

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) September 6, 2017

MILESTONE SCIENTIFIC INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-14053
(Commission
File Number)

13-3545623
(IRS Employer
Identification No.)

220 South Orange Avenue, Livingston Corporate Park, Livingston, New Jersey 07034
(Address of principal executive office) (Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 8.01. Other Events.

Daniel S. Goldberger, President and Chief Executive Officer of Milestone Scientific Inc. (the “Company”), is scheduled to present an Investor Presentation at each of the 6th Annual Gateway Conference in San Francisco on Thursday, September 7, 2017 and at the Rodman & Renshaw 19th Annual Global Investment Conference in New York on Tuesday, September 12, 2017. A copy of the Investor Presentation is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.

99.1

[Investor Presentation.](#)

Description

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 6, 2017

MILESTONE SCIENTIFIC INC.

By: /s/ Joseph D'Agostino

Joseph D'Agostino
Chief Financial Officer



INVESTOR PRESENTATION

DAN GOLDBERGER- PRESIDENT & CEO OF MILESTONE SCIENTIFIC INC.

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SAFE HARBOR

This presentation contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, expected revenues and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to 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 Milestone's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and risk factors detailed from time to time in Milestone's periodic filings with the Securities and Exchange Commission, including without limitation, Milestone's Annual Report for the year ended December 31, 2016. The forward-looking statements in this presentation are based upon management's reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

INVESTMENT HIGHLIGHTS

- Platform Technology for computerized injections
 - Can be customized for a variety of verticals
- Wand Dental subsidiary demonstrates profitable growth model
 - Exclusive distribution with Henry Schein in US & Canada
- FDA & CE approval of CompuFlo® Epidural
 - COMPASS pivotal trial will be published
- CE approval of Intra-Articular indication
- Solid IP, 23 US patents, foreign counterparts
- Scalable recurring revenue business model can be extended to a variety of verticals

REDEFINING INJECTION TECHNOLOGY

The hypodermic syringe was invented over 160 years ago



THE PROBLEM

Pain
Discomfort
Anxiety



THE SOLUTION

Painless Injection
Comfort
Precise Injection



Milestone's Patented
DPS® Dynamic Pressure
Sensing Technology



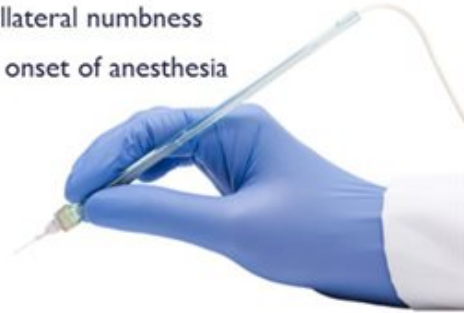
IT BEGAN WITH DENTAL - THE WAND®

For Clinicians:

- Anesthetize a single tooth
- Reduction in chair time
- Reduced quantity of anesthetic
- Fewer complications
- Ergonomic grip
- Reduced patient cancellations

For Patients:

- Painless injection
- No collateral numbness
- Faster onset of anesthesia



THE WAND[®] SINGLE TOOTH ANESTHESIA INSTRUMENT

- FDA and CE marketing clearance
- Over 70 MM injections delivered to date
 - Over \$10.5M in sales in 2016
- Favorable evaluations in more than 50 peer reviewed and independent clinical research reports
- 21 patents around DPS[®] Dynamic Pressure Sensing technology

Wand Dental subsidiary is cash flow positive on a standalone basis



Wand STA



MILESTONE
SCIENTIFIC

US DENTAL DISTRIBUTION - HENRY SCHEIN

- Recently announced a 10-year exclusive agreement with Henry Schein, Inc. (NASDAQ: HSIC), the world's largest provider of dental products
- Henry Schein's Exclusive Products Sales Specialist Team will exclusively market and distribute The Wand® STA®
 - 25 sales representatives and supported by 900 field service representatives
 - Minimum purchase orders to maintain exclusivity in the third through tenth years
- TAM: About 150,000 dentists in the US will perform about 75,000,000 injections this year alone
 - We plan to ship about 3,500,000 disposables in 2017, representing about 5% market penetration



REVENUE GROWTH

(\$ millions)

	2015	2016	6 months ended June 30, 2017
Revenue	\$ 9.5	\$ 10.5	\$ 6.2
GM%	68%	60%	65%



THE FUTURE



BEYOND DENTAL – THE MEDICAL OPPORTUNITY



Epidural



Intra-Articular



Peripheral Nerve Block



Cosmetic

- **TOTAL ADDRESSABLE MARKET > \$1B in the US alone**
- Unique ability to identify tissue type and control flow rate
 - Allows for wide array of medical instruments across disciplines
- Completed development on first two medical instruments
 - Received CE Mark approval on epidural and intra-articular instruments
 - Received FDA clearance for epidural
 - Pursuing FDA clearance for Intra-Articular
- Other applications under review in attractive markets with favorable competitive landscape

