MILESTONE SCIENTIFIC INC.
Form 424B5
January 31, 2019
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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.

SUBJECT TO COMPLETION, DATED January 31, 2019

Prospectus Supplement

(To the Prospectus dated May 4, 2016)

MILESTONE SCIENTIFIC INC.

_____ Shares of Common Stock

Warrants to Purchase _____ Shares of Common Stock

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 February [___], 2024. 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 American stock exchange under the symbol "MLSS." On January [__], 2019, the last reported sales price of our common stock on the NYSE American was $[ ] 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 American, any other national securities exchange or any other nationally recognized trading system.

Based on 33,825,701 shares of outstanding common stock as of January 30, 2019, of which 20,580,723 were held by non-affiliates as of such date, and a per share price of $0.54 as of December 12, 2018, the last reported sales price of our common stock on the NYSE American on such date, the aggregate market value of our outstanding common stock held by non-affiliates is approximately $11,113,590. The aggregate amount of all securities we have offered and sold and continue to offer for sale pursuant to General Instruction I.B.6 of Form S-3 during the twelve calendar month period that ends on, and includes, the date of this prospectus supplement is $[ ], inclusive of the shares offered hereby.

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-6 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.

	Per Share and Accompanying Warrant	**Total**
Offering price	$	$
Underwriting discount and commissions (1)	$	$
Proceeds, before expenses, to us (1)	$	$

In addition, we have agreed to reimburse up to $[ ] of the out-of-pocket fees and expenses of the underwriter in connection with this offering. See "Underwriting" for additional information about our compensation arrangements with the Underwriter.

We have granted the underwriter 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 February [___], 2019.

Sole Book Running Manager

Maxim Group LLC

February [__], 2019

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Prospectus Supplement

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Prospectus

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 consolidated subsidiaries, unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent*®; *CompuMed*®; *CompuFlo*®; *DPS Dynamic Pressure Sensing technology*®; *Milestone Scientific*®; *the Milestone logo*®; *SafetyWand*®; *STA Single Tooth Anesthesia System*®; and *The Wand*®. 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 accompanying 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, management believes are reasonable. 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 behalf or on behalf of any of our affiliates and none of the sources cited by us consented to the inclusion of any data from its reports, and we have not 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.

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," "estim "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

Milestone Scientific is a biomedical technology research and development company that patents, designs, develops and commercializes innovative diagnostic and therapeutic injection technologies and devices for medical, dental, cosmetic and veterinary applications. 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 resources on redefining the worldwide standard of care for injection techniques by making the experience more comfortable for the patient by reducing the anxiety and stress of receiving injections from the healthcare provider. Our computer-controlled injection systems make injections precise, efficient and virtually painless. Milestone's proprietary *DPS* Dynamic Pressure Sensing technology® is our technology platform that advances the development of next-generation devices, regulating flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, with specific applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections.

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

- Establishing Milestone's *DPS* Dynamic Pressure Sensing technology platform as the standard-of-care in painless and precise drug delivery, providing for the first time objective visual and audible in-tissue pressure feedback, and continuing to expand platform applications;

- Following obtaining successful FDA clearance of our first medical devices in June 2017, Milestone Scientific is transitioning from a research and development organization to a commercially focused medical device company;

- Commercializing our *CompuFlo*® Epidural System, a transformative device for epidural anesthesia procedures;

- Expanding our global footprint of our *CompuFlo* Epidural System by partnering with distribution companies worldwide; and

- Obtaining regulatory approval for our proprietary cosmetic injection device for delivery of botulinum toxin (such as *Botox*® and *Dysport*®) and subsequent commercial launch.

Recent Developments

On November 20, 2018, the Company received a letter from the NYSE American LLC (the "Exchange") stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the "Company Guide"). On December 20, 2018, the Company submitted a plan of compliance (the "Plan") to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020. On January 24, 2019, the Company received a letter from the Exchange stating that the Company's Plan has been accepted by the Exchange. The Company is still not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide and its listing on the Exchange is being continued pursuant to an extension granted by the Exchange. If the Company is not in compliance with the continued listing standards by May 20, 2020, or if the Company does not make progress consistent with the Plan, the Exchange will initiate delisting procedures as appropriate. The Company may appeal a delisting determination in accordance with Section 1010 and Part 12 of the Company Guide.

