from time to time, authorize dealers, acting as our agents, to offer and sell the securities upon such terms and conditions as set forth in the applicable prospectus supplement.

If we use underwriters to sell securities, we will enter into an underwriting agreement with them at the time of the sale to them. In connection with the sale of the securities, underwriters may receive compensation from us in the form of underwriting discounts or commissions and may also receive commissions from purchasers of the securities for whom they may act as agent. Any underwriting compensation paid by us to underwriters or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers, will be set forth in the applicable prospectus supplement to the extent required by applicable law.

Underwriters may sell the securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions (which may be changed from time to time) from the purchasers for whom they may act as agents.

Dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions under the Securities Act. Unless otherwise indicated in the applicable prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase debt securities as a principal, and may then resell the debt securities at varying prices to be determined by the dealer.

If so indicated in the prospectus supplement, we will authorize underwriters, dealers or agents to solicit offers by certain specified institutions to purchase offered securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. Such contracts will be subject to any conditions set forth in the applicable prospectus supplement and the prospectus supplement will set forth the commission payable for solicitation of such contracts. The underwriters and other persons soliciting such contracts will have no responsibility for the validity or performance of any such contracts.

Underwriters, dealers and agents may be entitled, under agreements entered into with us, to indemnification against and contribution towards certain civil liabilities, including any liabilities under the Securities Act.

To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the price of the securities. These may include over-allotment, stabilization, syndicate short covering transactions and penalty bids. Over-allotment involves sales in excess of the offering size, which creates a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriters to reclaim selling concessions from dealers when the securities originally sold by the dealers are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the securities sold in an offering to be higher than it would otherwise be. These transactions, if commenced, may be discontinued by the underwriters at any time.

Any securities other than our common stock issued hereunder may be new issues of securities with no established trading market. Any underwriters or agents to or through whom such securities are sold for public offering and sale may make a market in such securities, but such underwriters or agents will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given as to the liquidity of the trading market for any such securities. The amount of expenses expected to be incurred by us in connection with any issuance of securities will be set forth in the applicable prospectus supplement. Certain of the underwriters, dealers or agents and their associates may engage in transactions with, and perform services for, us and certain of our affiliates in the ordinary course of business.

During such time as we may be engaged in a distribution of the securities covered by this prospectus we are required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes us, any affiliated purchasers, and any broker-dealer or other person who participates in such distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase, any security which is the subject of the distribution until the entire distribution is complete. Regulation M also restricts bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of our shares of common stock.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

## **INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Our certificate of incorporation provides that a director will not be personally liable to us or to our stockholders for monetary damages for breach of the fiduciary duty of care as a director, including breaches which constitute gross negligence. This provision does not eliminate or limit the liability of a director:

- for breach of his or her duty of loyalty to us or to our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (relating to unlawful payments or dividends or unlawful stock repurchases or redemptions);
- for any improper benefit; or
- for breaches of a director's responsibilities under the federal securities laws.

Our certificate of incorporation also provides that we indemnify and hold harmless each of our directors and officers to the fullest extent authorized by the DGCL, against all expense, liability and loss (including attorney's fees, judgments, fines, ERISA excise taxes or penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such person in connection therewith.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of Milestone, pursuant to the forgoing provisions or otherwise, Milestone has been informed that in the opinion of the SEC such indemnification by it is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

## **INTERESTS OF NAMED EXPERTS AND COUNSEL**

The validity of the securities being offered by this prospectus will be passed upon for us by Morse, Zelnick, Rose & Lander, LLP, 825 Third Avenue, New York, NY 10022. A partner in Morse, Zelnick, Rose & Lander, LLP owns 22,333 shares of Milestone common stock.

Baker Tilly Virchow Krause, LLP, an independent registered public accounting firm, has audited our consolidated financial statements for 2014 and 2015 included in our 2015 Annual Report, as set forth in their report, which is incorporated by reference in this Prospectus and elsewhere in the registration statement. Our consolidated financial

statements for 2014 and 2015 are incorporated by reference in reliance on Baker Tilly Virchow Krause, LLP's report, given on their authority as experts in accounting and auditing.