## MILEST NE SCIENTIFIC'

### NYSE: MLSS

### **Investor Presentation**

August 2023



### Safe Harbor Statement

This presentation contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, expected revenues, timing of regulatory approvals 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, future business decisions and regulatory developments, 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 the 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, 2022. 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.

### **Executive Summary**

3

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- Milestone Scientific Inc. is a leading developer of computerized drug delivery instruments that provides virtually painless and precise injections
  - Rapidly expanding within the world-wide dental market
  - Leveraging track record in dental to aggressively expand into larger medical markets such as anesthesiology
  - High margin, recurring razor/razor blade business model
  - 20+ years of patent protection. With 19 US patents and 133 foreign patents issued, Milestone Scientific is the leader in modern injection technology.
  - Solid balance sheet with \$5.7M cash and marketable securities, with no long-term debt



### **THE STA - Single Tooth Anesthesia System**

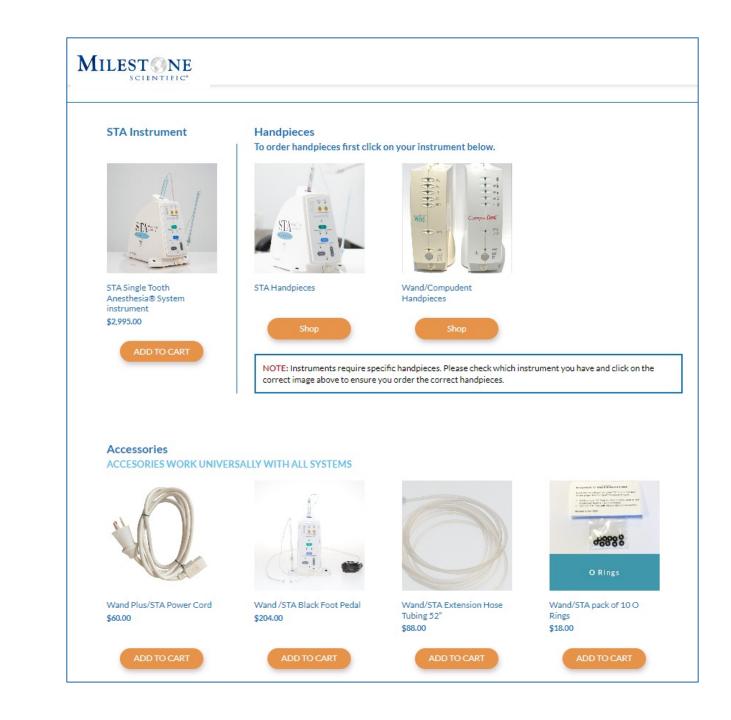
- FDA and CE marketing clearance in over 50 countries
- Over 90 Million injections delivered to date
- Key Opinion Leader recognition worldwide
- Included in dental school programs as best practice
- Aggressive domestic and international marketing initiatives underway
- Wand Dental Inc. subsidiary is cash flow positive on a standalone basis



4

### **Direct Sales Model**

- Launched January 2023
- Satisfied traction obtained
- Margin improvement
- Increased knowledge about customer ordering patterns
- Potential for up-selling and customer reactivation



5

### Why Enter the Epidural Market?

### **Market Size**

6

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- Epidural procedures are one of the fastest growing procedures in the US and worldwide
- It is estimated that over 11M epidural procedures are performed each year in the US and over 30M worldwide
- Over \$5B spent annually on epidural injections in the US alone
- Approximate breakdown of U.S. epidural procedures:
  - 2.4M epidural procedures out of ~4M births
  - 9M intervention steroid injections
  - ~900,000 total and growing Neuroaxial Regional Blocks for hip and knee surgeries



# Current Epidural Technology – the hypodermic syringe from 1860

The technique of "single-shot" lumbar epidural anesthesia was first developed in 1921 by Spanish military surgeon, Fidel Pagés, and hasn't changed significantly since.







7

1946 Glass Loss of Resistance (LOR)

"Modern" LOR Syringes

### **Listening to the Market - Addressing the Needs**

- Placement of an epidural needle is difficult
- Requires 60-90 placements before reaching an adequate skill level
- 17% of failure rates are due to false loss of resistance (when the needle enters soft tissue or fatty tissue and the provider believes it is in the epidural space when it is not) resulting in a failure to provide pain relief. This requires another attempt while the patient remains in labor and pain.