Intra-Articular Instrument Regulatory Approval

As of January 30, 2019, the Company's application for the intra-articular instrument, U.S. Food and Drug Administration (“FDA”) 510(k) market clearance, expired without being approved. The Company intends to submit a new application with the FDA for the 510(k) market clearance on this instrument later in 2019.

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. Information contained on or accessed through our website is not part of this prospectus supplement. Our common stock is listed on the NYSE American stock exchange under the ticker symbol “MLSS”.

THE OFFERING

Issuer:	Milestone Scientific Inc.
Securities offered by us:	[_____] shares of our common stock and warrants to purchase up to an aggregate of [_____] 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 February [__], 2024. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Public offering price	$[ ] per share of common stock and warrant.
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 underwriter a 45-day option to purchase up to an additional [_____] shares of common stock and/or 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 manufacturing, marketing, sales and distribution of our epidural instrument and development of new products and new product uses, working capital and general corporate purposes. See “Use of Proceeds.”
NYSE American listing:	Our common stock is listed on the NYSE American 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 American, 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 [_____] shares of our common stock outstanding as of January [__], 2019. The number of shares of common stock outstanding excludes [_____] shares of common stock issuable upon exercise of outstanding stock options, which have a weighted average exercise price of $[ ] per share, and [_____] shares of common stock issuable upon exercise of outstanding warrants, which have a weighted average exercise price of $[ ] per share.

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

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $[ ] per share in the net tangible book value of the common stock you purchase in this offering. See "Dilution" on page S-[__] for a more detailed discussion of the dilution you will incur if you purchase shares of our common stock in this offering.

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 American. Without an active market, the liquidity of the warrants will be limited.

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.

Provisions of the warrants in this offering could discourage an acquisition of us by a third party.

In addition to the discussion of the provisions of our certificate of incorporation, as amended, certain provisions of the warrants in this offering could make it more difficult or expensive for a third party to acquire us. Such warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the warrants. Further, the warrants provide that, in the event of certain transactions constituting “fundamental transactions,” with some exception, holders of such warrants will have the right, at their option, to require us to repurchase such warrants at a price described in the warrants. These and other provisions of the warrants in this offering could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating our strategy to commercialize our *CompuFlo* Epidural System;
- the success of our strategy to commercialize our *CompuFlo* Epidural System;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions that could adversely impact the market acceptance or competitive advantages of our *CompuFlo* Epidural System;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- our ability to successfully develop and commercialize our products and services for the healthcare industry;
- conditions in the medical device industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for small, medical device companies, in particular, have historically experienced extreme price and volume fluctuations. These fluctuations

often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

Almost all of our outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended. In addition, we have an effective S-3 registration statement on file with the SEC covering the sale by us of up to $30 million of securities, including common stock, preferred stock, debt, convertible debt, warrants and units. To date, we have sold $[ ] of common stock under that registration statement. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

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 the warrants, for the manufacturing, marketing, sales and distribution of our epidural instrument, the development of new products and new product uses, general corporate and working capital purposes.

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 $[___] 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, 2018 was approximately $[ ], or approximately $[ ] per share. Net tangible book value is determined by subtracting our total liabilities from our total tangible assets, and net tangible book value per share is determined by dividing our net tangible book value by the number of outstanding shares of our common stock. After giving effect to the sale of [_____] shares of our common stock and accompanying warrants to purchase [_____] shares of our common stock in this offering at the public offering price of $[ ] per share (assuming $[**0.01**] of the public offering price is attributable to each warrant to purchase [___] shares of common stock), and after deducting the underwriting discount and commissions, and 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 adjusted net tangible book value as of September 30, 2018 would have been approximately $[ ], or approximately $[ ] per share. This represents an immediate increase in net tangible book value of approximately $[ ] per share to our existing stockholders and an immediate dilution in net tangible book value of approximately $[ ] per share to investors participating in this offering. The following table illustrates this calculation on a per share basis:

Public offering price per share of common stock, not including $[___] 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, 2018	$
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 underwriter does not exercise its over-allotment option. If the underwriter exercises its 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 participants in this offering.

The above discussion and table are based on [_____] shares of common stock issued and outstanding as of September 30, 2018 and exclude [_____] shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2018, which have a weighted average exercise price of $[ ] per share, and [_____] shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2018, which have a weighted average exercise price of $[ ] per share.