NYSE MKT: MLSS

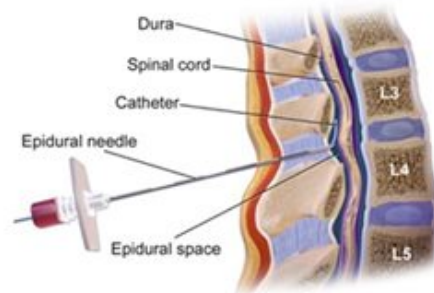
**TOTAL ADDRESSABLE MARKET:
> \$1B IN THE US ALONE**

Procedure	Application Area	# Injections per Year (millions)
Epidural	Labor & Delivery	1.8
	Periop Pain Management	3.0
	Chronic Pain	8.0
Peripheral Nerve Block		9.0
Intra-articular	Knees	2.5
	Shoulders	1.5
	Hips/Other	1.0
Cosmetic	Botox	8.4
	Fillers	3.7
TOTAL		39.0

* Company estimates derived from CDC, CMS, NCHS, AHRQ, NVSS, ASPS, and ASDS data

EPIDURAL ANESTHESIA APPLICATION

- CompuFlo makes the procedure more reliable for the clinician
- Reliably identify epidural space, reducing the risk of human error
 - Confirmation that epidural space is identified



THE COMPUFLO® EPIDURAL INSTRUMENT

- Patented DPS® Technology improves clinical outcomes and patient satisfaction
- Control fluid flow rate
- Monitor pressure
- Portable with battery backup



510(k) #161883 Indication for Use: The CompuFlo Epidural Computer Controlled Anesthesia System is intended for use with an epidural needle for the real time verification of needle tip placement in the lumbar epidural space....

COMPUFLO® EPIDURAL – PIVOTAL STUDY

- Completed COMPASS Study (CompuFlo® Assessment Study), a randomized, controlled, parallel group, multicenter, pivotal study
 - Designed to assess the safety and effectiveness of the epidural space verification
 - Reached enrollment of 400 patients consisting of two separate arms:
 - (i) pain management;
 - (ii) labor and delivery
- Demonstrated the reliability of the CompuFlo technology in identifying and confirming the epidural space location
 - Success rates of 99% in labor/delivery and in the epidural management of pain
 - Clinically proven superior to LOR in labor/delivery patients with BMI > 31

INTRA-ARTICULAR INJECTION APPLICATION

- Reliably and Precisely place the therapeutic agent where the physician wants it
- Approved in the EU
- Pursuing 510(k) clearance in the US



COSMETIC

- Under development for use with aesthetic injections
 - Fast, precise, painless injections
 - Accurate & comfortable stylus grip
 - Simple electronic records



INVESTMENT THESIS

- ✓ Wand Dental subsidiary is growing profitably continuing to prove that the technology and business model works
- ✓ Proprietary disposables provide recurring revenue with high margins
- ✓ Entering medical markets with clinically proven Indications for Use
 - ✓ Anesthesia is approved in the US and EU
 - ✓ Intra-Articular is approved in EU and in process in the US
 - ✓ Cosmetic under development
- ✓ Operating margins will expand with growing revenue
 - ✓ Highly scalable business model
- ✓ Value Drivers 2017/2018:
 - ✓ Operating Results
 - ✓ COMPASS Study Publications
 - ✓ Distribution Contracts



THANK YOU

The Wand, STA Single Tooth Anesthesia System, and DPS Dynamic Pressure Sensing Technology are registered trademarks of Milestone Scientific, Inc.

TWELVE MONTHS 2016 (AUDITED)

Income Statement

	Twelve Months Ended	
	December 31,	
	2016	2015
Revenue	\$10,482,005	\$9,491,569
Gross Profit	\$6,306,472	\$6,443,309
Gross Margin	60%	68%
Operating		
Loss	\$(6,513,960)	\$(3,056,748)
Net Loss	\$(5,946,507)	\$(5,467,522)

Balance Sheet

	31/Dec/16	31/Dec/15
Cash and cash equivalents	\$ 3,602,229	\$ 4,194,384
Total current assets	\$ 12,713,812	\$ 11,824,151
Other assets	\$ 17,355	\$ 17,355
Total assets	\$ 13,550,650	\$ 12,809,327
Total current liabilities	\$ 5,014,321	\$ 3,643,835
Total long-term liabilities	\$ -	\$ -
Total liabilities	\$ 5,014,321	\$ 3,643,835
Working Capital	\$ 7,699,491	\$ 8,180,316
Total stockholders' equity	\$ 8,536,329	\$ 9,165,492

Clean capital structure with no debt

CAP TABLE AS OF AUGUST 31, 2017

Issued and Outstanding	33,000,000
Options, \$2.04 average strike price	3,186,782
Warrants, \$2.55 average strike price	1,592,775
Preferred as converted (\$7,000,000/\$2.37 per share)	3,000,000
Fully Diluted Capitalization	40,779,557

KEY STATISTICS & NUMBERS AS OF DEC 31, 2016

▪ Ticker:	MLSS
▪ Exchange:	NYSE MKT
▪ Cash and Treasury Bills:	\$3.6 M
▪ Working Capital:	\$7.7 M
▪ Total Stockholder's Equity:	\$8.5 M
▪ Security Ownership of Management:	32.8%

