MILESTONE SCIENTIFIC INC.
Form 10-K
April 01, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

Or

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

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3545623**

State or other jurisdiction of Incorporation or organization (I.R.S. Employer Identification No.)

220 South Orange Avenue, Livingston, NJ 07039

(Address of principal executive offices)

Registrant's telephone number, including area code: 973-535-2717

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $.001 per share	NYSE American

Securities registered pursuant to section 12(g) of the Act: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or

information statements incorporated by reference in Part III of this Form 10-K or any amendment of this Form 10-K.

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging Growth Company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of June 29, 2018, the last business day of the registrants most recently completed second fiscal quarter, the aggregate market value of the common stock held by non- affiliates of the issuer was $15,368,647. This amount is based on the closing price of $.79 per share of the registrant's common stock as of such date, as reported on the NYSE American. As of March 29, 2019, the registrant has a total of 40,855,720 shares of Common Stock, $0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

MILESTONE SCIENTIFIC INC.

Form 10-K Annual Report

TABLE OF CONTENTS

PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	15
Item 1B.	Unresolved Staff Comments	23
Item 2.	Description of Property	23
Item 3.	Legal Proceedings	23
Item 4.	Mine Safety Disclosure	23
PART II		
Item 5.	Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities	24
Item 6.	Selected Financial Data	24
Item 7.	Management's Discussion and Analysis or Plan of Operations	25
Item 7A.	Quantitative and Qualitative Disclosure about Market Risk	32
Item 8.	Financial Statements	32
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	33
Item 9A.	Controls and Procedures	33
Item 9B.	Other Information	33
PART III		
Item 10.	Directors, Executive Officers, Promoters and Control Persons and Corporate Governance; Compliance with Section 16 (a) of the Exchange Act	34
Item 11.	Executive Compensation	37
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	41
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accounting Fees and Services	43
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	45
SIGNATURES		47
EXHIBITS		

FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K are "forward-looking statements" (within the meaning of the Private Securities Litigation Reform Act of 1995) regarding the plans and objectives of management for future operations. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Milestone Scientific Inc. ("Milestone Scientific") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Milestone Scientific's plans and objectives are based, in part, on assumptions involving the continued expansion of its business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific. Although Milestone Scientific believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. Considering the significant uncertainties inherent in the forward-looking statements included herein, particularly in view of Milestone Scientific's early stage operations, the inclusion of such information should not be regarded as a representation by Milestone Scientific or any other person that the objectives and plans of Milestone Scientific will be achieved. Milestone Scientific undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

PART I

All references in this report to "Milestone Scientific, Inc.," "us," "our," "we," the "Company "or "Milestone" refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Inc. and Milestone Medical Inc. and affiliate, Milestone Education LLC, 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*®; *Safety Wand*®; *STA Single Tooth Anesthesia System*®; and *The Wand*®.

Item 1. Business

Overview

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 believe our technologies are proven and well established.

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, used in various dental injections, with specific applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections.

In 1997, Milestone Scientific released its first commercial product, the first computer-controlled local anesthesia delivery (C-CLAD) system, into the North American marketplace. This product was our proprietary, computer-controlled anesthetic delivery device, initially marketed as *The Wand*®, a computer-controlled local anesthesia delivery (C-CLAD) device with a single-use disposable handpiece for the dental market, regulating and controlling the flow rate of anesthetics. This device was later re-branded commercially as the *CompuDent*® System with the addition of several new features.

In 2001, Milestone Scientific was issued the initial United States Patent for *CompuFlo*® technology, entitled "Pressure/Force Computer Controlled Drug Delivery Instrument with Exit Pressure," allowing the device to continuously monitor and control the exit pressure of medication and/or fluid during an injection. We call this innovation *DPS* Dynamic Pressure Sensing technology. This same technology also enables doctors to accurately identify different tissue types based on detecting exit pressure during an injection. Later in 2004, the United States Patent Office issued a "Notice of Allowance" for patent protection on two additional critical elements of our *CompuFlo* technology: "Drug Delivery Instrument with Profiles" and "Pressure/Force Computer Controlled Drug Delivery with Automated Charging".

