



| Ticker: MLS                             | SS |
|---|----|
| Exchange:NYS                            | SΕ |
| Share price (as of 10/01/15):\$3.0      | 00 |
| Common shares outstanding:21.5          | M  |
| Market capitalization:\$64.5 I          | M  |
| 2014 revenue:\$10.3 l                   | M  |
| 2014 net income: \$(1.7) I              | M  |
| Shareholders' Equity (6/30/15):\$13.4 I | M  |
| Fiscal year-end:December 3              | 31 |
| Security Ownership of Mngmt*: 37.8      | %  |

R&D company with growing portfolio of computer-controlled drug delivery injection instruments; strategy to incubate, commercialize and monetize applications through an equipment/disposable model

- Alternative to the syringe; provides safe, controlled and painless injections and
- Reduced malpractice risk & ability to electronically record data mandated under ACA

Broad IP

Over 20 patents surrounding injection/drug delivery system Many high impact applications identified for development

Regulatory

- FDA & CE approval on dental injection/drug delivery instruments
- CE approval on first two medical instruments; FDA approval pending

- Commercialize products through JV, licensing, and distribution partnerships
- Recurring revenue model with growing margins

Solid

- \$10.3 million in revenue in 2014 generated by core dental division
- Clean balance sheet with over \$13.4M shareholder's equity and no long term debt

### **Drug Delivery Evolution**

- The hypodermic syringe has been the primary injection means for almost 160 years
- Syringe presents several weaknesses not yet addressed
  - Pain and the fear of pain
  - Tissue damage caused by uncontrolled flow rates
  - Transient or permanent paralysis
  - Post-operative complications
  - Risk of medical emergencies including patient fatality
  - Inability to know precisely where the drug is placed
- Milestone's instrument overcomes the traditional syringe's drawbacks through innovative features:
  - Measures tissue density to identify the precise needle location
  - Regulates & controls flow rate of fluid with consistency & accuracy
  - Disposable handpiece provides precise tactile control
  - Controls pain that patients typically associate with injections

#### **Market Overview**

- Unique ability to identify tissue type and control flow rate
  - Allows for wide array of medical instruments across disciplines
- >700 potential applications identified by independent analysis
- JVs and Licensing in place for epidural, intra-articular, botox and ophthalmic instruments
- Completed development on first 2 medical instruments
  - Received CE Mark approval on epidural and intra-articular instruments
  - Pending FDA approval on epidural and intra-articular instruments
- Other potential applications under review in attractive markets with favorable competitive landscape
- Plan to develop and commercialize through partnerships with key players

#### **Subsidiary Level Growth**

# Strategy

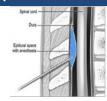


- Operate as a medical technology company at public company level
  - Focus on core competency in R&D
  - Identify applications with greatest potential
  - Hold all patents in Milestone Scientific
- Bring products to commercialization
  - Joint-ventures and distribution partnerships
  - Ongoing revenue streams: product sales, license fees and royalties
  - Ability to monetize new ventures through IPO or asset sale



while minimizing dilution and creating value for shareholders

## **Epidural Instrument**



- ventional standard of care Wet Tap (1 in 30) Neurological injury for <1 year (1 in 6,700) Neurological

- leurological injury for >1 ear (1 in 240,000)
- legia (1 in 250,000)

#### Epidural market over \$1B per year in the US alone

- 2.4MM epidurals for childbirth (out of 4.2MM total child births)
- Additional 1.8MM potential epidurals for child birth
- More than 8.9MM other epidurals
- Conventional syringes present high risk for patients
  - Doctors identify epidural space relying on subjective perception
  - Average cost for epidural malpractice settlement: \$362,000

#### Milestone's instrument is able to reliably identify epidural space eliminating the risk of human error

- Real time analysis of pressure characteristics of different tissues
- Location of the needle easily determined in real time
- Injection record database; soon mandatory under U.S. ACA

100% success in clinical studies using medical residents

## **Intra-Articular Instrument**





- Intra-articular market projected \$7B by 2015 in US alone
- Osteoarthritis affects 33Mil patients in US
- 21Mil people receive intra-articular injections
- Low effectiveness of conventional injections:
  - Failure to locate intra-articular space
  - Inappropriate use of volume of hyaluronic acid
  - Only 77.3% success using traditional techniques in knee injections
- Ultrasound techniques capital intensive & requires changes
  - Estimated cost of equipment: \$20/40k
  - Relevant training need
  - Significantly changes the way of administering injections
- Dynamic Pressure Sensing (DPS\*) has been successful in identifying intra-articular space for administration of medications to treat a variety of joint pathologies in an independent study\*

### **Other Medical Instruments**

#### • Cosmetic Instrument

- Botox®/Dysport® injections are a multi-billion dollar worldwide market
- Opportunity exists to reduce pain and complications

#### Opthalmic Instrument

- Intravitreal (IVT) injections are one of the most commonly performed procedures across all specialties
  - According to the AMA, IVT injections are the fastest growing procedure
  - Opportunity to reduce or avoid complications and provide better experience for patients

#### · Veterinary Instruments

- Signed Letter of Intent in April 2015 with MILA International (a U.S.-based global marketer and distributor of veterinary products)
- Collaboration to develop and market anesthetic drug delivery instrument for nerve block procedures in horses
  - Initial research and clinical validation conducted by Cornell University College of Veterinary Medicine
- FDA approval not required
- Global animal health industry is a \$24 billion market

## **Partnerships and Developments**



Exclusive distribution agreement with Poland-based TRIMED for Milestone's epidural instrument

TRIMED is one of the largest distributors of diagnostic equipment in Poland



Exclusive distribution agreement with Italy-based Moss for Milestone's epidural instrument

> Moss is one of Italy's leading distributors of diagnostic and specialty surgery equipment



Agreements signed for distribution of epidural and IA instruments in China pending CFDA approval; Regional coverage to include China and other parts of Asia

--Milestone China is a J/V between Milestone Scientific and a team headed by a senior healthcare executives from China



Signed a MOA with Fidia Farmaceuti for the codevelopment and manufacture of custom IA instrument to deliver Fidia's hyaluronic acid formulations



Signed Letter of Intent in April 2015 with MILA International to develop nerve block procedures in

Milestone Led Consortium Awarded \$2.4MM to develop Stem Cell Medium and Instrument for treatment of Diabetes

#### **Milestone Dental Instrument**

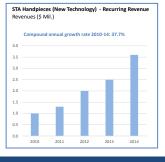
- · Dentists administer injections accurately & painlessly
  - Capable of performing all injections done with conventional syringe
  - Allows for anesthetizing a single tooth as primary injection
- · Proven effectiveness
  - Over 65Mil injections delivered to date
  - Favorably evaluated in 50 peer reviewed and independent clinical research reports
- Better experience for patients
  - Painless and reduction of injection anxiety
  - No collateral anesthesia in the cheek, lips or tongue
  - Reduction in chair time
- · Improved effectiveness for doctors
  - Fewer Compl
  - Reduced quantity of anesthetic
  - Increase in number of procedures



Wand STA

## **Future Growth & Profitabilty**

- Distribution partnerships and/or licensing of instruments and disposables
- Expansion into higher price/margin medical instruments and disposables
- Disposables provide a high margin recurring revenue stream
- Structural margin improvement with growth of installed base of instruments
- Highly scalable business model due to outsourced production model



## **For Additional Information**

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