### Listening to the Market – Addressing the Needs

- Epidural Dural punctures are as high as 5+%
- An Epidural puncture is when the Dura is breached and the needle enters the spinal canal, causing cerebral spinal fluid to leak resulting in headaches, pain, infection, and other morbidities costing insurance companies and hospitals additional time and money
- 20% of epidural blood patches also fail and require additional care (a blood patch is a procedure to try and repair the Dural punctures)



### **Cost Effectiveness Analysis of Two Labor Epidural Techniques**

Cost Effectiveness Analysis of Two Labor Epidural Analgesia Techniques; Real-Time Pressure Sensing Technology and Traditional Technique

Rovnat Babazade; Yu-li Lin; Hsu, En Shuo; Guillermo Hidalgo; Giorgio Capogna; Massimo Micaglio; Rakesh Vadhera; Ralf Gebhard Department of Anesthesiology, University of Texas Medical Branch at Galveston

#### Introduction

Accidental dural puncture (ADP) is a complication of epidural anesthesia with reported rates of 0.5-4% (1). Following ADP, the incidence of post-dural puncture headache (PDPH) has been reported to be more than 75%. It is a significant cause of increased cost, prolonged hospitalization and need for further treatment and interventions such as epidural blood patch (2). The use of continuous real-time pressure sensing technology

(Compuflo) has been recently validated as a tool to identify the epidural space and is gaining popularity as an alternative to traditional loss of resistance (LOR) technique (3).

The aim of this study was to conduct a cost-effectiveness analysis of real-time pressure sensing technology and traditional LOR technique in parturients requesting labor epidural analgesia.



#### Methods

With approval of the Institutional Review Board, we collected data from electronic health records at UTMB to identify parturients aged between 18 and 50 who had epidural anesthesia for planned vaginal delivery between 2015 and 2019.

For the cost-effectiveness analysis, we estimated the total cost for the hospital stay for delivery and readmission for epidural blood patch (EBP) if any. We first categorized patients into two groups by the presence of epidural replacement. Within each group, we further categorized the patients into three groups: 1) no headache or EBP; 2) with headache but no EBP; 3) with EBP. Patients who had multiple orders for epidural anesthesia during the hospitalization were considered to have epidural replacement. Headache after epidural anesthesia was identified using international classification of diseases codes. All costs were adjusted to the same time period, using the consumer price index for medical care.

#### Results

We included 4483 deliveries from 4353 parturients in this study. We examined the parturient characteristics at the inpatient visit for delivery are presented in **Table1**. The cost-effectiveness was performed using TreeAge. The model is presented in **Figure1**. Incremental cost of both techniques are presented in **Table 3**.

aturient characteristic	Mean ± SD	Median
Age (years)	27.4 ± 5.7	26.7
BMI (kg/m <sup>2</sup> )*	32.3 ± 6.5	31.3
Gravidity	2.7 ± 1.7	2.0
Parity	1.7±1.3	1.0
	N	%
Race/ethnicity		
Asian	168	3.75
African American	506	11.29
Caucasian/White	1197	26.70
Hispanic or Latino	2591	57.80
Other	21	0.47

Table 2. Incremental cost of traditional method compared to real-time pressure sensing technology method

Method	Cost	Incremental Cost	Effect (pain score)	Dominance
Study device	16363.02	0.00	2.00	
Traditional	16866.96	503.94	2.00	Dominated

#### Conclusion

To our knowledge, this is the first study in the literature, we report cos of the real-time pressure sensing technique and the traditional LOI technique in parturients requesting labor epidural analgesia Compared to the traditional LOR technique, real-time pressur sensing technology costs about 504 dollar less per hospital stay o average.