Given our experience and established brand awareness within the dental industry, we elected to focus our initial product development efforts on the integration of *CompuFlo's DPS* Dynamic Pressure Sensing technology into our legacy dental injection system. In 2006, the FDA cleared the first system utilizing *CompuFlo's* DPS Dynamic Pressure Sensing technology— the STA (Single Tooth Anesthesia) System and handpiece for use in the dental market, providing continuous real-time visual and audible pressure feedback from the tip of the needle while also precisely regulating the flow rate. Because of combining the ability to regulate the flow rate and monitor pressure at the tip of the needle, Milestone Scientific developed the industry's first solution for painlessly administering an intra-ligamentary injection, i.e., "*single-tooth anesthesia*" which could be used as the only injection necessary for achieving dental anesthesia, foregoing the need to administer traditional injections such as a nerve branch block. In addition to *single-tooth anesthesia*, the STA System can effectively perform all the traditional injections that dentists routinely give but can provide them virtually pain free and with numerous clinical advantages. This device, which also utilizes a disposable handpiece, is currently marketed by Milestone Scientific as the *Wand STA*® System.

Milestone Scientific believes our dental devices have set a new standard of care for dental injections. Our dental devices have been used to administer tens of millions of injections worldwide. Each of our devices has a related single use disposable handpiece, leading to a continuing revenue stream following sale of the device. At present, we sell disposable handpieces unique to our legacy product (the *Wand* and *CompuDent*) to users who have not upgraded to our current dental product, the *Wand STA* System.

Building on the success of our proprietary, core technology platform for dental injections, and desiring to pursue other growth opportunities, we have recently begun to expand the uses and applications of our proprietary, patented technologies to achieve greater operational efficiencies, enhanced patient safety and therapeutic adherence, patient satisfaction, and improved quality of care across a broad range of medical specialties. In June 2017, we received FDA regulatory clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for certain medical applications. We intend to continue to expand the uses and applications of our *DPS* Dynamic Pressure Sensing technology.

We believe that we and our technology solutions are widely recognized by key opinion leaders (i.e., academics, anesthesiologists and practicing dentists whose opinions are widely respected), industry experts and medical and dental practitioners as a leader in the emerging, computer-controlled injection industry.

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 device 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 the global footprint of our *CompuFlo* Epidural System by partnering with distribution companies worldwide; and
- Continuing the commercial launch of our proprietary cosmetic injection device for delivery of botulinum toxin (such as *Botox*® and *Dysport*®).

Our dental devices are sold in the United States, US territories, Canada and in 60 other countries with FDA, CE and other clearances since receiving FDA clearance in 2017, our epidural devices have had minimal sales in the United States and Europe.

***DPS* Dynamic Pressure Sensing Technology; Our Proprietary Core Technology Platform**

Our first commercial product, our proprietary, computer-controlled anesthetic delivery device, initially marketed as the *CompuDent*® Wand/STA system later re-branded commercially as the *Wand /STA* System, for the dental market, uses patented technology, including a single-use disposable handpiece, to control the flow rate of the anesthesia during the injection, allowing virtually painless injections for all dental procedures with optimal effectiveness. Over the years, the *CompuDent* System has been widely heralded as a revolutionary device, considered one of the major advances in dentistry in the 20th century, and has been favorably evaluated in more than 50 peers reviewed or

independent clinical research reports.

Our next significant intellectual property advancement was a quantum improvement over our *CompuDent*® System – the development of our proprietary *CompuFlo*® Computer-Controlled Drug Delivery System with *DPS* Dynamic Pressure Sensing technology, an advanced and FDA-approved 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 the flow rate continues to provide painless delivery benefits, while its innovative 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. Such pressure feedback, part of our *DPS* Dynamic Pressure Sensing technology, 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, real-time continuous pressure feedback can prevent the injection to tissue outside the intended target area, an important characteristic in the injection of chemotherapeutics and other toxic substances.

In addition to the ability to determine exit pressure In-Situ (in the injection site tissue) at the tip of the needle, minimizing tissue damage (and eliminating the pain of the injection) because the flow rate and pressure of the injection are precisely controlled, *CompuFlo*® computer-controlled Drug Delivery Systems features a proprietary algorithm, which allow for the measurement of the exit pressure. These algorithms contain 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. *CompuFlo*® technology also enables devices to provide a digital record of the time and volume of anesthetic or medicament injected.

Each CompuDent® and Wand/STA System also includes a disposable injection handpiece that is extremely comfortable, light and easy to use, providing for precise tactile control during the injection, an electro-mechanical (computer-controlled) fluid delivery instrument and the ability to record data from the injection event. The pencil grip used with the handpieces provides the practitioner with enhanced tactile sense and accurate control and allows bi-directional rotation, eliminating needle deflection, resulting in a greater accuracy and success. The handpiece is vibration-free because it does not have a motor or electrical component in it and, since the handpiece does not look like a typical syringe, we believe it also reduces patient anxiety and offers the possibility of curing dental phobia of which an estimated 40 million Americans suffer.