The issuance of the shares of common stock in the offering will result in an anti-dilution adjustment to the Company's Series A Preferred Stock, reducing the optional and contingent conversion prices of the Series A Preferred Stock to $[ ] and $[ ], respectively. Upon issuance of the shares of common stock upon exercise of the warrants, if the exercise price thereof shall be less than either of such conversion prices of the Series A Preferred Stock then in effect, such issuance would so result in a further anti-dilution adjustment to such conversion price.

capitalization

The following table sets forth our cash and cash equivalents and capitalization, as of September 30, 2018:

- on an actual basis; and
- on a pro forma, as adjusted basis, as adjusted based on an offering price of $[ ] per share of common stock to give effect to the sale of [_____] 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.

	As of September 30, 2018	
	Unaudited, Actual	**Unaudited, Pro forma, As Adjusted**
Cash and cash equivalents	$414,829	
Stockholders' Equity:		
Series A Preferred stock	7	
Common stock	35,655	
Additional paid-in capital	87,971,298	
Accumulated deficit	(86,179,797)	
Treasury stock, at cost, 33,333 shares	(911,516)	
Total Stockholders' Equity	$915,647	

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 January 31, 2019, there were 33,825,701 shares of common stock outstanding and 33,333 shares held in the treasury.

Subject to preferences that may apply to any shares of preferred stock 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 is 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.

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 American, which apply for so long as our common stock is listed on the NYSE American, 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 February [__], 2024. 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 shares 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.

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 make a distribution or distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock (not including any shares of common stock issued by us upon exercise of the warrant), (ii) subdivide outstanding shares of common stock into a larger number of shares, (iii) combine (including by way of reverse stock split) outstanding shares of common stock into a smaller number of shares, or (iv) issue 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 American, 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 for the offering. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase, and we have agreed to sell to it, the number of shares of common stock and warrants 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:

Underwriter	Number of Shares	Number of Warrants
Maxim Group LLC		
Total		

The underwriting agreement provides that the obligation of the underwriter 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 its counsel and to other conditions. The underwriter is 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 underwriter 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 underwriter may exercise this option only to cover over-allotments made in connection with this offering. We will be obligated, pursuant to the option, to sell these additional shares and additional warrants to the underwriter to the extent the option is exercised. If any additional shares and/or additional warrants are purchased, the underwriter will offer the additional shares and/or 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 underwriter a cash fee equal to 7% of the gross proceeds raised in this offering. The underwriter proposes 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 underwriter may offer some of the shares and warrants to other securities dealers at such price less a concession of up to [ ]% or $[ ] per share and accompanying warrant. After the offering to the public, the offering price and other selling terms may be changed by the underwriter without changing the proceeds we will receive from the underwriter.

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 underwriter's 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 underwriter pays 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 executive officers and directors 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 underwriter 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 underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriter 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 underwriter's 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 underwriter 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 underwriter may elect to exercise all or part of the over-allotment option. The underwriter 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 underwriter 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 underwriter 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 underwriter is 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 the NYSE American stock exchange, in the over-the-counter market, or otherwise.

In connection with this offering, the underwriter 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 Securities Exchange Act of 1934, as amended. 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 underwriter for all reasonable out-of-pocket expenses actually incurred up to $[ ], including but not limited to reasonable legal fees, incurred by the underwriters in connection with the offering. We will reimburse the underwriter for all such expenses regardless of whether the offering is consummated.

We have also granted the underwriter a right of first refusal to act as placement agent, underwriter or investment bank on any subsequent private or public offering of our securities for a period of nine months from the sale of common stock and warrants in this offering.

Our Relationships with the Underwriter

The underwriter and its 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. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriter and its 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 underwriter and its 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 underwriter against liabilities relating to the offering arising under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, 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 underwriter 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 underwriter. The underwriter may agree to allocate a number of shares for sale to its online brokerage account holders. The underwriter may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriter may distribute prospectus supplements and accompanying base prospectuses electronically. The underwriter has informed us that it does not expect to confirm sales of shares offered by this prospectus supplement to accounts over which it exercises 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.

The underwriter 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 permitted to do so.

Listing

Our common stock is listed on the NYSE American stock exchange 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.

