



## Delivering *Precise,* *Pain-Free* Injections

(NYSE: MLSS)

Shares Outstanding: 77.3m

Price 9/25/24: \$0.99

Market Capitalization: \$76.5M

Cash (Q2 6/30/2024): \$5.8M

Debt: \$0

Insider Ownership: 25%

September 2024



## Safe Harbor Statement

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This presentation contains forward-looking statements regarding events, conditions and financial trends, including the timing and financial impact of Milestone's ability to implement its business plan, expected revenues and timing of regulatory approvals, that may affect Milestone's future operations, business strategy, results of operations and financial condition. 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. The primary assumptions which drive Milestone's business plan and outlook are based on the timing and amount of additional capital which Milestone may be able to raise when needed (which if not raised or delayed may force us to delay, curtail or eliminate commercialization efforts of our CompuFlo® Epidural System), the cost and rate of acceptance of our medical products, the continued performance of two third parties to manufacture our products without material change in our informal manufacturing arrangements, the lack of disruptions at a manufacturing facility of our manufacturers, including shortages of or delays in obtaining chips and other components, and the growth of our distribution arrangements and penetration of our new marketing channels.

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, 2023. 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

**Innovative Injection Technology:** Patented, computer-controlled systems for precise, efficient, and safe medical and dental injections.

**Dynamic Pressure Sensing Technology®:** Regulates flow rate and measures pressure for next-gen devices, with applications in drug delivery and anesthesia.

**Established Legacy Business:** STA Single Tooth Anesthesia for dental market

- 80M+ Injections to date
- Patent Protected
- Generating **\$10M** in annual revenue
- High Gross Margins (more than **70%**)



### Entering High-Growth Pain Management Epidural Market

- **\$2B** growing market with recurring revenue characteristics
- Expanding Medicare coverage in process
- Distribution growing rapidly

## Problem: Placing Epidurals Can be Challenging



**Needle placement  
is difficult**

Requires **60 placements**  
before adequate skill  
level reached<sup>4</sup>



**17%  
failure rates**

Requires re-placement  
of epidural<sup>5</sup>



**Epidural Dural  
punctures are high**

Up to 5+% in the lumbar  
region, and **17%** and **30%** for  
the thoracic and cervical spine<sup>6</sup>

<sup>4</sup> Kipac DJ et al. "The regional anesthesia 'learning curve': What is the minimum number of epidural and spinal blocks to reach consistency?" Regional Anesthesia 1996

<sup>5</sup> Mark Hochman, DOG et al. "Objective Epidural Space Identification Using Continuous, Real-Time Pressure Sensing Technology: A Randomized Controlled Comparison With Fluoroscopy and Traditional Loss of Resistance." Anesth Analg 2019;129:1319-27

<sup>6</sup> Effectiveness of Epidural Blood Patch in the Management of Post-Dural Puncture Headache - Anesthesiology August 2001, Vol 95, 204-209



# Solution: Introducing CompuFlo® Epidural System

*A New Standard of Care in Anesthesia*

Tackling the vast epidural market | Technology for precise needle placement and verification in epidural anesthesia



# Solution: CompuFlo® Epidural System

Advanced innovation in the anesthesiology market = A New Standard of Care

- **FDA cleared** for use in lumbar, thoracic, and cervical-thoracic junction of the spine (Feb. 2023)
- **Patented CompuWave and CathCheck Verification System** allow anesthesiologists to save significant time, costs
- Provides **visual + audible verification** of pressure changes
- Offers **real-time needle location** + shows loss of resistance
- Builds **physician confidence**, resulting in fewer attempts; accelerates learning curve for residents + trainees
- **No Dural punctures**, reducing complications and costs