As confirmed by numerous noted medical and dental experts within academia and the clinical practice arenas, *CompuFlo* Systems using *DPS* Dynamic Pressure Sensing technology have 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.

Devices using *DPS* Dynamic Pressure Sensing technology such as the *CompuFlo* System can be used to inject a wide variety of liquid medicaments as well as anesthetics. We believe our *CompuFlo* System avoids the negative side effects from the use of traditional hypodermic drug delivery injection devices, which are well documented in dental and medical literature and include risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications. Pain and tissue damage often result from uncontrolled flow rates and pressure created during the administration of drug solutions into human tissue. While several technologies have can control the flow rate, we believe our patented *DPS* Dynamic Pressure Sensing technology and *CompuFlo* Systems provide the ability to accurately and precisely control the pressure of the injection as well.

We believe our DPS Dynamic Pressure Sensing technology and *CompuFlo* Systems provides the following benefits:

- minimizes the pain associated with injections, resulting in a more comfortable injection experience for the patient;
- provides visual and audible in-tissue pressure feedback, identifying the desired target location to the healthcare provider, extending 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;
- allows the healthcare provider to know when the target location is present and permits the healthcare provider to inject medicaments precisely at the desired location;
- provides a digital record of the time and volume of anesthetic or medicament injected;
- minimizes tissue damage because the flow rate and pressure of the injection are controlled;
- provides an integrated injection database of algorithms that have been defined which allow for the measurement of the exit pressure, containing 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;
- the pencil grip used with the handpieces allows significant tactile sense and accurate control;
- new injections made possible with the technology eliminate collateral numbness;
- bi-directional rotation of the handpieces eliminates needle deflection resulting in greater success and more rapid onset of anesthesia in injections; and

the use of a single patient use, disposable handpieces minimize the risk of cross contamination.

Our first system utilizing a *DPS* Dynamic Pressure Sensing technology platform was our STA System and related handpiece for the dental market, currently marketed as the *Wand/ STA System*. Another platform extension of our *DPS* Dynamic Pressure Sensing technology platform is the *CompuFlo* Epidural System. In addition, we have developed platform extensions of our *DPS* Dynamic Pressure Sensing technology platform for intra-articular (for administering corticosteroids, hyaluronic acid and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions), cosmetic and veterinary applications. We intend to continue to develop and commercialize new applications of our *DPS* Dynamic Pressure Sensing technology platform as commercial line extensions.

CompuFlo **Epidural Computer Controlled Anesthesia System**

In June 2017, we received FDA regulatory clearance to sell the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States for certain medical applications. The *CompuFlo* Epidural Computer Controlled Anesthesia System obtained CE mark approval in September 2014, allowing it to be marketed and sold in most European countries and many other countries accepting CE approved devices.

The *CompuFlo* Epidural Computer Controlled Anesthesia System (or the *CompuFlo* Epidural System) is one such platform extension of our *DPS* Dynamic Pressure Sensing technology platform, providing anesthesiologists and other healthcare providers the ability, for the first time, to quantitatively determine and document the pressure at the needle tip in real-time for proper needle placement in epidural procedures used for labor/delivery and back pain management. Our proprietary *DPS* Dynamic Pressure Sensing technology allows the *CompuFlo* Epidural System to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify and confirm placement in the epidural space.

Our *CompuFlo* Epidural System provides an objective tool that we believe consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the intrafilamentary tissue. In studies, the *CompuFlo* Epidural System with *DPS* Dynamic Pressure Sensing technology has been shown to be effective in correctly identifying the epidural space. Knowing the precise location of a needle tip during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes. In the absence of fluoroscopy, identifying the epidural space by relying on the subjective perception of loss of resistance to saline requires a very long education period and learning curve and could result in morbidity and lack of efficacy. During back pain management epidural procedures, where fluoroscopy is commonly used, the *CompuFlo* Epidural System allows the clinician to locate the epidural space, without using fluoroscopy, thereby protecting the patient and clinician from unnecessary exposure to radiation along with significantly reducing capital and operating costs.

An abstract presented at the 45th Chilean Congress of Anesthesiology on November 11, 2017, entitled: Utilization of Dynamic Pressure Sensing™ in Epidural Procedures for Child Birth and representing the first formal presentation of our *CompuFlo* Epidural System in South America, summarized the results of a recent independent, investigator-led clinical study evaluating the use of Milestone's *CompuFlo* Epidural System in 50 labor and delivery patients, concluding that the epidural space was correctly identified in 100% of the patients. In addition, the epidural space was located on the first attempt with all the patients. There were no cases of accidental puncture of the dura, a common risk factor for traditional epidural procedures using the loss of resistance technique. We believe that this represents a significant benefit for the payors, physicians, and most importantly, the patients.