RECENT PUBLICATIONS

ASA 41st Annual Regional Anesthesiology and Acute Pain Medicine Meeting, 2016 New Orleans, LA
Objective Epidural Space Identification with the Compuflo® Epidural Instrument is Equivalent to Fluoroscopy/LOR

R.E. Gebhard*, T. Muller-Bertram, D. Dobecsi, M. Walker, S. Ilic
 * Department of Anesthesiology, Perioperative Medicine, and Pain Management
 University of Miami – Miller School of Medicine

Introduction:
 Successful and safe performance of epidural anesthesia or epidural injections relies on correct identification of the epidural space (ES). While methods for simple and objective identification of the ES have been proposed, most anesthesiologists and/or pain physicians still utilize either the subjective manual feeling of a loss of resistance (LOR) or objective but relatively invasive radiological confirmation via fluoroscopy (F). Pressure measurement at the tip of the epidural needle and real-time graphs and numeric display of such pressures via a computerized epidural pump (Compuflo® Epidural Instrument) has previously been demonstrated to successfully identify ES (1). The aim of this investigation is to evaluate this simple, objective, and non-invasive technology when compared to LOR and/or fluoroscopy.

Methods:
 After IRB approval, a total of 106 patients scheduled to receive epidural needle placement, as part of their medical management, will be enrolled in this prospective controlled multi-center trial. Patients will be randomized to either have the ES identified by standard of care methods utilizing either LOR or fluoroscopy (C Group) or by utilizing real-time pressure measurement at the epidural needle tip via the Compuflo® Epidural Instrument (EP Group). A blinded independent observer will evaluate correct identification of the ES. Successful identification of the ES is defined by either loss of sensation in at least 2 dermatomes bilaterally after local anesthetic injection, or correct spread of dye as demonstrated by fluoroscopy.

Results:
 This is a preliminary report of the first 106 patients enrolled in this investigation. Groups were similar in terms of demographics. Identification of the ES in Group EP resulted in equal success rates and number of required attempts as in Group SC (Table 1). No evidence of clinically significant adverse events was seen in any patient.



Compuflo® Visual Confirmation of the Epidural Space Location



Limited By Federal Law to Investigational Use Only

Conclusion:
 Our preliminary data suggest that identification of the ES by utilizing a computerized injection pump technology and obtaining real-time pressure measurements from the needle tip, results in non-inferior success rate and equivalent safety when compared to fluoroscopy.

This simple, compact, and mobile technology may have the potential to avoid exposure of the patient to radiation and also allow for greater flexibility and cost savings.

References:
 1. Howell TK et al. Anesthesia 1996; 13: 238-43
 2. Churba O et al. Reg Anesth Pain Med 2008; 13: 346-52

RECENT PUBLICATIONS



RESEARCH
EDUCATION
TREATMENT
ADVOCACY

Real-Time Epidural Space Identification with the CompuFlo® Epidural Instrument is Equivalent to Loss of Resistance Technique coupled with the Fluoroscopy Confirmation



E. Moller-Bertram¹, R.E. Gelband², D. Doback³, M. Walker¹, J. Shi¹, S. Bai¹
 1. Desert Pain Clinic, Rancho Mirage, CA, 2. University of Miami Department of Neurology
 3. San Diego Pain Institute, San Diego, CA, 4. Gelband, CA

INTRODUCTION

Success of the epidural technique depends upon the correct identification of the epidural space (ES). The incidence of difficult epidural catheter placement and early failure is significantly more likely among the morbidly obese population. The increased amount of subcutaneous and epidural fat in the obese population can pose a significant challenge to successful epidural catheter placement.

METHODOLOGY

After IRB approval and under United States Food and Drug Administration Investigations Device Exemption, a total of 400 patients were scheduled to receive epidural needle placement, as part of their medical management, and were enrolled in prospective controlled multi-center trial. Patients were randomized to either have the ES identified by standard of care methods utilizing either Loss of Resistance Technique (LOR) or by utilizing real-time pressure measurement at the epidural needle tip via the CompuFlo® Epidural Instrument (EP Group). A blinded independent observer evaluated correct identification of the ES defined as correct spread of dye demonstrated by fluoroscopy.



CompuFlo® Audio/Visual Confirmation of the Epidural Space Location

RESULTS

This is a preliminary report of 70 subject whose Body Mass Index exceeded 31 Kg/m². Groups were similar in terms of demographics, average age 49.4 and 52.5. Identification of the ES in Group EP resulted in equal success rates and number of required attempts as in Group SC (100% and 1) (p=0.78 - NS). No evidence of clinically significant adverse events was seen in any patient.

This initial data suggest that identification of the ES by utilizing a computerized injection pump technology and obtaining real-time pressure measurements from the needle tip, results in equivalent success rate and safety when compared to fluoroscopy. This compact and mobile technology may have the potential to avoid exposure of the patient to radiation without compromising procedure effectiveness.

Study was implemented under US FDA IDE sponsored by Milestone Scientific, Inc.

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