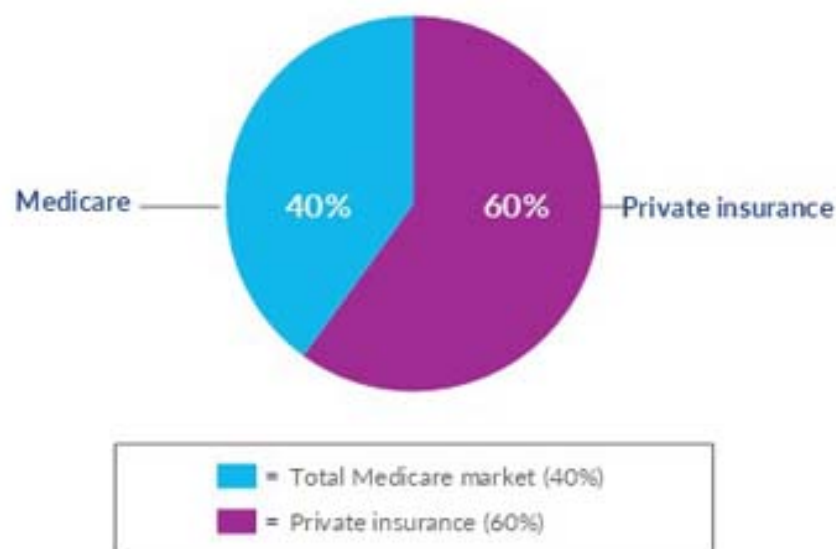


## Opportunity: Millions Seeking Chronic Back Pain Relief

Epidurals for chronic back pain = One of the fastest growing procedures in the US and worldwide

- 9 million Epidural Steroid Injections (ESI) performed annually in the U.S.
  - Represents a **\$2 billion** market
- Medicare accounts for 40% of the total U.S. ESI volume, valued at **\$800 million**
- Private insurance accounts for the remaining **\$1.2 billion**
  - Conservatively, using Medicare pricing

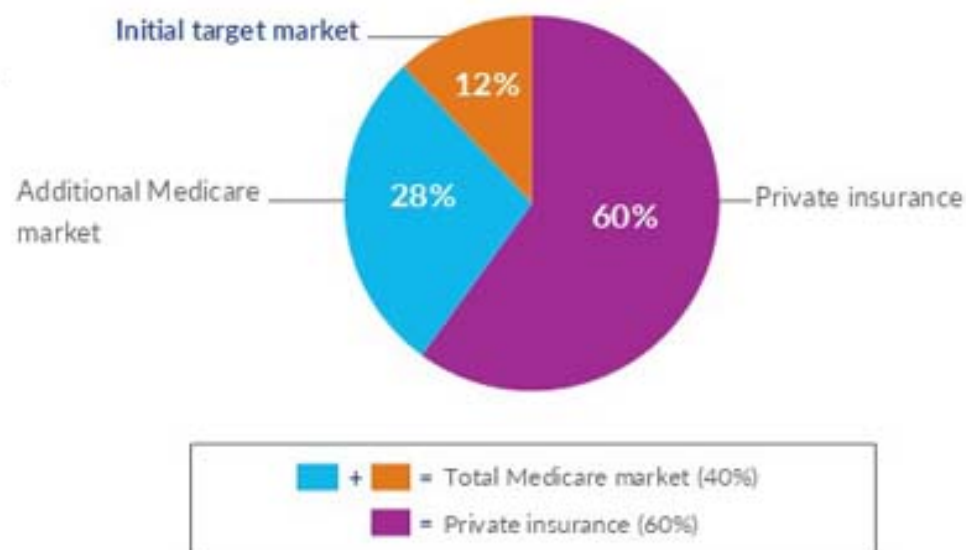
US Overall ESI Market (\$2B)



# Medicare Reimbursement Expansion for CompuFlo® Epidural System

- Medicare Payment Rate Granted in 3 Jurisdictions (as of July 23, 2024)
- Covering 30% of Medicare ESI Procedures:
  - Jurisdiction N (JN): Florida, Virgin Islands, Puerto Rico
  - Jurisdiction L (JL): Delaware, DC, Maryland, New Jersey, Pennsylvania
  - Jurisdiction H (JH): Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, Texas
- Equating to \$250M Initial Target
- Future Opportunities:
  - Penetration into commercial market
  - Expanding jurisdiction into an additional 30% of Medicare procedures

## Near-term Target Markets





# Benefits of Medicare Reimbursement



## Increased Accessibility

- More patients can benefit from safer, more comfortable epidural procedures



## Enhanced Patient Outcomes

- CompuFlo® reduces the risk of complications, leading to better patient outcomes + higher satisfaction