In July 2017, Milestone Scientific acquired certain patent rights and other intellectual property rights related to the computer-controlled injection device of APAD Octrooi B.V. and APAD B.V. This patent portfolio solidifies our patent rights for computer-controlled local anesthetic delivery (C-CLAD) technology and expands our proprietary rights and provides low cost and simple instrument to deliver epidural injections.

In November 2018, a new clinical study published in the International Journal of Obstetric Anesthesia that finds the *CompuFlo* Epidural System to be successful in objectively identifying the epidural space—even in difficult patients. Accurate epidural space identification can build physician and resident confidence while reducing the number of attempts, poor catheter placement and accidental dural punctures that can be costly to the hospital and painful for the patient.

In January 2019, the Company announced the results of a four hundred patient clinical trial by researchers from the University of Miami, University of Texas and Northwestern University, and two prominent California-based pain clinics. Published-Ahead-of-Print in Anesthesia & Analgesia (the official Journal of the International Anesthesia Research Society), the randomized, controlled study compared the effectiveness of the *CompuFlo* Epidural System in labor and delivery and chronic pain management, where loss of resistance and fluoroscopy are the current standards of care. The *CompuFlo* Epidural System was found to be ninety-nine percent successful in objectively identifying the epidural space even in challenging patients with a higher body mass index.

In February 2019, the company announced a new 120-patient clinical study published in Anesthesiology Research & Practice that verifies the *CompuFlo* Epidural System consistently differentiates false loss of resistance from true loss of resistance during epidural placement. In all cases where the *CompuFlo* Epidural System's pressure measurements were used to objectively identify the epidural space, the block was performed successfully with no complications.

In February 2019, the Company announced Ospedale "Pugliese Ciaccio" di Catanzaro is the first hospital in Italy to use the *CompuFlo* Epidural System for all epidurals in labor and delivery. For a local hospital performing a limited number of epidurals, the *CompuFlo* Epidural System offers a real-time, objective tool for accurate epidural space identification to help reduce failure rates and accidental dural punctures that can require further treatment and interventions.

CompuFlo **Intra-Articular Computer Controlled Injection System**

Another platform extension utilizing our DPS Dynamic Pressure Sensing technology platform and *CompuFlo Epidural* System are our devices for administering corticosteroids and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions. As features of our DPS Dynamic Pressure Sensing technology, this device also precisely controls in-tissue pressure, increasing 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 intra-articular injections and numerous organs, subcutaneous and intramuscular injections.

We believe our intra-articular injection device is particularly efficacious for arthritis patients who are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious because the doctor using a syringe fails to locate the intra-articular space or does not inject the appropriate volume of corticosteroids or other medicament into that space. Our *CompuFlo* Epidural System has been shown successful in an independent animal study in administering medicaments into a certain intra-articular space using its computer-controlled pressure sensing capabilities.

The intra-articular device has obtained CE mark clearance and may be marketed and sold in most European countries and many other countries accepting CE approved devices. In December 2016, we received notification from the FDA that our 510(k) applications for marketing approval of the intra-articular device did not demonstrate that the device was as safe and effective as a legally marketed devices. The original 510K filed with FDA expired in January 2019. We intend to submit a new 510(k) application in 2019 that we believe will demonstrate substantial equivalency; however, we can provide no assurances of when, if ever, we will receive FDA clearance for our intra-articular device.

Cosmetic Botulinum Injection Device

The American Society of Plastic Surgeons (ASPS) reported that among the 14.2 million cosmetic minimally-invasive procedures performed in 2015, the top performed procedure, at 6.7 million procedures, was Botulinum Toxin Type A (commonly known as Botox) injection. Leveraging our experience in minimizing the pain of dental anesthetic injections, we established a joint venture in 2014 to develop and commercialize a device for the pain free injection of botulinum toxin. The joint venture entity, Milestone Advanced Cosmetic Systems, Inc., is owned 50% by us and 50% by Milestone China Company Limited (“Milestone China”), a company organized under the laws of Hong Kong and owned 40% by Milestone Scientific. Milestone China contributed $900,000 of cash to the joint venture and we have provided a royalty-free license to utilize our technology to the joint venture to develop a botulinum toxin injection device.