LEGAL MATTERS

The validity of the securities offered by this prospectus supplement will be passed upon for us by Golenbock Eiseman Assor Bell & Peskoe LLP, New York, New York. Harter Secrest & Emery LLP, Rochester, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The consolidated financial statements of Milestone Scientific Inc. included in our Annual Report on Form 10-K for the year ended December 31, 2017 have been audited by Friedman LLP, an independent registered public accounting firm, as stated in their report which is incorporated by reference herein, and has been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

INFORMATION INCORPORATED BY REFERENCE

This prospectus supplement "incorporates by reference" certain information that we have filed with the SEC under the Securities Exchange Act of 1934, as amended. 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, 2017, filed on April 2, 2018;
- Quarterly Report on Form 10-Q for the quarters ended March 31, 2018, as filed on May 15, 2018, June 30, 2018, as filed on August 14, 2018, and September 30, 2018, as filed on November 14, 2018;
- Current Reports on Form 8-K filed on June 1, 2018, November 23, 2018 and January 25, 2019; 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.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement under the Securities Act that registers the securities offered hereby. The registration statement, including the exhibits and schedules attached thereto and the information incorporated by reference therein, contains additional relevant information about the securities and our Company, which we are allowed to omit from this prospectus supplement pursuant to the rules and regulations of the SEC. In addition, we file annual, quarterly and current reports and proxy statements and other information with the SEC. Our SEC filings are also available on the SEC's website at www.sec.gov. Copies of certain information filed by us with the SEC are also available on our website at www.milestonescientific.com. We have not incorporated by reference into this prospectus supplement the information on our website and it is not a part of this document.

$30,000,000

MILESTONE SCIENTIFIC INC.

Common Stock

Preferred Stock

Debt Securities

Warrants

Units

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

Our common stock is listed on the NYSE MKTS under the symbol “MLSS”. As of April 25, 2016, the aggregate market value of our outstanding common stock held by non-affiliates was $23,954,939 based on 21,687,164 shares of outstanding common stock, of which 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). Our web site is located at 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.

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," "estim "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*® (*CompuDent*® instrument) and the disposable *Wand* handpiece. *CompuDent* provides painless injections for all routine dental treatments, including root canals, crowns, fillings and cleanings. Milestone's Computer-Controlled Local Anesthetic Delivery (C-CLAD) instrument handpiece does not look or feel like a syringe and 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*® 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*® technology for the precise delivery of medicaments**.** The *CompuFlo* pressure/force Computer-Controlled Local Anesthetic Delivery (C-CLAD) technology is an advanced, patented and FDA-approved medical technology for the painless and accurate delivery of drugs, anesthetics and other medicaments into all tissue types, as well as for the aspiration of bodily fluids or previously injected substances. Its regulation and control of flow rate continues to provide the *CompuDent* and *CompuMed* benefits of painless injections, while its *Dynamic Pressure Sensing*® capability provides visual and audible in-tissue pressure feedback, identifying tissue types to the healthcare provider. This pressure feedback extends the benefit of painlessness from anesthetics with known viscosities to a wide range of liquid drugs and other medicaments with varying viscosities and flow rates. *Dynamic Pressure Sensing* also allows the healthcare provider to know when certain types of tissues have been penetrated and permits the healthcare provider to inject medicaments precisely at the desired location. Thus, pressure feedback can prevent the suffusion of tissue outside the intended target area, a vitally important characteristic in the injection of chemotherapeutics and other toxic substances.

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

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

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

Initial market response to the *STA Instrument* following its commercial debut in February 2007 proved to be less than robust. Moreover, at that time, 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® 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 20th Century. The instrument has been favorably evaluated in more than 50 peer reviewed or independent clinical research reports. *CompuDent*, including its ergonomically designed single-use handpieces (*The Wand*®*)*, provides numerous, well documented benefits:

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

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®

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®

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:

	U.S. NUMBER	DATE OF ISSUE
Computer Controlled Drug Delivery Systems		
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
Engineered Sharps Injury Protection Devices		
Handpiece for Injection Device with a Retractable and Rotating Needle	6,428,517	8/6/2002
Safety IV Catheter Device	6,726,658	4/27/2004
Safety IV Catheter Infusion Device	6,905,482	6/14/2005
Handpiece for Injection Device with a Retractable and Rotating Needle	6,966,899	11/22/2005

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. 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;