## Support for Healthcare Providers

- Providers can offer advanced pain management solutions without financial barriers
- Improved overall quality of care



## Growing Distribution

### Strategic Partnership with Axial Biologics to Distribute CompuFlo® in New Jersey, Texas, and Florida Jurisdictions

- Company has a vast network of pain management doctors
- 30+ salespeople in the field

### Targeted, direct distribution

- 4 dedicated salespeople driving awareness
- Implementing advisory sites in uncovered markets



Recent Medicare Price Assignment is, “positioning CompuFlo® to disrupt the market with its unparalleled safety and economic benefits”

— Ryan Paul, CEO of Axial Biologics

# Beyond Epidural: Future Growth Opportunities



Specific  
Addressable  
Market >\$1B in  
the US alone



## Epidural During Labor and Delivery:

- 2.4M procedures per year
- More than 50% of women giving birth in the US use an epidural for pain relief
- Subsequent catheter checks can add 750K procedures



## Peripheral Nerve Block:

- 8M procedures per year
- Open to strategic partnership to accelerate opportunity

# Milestone Scientific: Proven Success Minimizing Injection Pain

Leading developer of computerized drug delivery devices providing virtually painless + precise injections



## \$2B high-margin recurring revenue opportunity

- FDA approved product **CompuFlo®** (Feb 2023)
- **20+ years** of patent protection



## Expanding reimbursement and growing distribution



## High Incremental Margins.

Only **40K/year ESI** procedure run rate required to break even.



## The Team



**Arjan Haverhals, M.S.**  
*CEO & President*

Mr. Haverhals has served as Milestone Scientific's President since September 2020 and as President and Chief Executive Officer of Milestone Scientific's Dental Division, Wand Dental Inc. He brings more than 30 years of sales, marketing, product development, and international expansion experience within the medical device, pharmaceutical, and other industries. Prior to joining the Company, Mr. Haverhals was SVP of Sales at Xcentric Mold & Engineering, where he was instrumental in increasing sales productivity and efficiency. He holds an MS in Pharmacy from the University of Leyden in the Netherlands.



**Mark Hochman, D.D.S.**  
*Clinical Director*

Dr. Hochman is a multi-trained specialist completing post-graduate certificates in Orthodontics and Periodontics with advanced training in Implant Dentistry. He is a former Clinical Associate Professor from NYU College of Dentistry in the departments of Orthodontics and Implant Dentistry. He has contributed to the dental literature on a variety of topics ranging from periodontics, orthodontics and dental local anesthesia. He is a contributing author of one of the most widely referenced textbooks in dentistry, the *Handbook of Local Anesthesia* by Stanley F. Malamed. Dr. Hochman is the Clinical Director of Milestone Scientific, Inc. and holds over 25 patents.



**James Hippett, J.D.**  
*SVP, Global Sales & Business Development*

A British native, Mr. Hippett has an Honors Law degree from the UK, and initially came to the United States via a program with Major League Soccer. During a 15+ year career in the US sports industry, he moved into Capital Equipment within the US healthcare industry. He worked with Danish-based UVD Robots, moving into senior VP positions, and was responsible for key accounts and business development for the company, selling into US Hospitals and the OR. Mr. Hippett brings a strong record of achievement in sales management, business development, international business and systems creation to the Milestone Scientific Team.



**Keisha Harcum, M.B.A., M.S.**  
*VP of Finance*

Keisha Harcum has been Milestone's Vice President of Finance since 2024, and Controller since 2021. She first joined the company in 2014 with over 20 years of finance and accounting experience serving both publicly and privately held companies. Ms. Harcum previously served as Controller/Business Manager for Innovative Education Program, a private education company. Her additional experience includes Controller of Haynes Security, Inc., a leading security solutions company, and Senior Accountant for Casio, Inc., a leading manufacturer of consumer electronics with subsidiaries throughout the world.



**MILESTONE**  
SCIENTIFIC®

**Thank you**

Arjan Haverhals, CEO & President

[jhaverhals@milestonescientific.com](mailto:jhaverhals@milestonescientific.com)

[milestonescientific.com](http://milestonescientific.com)