In November 2017, we announced plans for the commercial launch of our proprietary cosmetic injection device using our DPS Dynamic Pressure Sensing technology platform and our *CompuFlo* Cosmetic System for delivery of botulinum toxin. Our proprietary cosmetic injection device features improved needle placement with a comfortable stylus grip, precise dosing, the same technology platform that has made dental and epidural injections painless, and an intuitive touch-screen interface. Based on the positive outcomes of a series of multi-state human factor studies with targeted customers, we are not moving towards the commercial launch of our cosmetic device and applying for marketing clearance in Europe (CE clearance), and United States (FDA clearance). Although the Company's instrument has progressed beyond the development stage, additional equity financing is necessary to fund the regulatory process and, if approved the commercialization of the instrument. To this end, the Company is currently in the process of pursuing additional financing. However, the Company and Milestone China can provide no assurance that additional financing will be consummated on acceptable terms, or at all.

We believe that the touch screen and other platform improvements embodied by our cosmetic device will form the basis for our next generation of devices.

Veterinary Nerve Block Anesthesia Device

The effectiveness of our veterinary nerve block anesthesia device (existing medical device) for such use was confirmed by a pilot study and final report completed by Cornell University, College of Veterinary Medicine. Additional studies with other universities are in process with respect to horses and small animals. We are exploring commercialization opportunities.

The Wand STA System

In 2006, we received FDA clearance for our Wand/STA System and disposable handpiece, the first system utilizing CompuFlo's DPS Dynamic Pressure Sensing technology, for use in the dental market. The Wand/STA System and handpiece continue to provide all of the benefits of the CompuDent System, allowing dentists to provide virtually painless injections for all dental procedures, including routine fillings, as well as more sophisticated implants, root canals and crowns, while better facilitating single tooth anesthesia (now generally performed with a high-pressure spring-loaded gun-like device), but also incorporates the

"pressure feedback" elements of Milestone Scientific's patented
CompuFlo

Epidural System, thereby allowing dentists to administer injections accurately and painlessly into the periodontal ligament space, effectively anesthetizing a single tooth. Injections made by the Wand/STA System eliminate collateral numbness of the tongue, lips and facial muscles and often hasten the onset of anesthesia by eliminating the need for mandibular blocks. The Wand/STA also identifies intrafilamentary tissue, so dentists can find the precise location for single tooth anesthesia. This injection is of significant value in that it allows the dentist to profoundly anesthetize the tooth within one minute per root, versus up to 15-18 minutes for a block injection to take effect. The Wand /STA System can perform all the injections that can be done with a conventional dental syringe, and in addition, we provide the ability to perform the following: the palatal-anterior superior alveolar, anterior middle superior alveolar and inferior alveolar nerve block. The Wand/ STA System achieves these injections predictably and reliably. To date, substantially all our revenue has been generated by the Wand/STA System for dental applications.
Since its market introduction in the spring of 2007, the Wand/STA System has received favorable reviews and awards from the dental industry. In July 2007, noted industry publication Dentistry Today featured the Wand/STA System as one of the "Top 100 Products in 2007", helping to promote much broader recognition of the instrument and validating the Wand/STA System's value proposition for dentists and patients, alike. In early 2008, Medical Device & Diagnostic Industry magazine distinguished the Wand/STA System as a 2008 Medical Design Excellence Award winner in the "Dental Instruments, Equipment and Supplies" product category. Of the 33 products to receive this coveted award, the Wand/STA System was one of only two winning products that serve dental practitioners.

In December 2008, Milestone Scientific continued to win broad acclaim for the *Wand/STA* System by winning a "Townie Choice Award". The "Townie Choice" awards were originally started by Dr. Howard Darran and Farran Media, publisher of Dentaltown Magazine, to assist dentists in making product purchasing decisions, and are considered the "people's choice" of the products and services available to the dental industry today. That same month, the *Wand/STA* System was also named as a Dental Products Report "Top 100 2008 Product of Distinction". Additionally, the *Wand/STA* System was named one of Dentistry Today's "Top 100 Products" for the third consecutive year in 2010.

Other Devices

At earlier stages of development are our products using *CompuFlo*'s *DPS* Dynamic Pressure Sensing technology for less painful injections for use in rhinoplasty, colorectal surgery, podiatry and other disciplines. In the self-injectable market, there are many injectable drugs routinely self-administered in a home or office setting using spring loaded automatic injection devices by people who suffer from long term chronic conditions such as multiple sclerosis, rheumatoid arthritis, and other diseases of the auto immune system. We believe *CompuFlo*'s *DPS* Dynamic Pressure

Sensing technology, using pressure sensing capabilities, can serve as a painless subcutaneous injection method for these self-administered drugs. However, there can be no assurance that we will be able to successfully develop any such products, or that if developed, that we will be able to obtain FDA approval to market any such products, or even if we do obtain such FDA approval, that any such products will generate any revenue for us or be a commercial success.