- Russell S. Management strategies for unintentional dural puncture: a Canadian experience survey in an academic settin Can J Anaesth. 2018
- 2. Amorim JA. Post-dural (post-lumbar) puncture headache: risk factors and clinical features. Cephalalgia. 2012
- 3. Gebhard RE. Objective epidural space identification using continuous real-time pressure sensing technology

### A New Standard of Care in Anesthesia

- Now with our patented CompuWave<sup>™</sup> and CathCheck<sup>™</sup> Verification System features, anesthesiologists should be able to save significant time and institutions should save significant costs
- Correlates subjective feel with objective visual and audible verification of pressure changes
- Offers real-time needle location with consistent distinction of true loss of resistance
- Builds physician confidence resulting in fewer attempts; less Dural punctures reducing complications and costs
- Accelerates procedure learning curve for residents and trainees



11

### New Features Added to CompuFlo Epidural Instrument

- With the addition of the patented CompuWave technology, we can now verify epidural placement <u>AND</u> confirm catheter placement in real time using the patients' pulse
- The waveform indicates whether or not the catheter is in the epidural space

12

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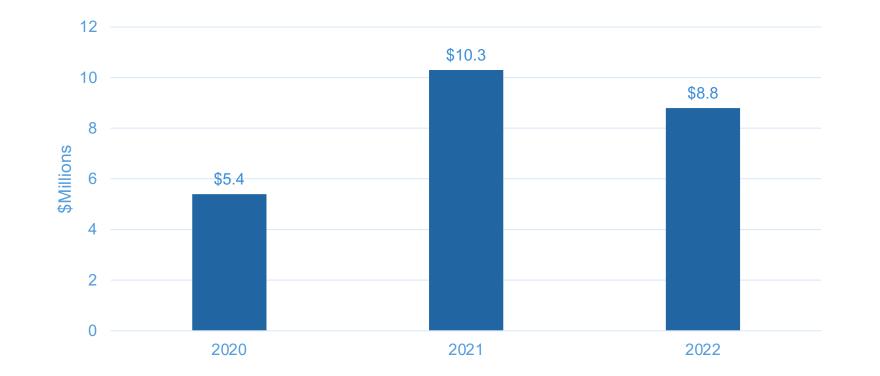
### **Beyond Epidural: The Medical Opportunity**

	Catheter Check	~	Now with our patented CompuWave <sup>™</sup> technology the CompuFlo Epidural Instrument can now check catheters in 1-2 minutes not 20- 40 minutes.
17	Thoracic	~	High-risk nature of procedure; 3 – 5 % of all epidurals; received 510(k) FDA clearance for use in the thoracic region of the spine, expanding the use of our technology within the area of pain management
	Peripheral Nerve Block	~	Received peripheral nerve block patent
	Intra-articular	~	Large worldwide market for injections into the joints
	Botox	~	Received US Patent in April 2020

### **Recent Milestones**

- ✓ Revenue for Q2 2023 increased 77% to \$2.9 million due domestic and international growth
  - Growth was due in part to the early success of the new online portal
  - The portal provides a closer and more direct relationship with dentists, which contributed to a 178% increase in gross profit to \$1.9 million for Q2 2023
- ✓ Received 510(k) FDA clearance for use in the thoracic region of the spine, expanding the use of the technology within the area of pain management
- ✓ CompuFlo Epidural System was registered with the U.S. Government's System for Award Management (SAM), which is required for bidding on contracts with federal government agencies
- ✓ Commenced sales of <u>CompuFlo</u>® Epidural disposables into a number of pain management clinics
- ✓ Reported positive reimbursement from first commercial payers for its CompuFlo Epidural System for patients who were involved in motor vehicle accidents

### **Historical Revenue**



The decrease in 2022 revenue was driven by lower revenue from China and deliberate termination of a U.S. distributor agreement, which is expected to drive future revenue growth and higher margins.

Dental division profitable standalone basis

### **Key Statistics**

•	Ticker:	MLSS
•	Exchange:	NYSE
•	Share Price (08/17/2023):	\$1.08
•	Shares Outstanding (08/14/2023):	71.4 M
•	Market Cap:	\$77.1 M
•	Cash and Marketable Securities (6/30/2023):	\$5.7 M
•	Long-Term Debt (6/30/2023):	\$0
•	Insider Ownership:	25.2%

### Thank You

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NYSE: MLSS Website: <u>https://www.milestonescientific.com/</u> Investor Relations: Crescendo Communications, LLC Email: <u>mlss@crescendo-ir.com</u> Tel: 212-671-1020