Distribution and Marketing Arrangements

Our dental devices are sold in the United States, US territories, Canada and in 60 other countries abroad. In June 2017, we received FDA regulatory clearance to sell our first medical device, the *CompuFlo* Epidural Computer Controlled Anesthesia System in the United States. Since receiving FDA clearance in 2017, our epidural devices have had minimal sales in the United States and Europe.

Dental Market

In the spring of 2009, Milestone Scientific signed a distribution and marketing agreement with China National Medicines Corporation, dba Sinopharm. In early October 2012, the State Food and Drug Administration ("CFDA") of the People's Republic of China approved the *Wand/STA* System. However, the CFDA's approval of the *Wand STA* handpieces was not received until May 2014 and the distribution of these handpieces in China began in the fourth quarter of 2014.

The distribution and marketing agreement with Sinopharm were terminated in September 2014. Proximate to that time, we entered into a new agreement with Milestone China to be our distributor for the *Wand/STA* System and handpieces in China. Milestone Scientific then owned, forty (40%) percent of Milestone China (the "Milestone China Shares"). In June 2017, Milestone Scientific sold its Milestone China Shares to an unaffiliated United States domiciled purchaser for a promissory note secured by a pledge of the Milestone China Shares, and received a 10-year option to repurchase the Milestone China Shares at the same price as the purchase price paid for the Milestone China Shares within the first two years and at fair market value (as defined in such agreement) for the remainder of the 10-year term.

As of March 2, 2018, the promissory note was in default. In April 2018, Milestone Scientific entered into a Release, Assignment and Termination Agreement (the "Termination Agreement") with the issuer of the promissory note, pursuant to which, Milestone Scientific repaid the $250,000 payment made by the issuer and the issuer returned the Milestone China Shares to Milestone Scientific and cancelled the promissory note. Because of the Termination Agreement and related repayment made by Milestone Scientific, the Company derecognized the outstanding note receivable balance of $1,150,000 and the related deferred gain from financing transaction of $1,400,000. No gain or loss was recognized on the transaction.

In November 2012, Milestone Scientific signed an exclusive distributor and marketing agreement with a well-known U.S. domestic manufacturer and distributor, for the sale and distribution of the *Wand/STA* System and handpieces in the United States and Canada. The marketing initiative included participation in United States 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 United States and Canada. This exclusive distributor and marketing agreement were converted to a non-exclusive agreement as of December 31, 2016.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016, that agreement was replaced by a new agreement with Henry Schein providing for an exclusive distribution arrangement for our dental products in the United States and Canada by a newly formed marketing and sales group at Henry Schein.

Under this arrangement, we have a semi-dedicated independent sales force visiting dentists. Henry Schein's exclusive products sales specialist team, which is comprised of 25 sales representatives and supported by over 1,000 field service representatives, will exclusively market and distribute the Wand/STA System and handpieces, together with a select group of other devices in the United States and Canada. Our agreement with Henry Schein has minimum purchase orders to maintain exclusivity in the third through tenth years. We believe that this exclusive arrangement will be more effective than previous arrangements relying on Wand Dental's appearances at dental shows and catalog sales.

Medical Market

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the *CompuFlo* Epidural System. In June 2017, the FDA approved the *CompuFlo* Epidural System for epidural injections. Milestone Scientific is in the process of meeting with medical device distributors within the United States and foreign markets. Milestone Scientific's immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA Office of Device Evaluation, we filed a new 510(k) application for the device in June 2018. In August 2018, the FDA provided Milestone Scientific with a list of questions on the intra-articular 510(k) application filed in June 2018. Due to the delay in responding to FDA questions Milestone Scientific will be required file a new 510(K) application in 2019.

In February and March 2018, Milestone Scientific hired an Executive VP of Global Sales and Marketing and a Vice President of US Sales to fill a significant gap in our commercialization efforts of the *CompuFlo* Epidural System. In October 2018, Milestone Medical signed a Distributor Agreement in the U.S. This agreement provides that this Distributor will purchase and hold an inventory of the *CompuFlo* Epidural System and disposables for sale. At this time there have been no minimum purchase established with the Distributor. The Distributor identified above purchased five *CompuFlo* Epidural Systems and disposables after executing the Agreement.

We have entered into a limited number of distributor arrangements in Europe and the Middle East for our *CompuFlo* Epidural System. Our distribution strategy is initially aimed at having KOLs use and accept the device and initiates their own studies.

Veterinary Market

We are exploring various commercialization opportunities.

Patents and Intellectual Property

Milestone Scientific and its subsidiaries currently hold approximately 214 U.S. and foreign patents, and many patent applications. The Company's patents and patent applications relate to drug delivery methodologies, drug flow rate measurement, pressure/force computer-controlled drug delivery with exit pressure, dynamic pressure sensing, automated rate control, automated charging, drug

profiles, audible and visual pressure/force feedback, tissue identification, drug delivery injection unit, drug drive unit for anesthetic, handpiece and injection device. Milestone Scientific and its subsidiaries also currently hold approximately 29 registered U.S. and foreign trademarks, including *CompuDent®, CompuFlo®, DPS Dynamic Pressure Sensing technology®, Safety Wand®, STA Single Tooth Anesthesia System®,* and *The Wand®*

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

If Milestone Scientific's products infringe upon patent or proprietary rights of others, we may be required to modify processes or to obtain licenses. There can be no assurance that Milestone Scientific would be able to do so in a timely manner, upon acceptable terms and conditions, or at all. The failure to do so could have a material adverse effect on our business, financial condition and results of operations

Manufacturing

Milestone Scientific has informal arrangements with the manufacturer of the *Wand/STA* System, epidural and intra-articular devices and with one of the principal manufacturers, related party, of the handpieces for those items, respectively. Pursuant to these informal arrangements, our third-party manufacturers manufacture the *Wand/STA*

System under specific purchase orders without minimum purchase commitments, and at prices to be agreed upon in each such purchase order.

Our agreement with the principal manufacturer of handpieces includes pricing terms. Milestone Scientific has been supplied by the manufacturer of the *Wand/STA* System and its predecessor, the *CompuDent* System, since the commencement of production in 1998, and by the manufacturer of its handpieces since 2003. The manufacturer of our handpieces is in the People's Republic of China and the manufacturer of the device is in the United States. Changes to pricing of the *Wand/STA* System by the manufacturer could have a material adverse effect on our financial condition, business and results of operations. Termination of the manufacturing relationship with any of these third-party manufacturers could significantly and adversely affect our ability to produce and sell the products. Though other alternate sources of supply for handpieces exist, Milestone Scientific would need to recover its existing tools or have new tools produced to establish relationships with new suppliers. Establishing new manufacturing relationships could involve significant expense and delay. Any curtailment or interruptions of the supply, whether as a result or termination of the relationship, would have a material adverse effect on our financial condition, business and results of operations.

Competition

As of this filing, there is no subcutaneous drug delivery platform or device on the market regulating the flow rate *and* pressure of an injection capable of delivering a painless injection at the desired location like Milestone Scientific's proprietary, patented devices having our *DPS* Dynamic Pressure Sensing technology.

Milestone Scientific's devices compete based on their performance characteristics and the benefits provided to the practitioner, patient and the business operations. Clinical studies have shown that our devices reduce fear, pain and anxiety for many patients, and Milestone Scientific believes that they can reduce practitioner stress levels, as well. Other computer-controlled local anesthesia delivery (C-CLAD) options are the Quicksleeper and SleeperOne, from Dental Hi Tec, Dentapen from Septodant, the Calajet from Aseptico, and the Comfort Control Syringe by Dentsply.

The Quicksleeper was invented in France by Dr. Alain Villette in 1991. It is marketed as the only local anesthetic delivery device in France that allows the ability to perform all intraoral local anesthetic injection techniques, including osteocentral anesthesia, quickly and without failure. The extra feature that gives the Quicksleeper this ability is a built-in motor in the syringe/handpiece that renders the syringe both an injector and a perforator of bone. That is, the handpiece of the Quicksleeper can perform an intraosseous injection via a motor driven perforation of the cortical plate of bone. A standard dental needle that attaches to the syringe spins as the motor rotates the handpiece thus acting as a perforator. However, the handpiece is relatively heavy, weighing 240 g. as compared to a standard syringe that weighs 80 g. Injection speed increases during the injection, but the operator cannot control when the injection speed increases.

Another computer-controlled injection instrument is called the Comfort Control Syringe or CCS. In the early 1990's, Dr. Mark Smith, a dentist from Ontario, Canada, invented a device that he incorporated into his practice as the local anesthetic delivery method. After perfecting the system, he released the rights of this device to Dentsply. In this system, many of the functions of the computer can be controlled directly from the syringe during the injection process. The base unit allows the dentist to program one of five different injections by pressing a single button. The five buttons marked on the base unit are block, infiltration, PDL, intraosseous and palatal. Each of these injections has a specific corresponding rate of local anesthetic delivery associated with it. The CCS enables a wide range of injection speeds controlled by the operator and the ability to control the computer directly from the syringe, but, since the CCS computer can be controlled by hand, the syringe must contain a certain amount of electronic equipment and this adds bulk to its circumference. The circumference of the CCS syringe is 112mm compared to 36mm for a traditional syringe, and 17mm for the *Wand/STA* System. In addition, because of the electronics in the syringe, the operator will feel a slight amount of vibration in the syringe while the injection occurs. This will not affect the anesthesia, but it certainly is a feeling that is different from the traditional syringe or the *Wand/STA* System, which both have no such vibration. The vibration in the Quicksleeper is minimal. This instrument is no longer being marketed.

The Calajet instrument is manufactured in Europe and has been very slow to grow market acceptances. It recently began marketing in the USA with similar result. The instrument is a higher price than the Wand STA and does not provide the DPS software. Although a competitor, we believe that without a substantial distribution network this instrument will have a difficult time to be successful in the USA.

The Dentapen from Septodent is the newest competitor in the market. This device is manufactured in Europe and began marketing in the USA in 2018. This device is priced similar to Wand/STA, but at this time, to our knowledge, it is slow to attract viable distribution in the USA.

Milestone Scientific’s proprietary, patented devices with its *DPS* Dynamic Pressure Sensing technology platform also 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.

Rapid technological change and research may affect our products. Current or new competitors could, at any time, introduce new or enhanced products with features that render our products less marketable or even obsolete. Therefore, Milestone Scientific 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 Scientific maintain an effective distribution network with a strong marketing plan. Any new products must comply with applicable regulatory authorities before they may be marketed. Milestone Scientific cannot assure that it can compete successfully, that competitors will not develop technologies or products that render our products less marketable or obsolete, or, that Milestone Scientific will succeed in improving its existing products, effectively develop new products, or obtain required regulatory approval for those products.

Government Regulation

The manufacture and sale of medical devices and other medical products are subject to extensive regulation by the FDA pursuant to the U.S. Food, Drug and Cosmetic Act (“FDC Act”), and by other federal, state and foreign authorities. Under the FDC Act, medical devices must receive FDA clearance before they can be marketed commercially in the United States. Some medical products must undergo rigorous pre-clinical and clinical testing and an extensive FDA approval process before they can be marketed. These processes can take many 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 U.S. Food, Drug and Cosmetic 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 devices. Class I devices are those devices whose safety and effectiveness can reasonably be ensured through general controls, such as adequate labeling, pre-market notification, and adherence to the FDA’s Quality

System Regulation (“QSR”), also referred to as “Good Manufacturing Practices” (“GMP”) regulations. Some Class I devices are further exempted from some of the general controls. Class II devices are those devices whose safety and effectiveness reasonably can be ensured using 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.

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. Currently, 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 United States. However, the FDA may determine that the proposed device is not substantially equivalent or may require further information, such as additional test data, before the FDA is able to decide regarding substantial equivalence. Such determination or request for additional information could delay market introduction of products. 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 United States. If a manufacturer or distributor cannot establish that a proposed device is substantially equivalent to a legally marketed device, the manufacturer or distributor will have to seek 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.

The FDA cleared the Wand, our *CompuDent* System and its disposable handpieces, for marketing in the United States for dental applications in July 1996; the *CompuMed*® System for marketing in the United States for medical applications in May 2001; the *Safety Wand*® for marketing in the United States for dental applications in September 2003; the *Wand/STA* System for dental applications in August 2006; and our *CompuFlo* Epidural System in June 2017. For us to commercialize other products in United States, Milestone Scientific would have to submit additional 510(k) applications to the FDA.

In 2017, the FDA reduced the barrier to marketing clearance for certain dental devices. As such the entry into the dental market for other manufactures of injection devices may increase. However, we believe that any new device will be very limited in sales volume without a significant distributor in the dental market.

Though certain dental devices have received FDA marketing clearance, there can be no assurance that any of the other medical devices 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.

Milestone Scientific 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, because of FDA inspections, MDR reports or other information, the FDA believes that Milestone Scientific 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, our officers or employees. Any action by the FDA could result in disruption of operations for an undetermined amount of time.