Nasdaq: AMDA
January 2017
Forward Looking Statements

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# About Us

We are a commercial-stage biomaterials company focused on using our cutting edge silicon nitride ceramic technology platform for a variety of orthopedic and dental implants

<table>
<thead>
<tr>
<th><strong>Biomaterial</strong></th>
<th>Silicon nitride ($\text{Si}_3\text{N}_4$) is an advanced ceramic</th>
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<tbody>
<tr>
<td></td>
<td>• Proven bone growth and anti-infective properties</td>
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<td></td>
<td>• Superior imaging, strength, and wear resistance</td>
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<table>
<thead>
<tr>
<th><strong>Hybrid Commercial Strategy</strong></th>
<th>Traditional distribution with private label and OEM partnerships</th>
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<tr>
<td></td>
<td>• Growth through expanded surgeon and distribution relationships</td>
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<tr>
<td></td>
<td>• Validates $\text{Si}_3\text{N}_4$ benefits AND penetrates market w/ improved operating margins</td>
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<table>
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<tr>
<th><strong>Broad Product Portfolio</strong></th>
<th>Interbody fusion devices and Metals business with pull-through effect of $\text{Si}_3\text{N}_4$</th>
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<tbody>
<tr>
<td></td>
<td>• &gt;25,000 $\text{Si}_3\text{N}_4$ spinal fusion devices implanted</td>
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<tr>
<td></td>
<td>• Metals business includes facet and pedicle screw systems</td>
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<table>
<thead>
<tr>
<th><strong>Manufacturing</strong></th>
<th>In-house manufacturing and Kyocera as secondary supplier</th>
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<tr>
<td></td>
<td>• Only FDA &amp; CE cleared $\text{Si}_3\text{N}_4$ medical device manufacturing facility</td>
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<tr>
<td></td>
<td>• Quick in-house prototyping and development</td>
</tr>
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<td></td>
<td>• Kyocera partnership allows for improved margins &amp; rapid expansion</td>
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<table>
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<tr>
<th><strong>Seasoned Management</strong></th>
<th>Surgery, science, manufacturing, &amp; product development expertise</th>
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<tr>
<td></td>
<td>• Superb people behind the product</td>
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Upcoming Milestones

2017 Milestones

- Final determination by FDA for composite silicon nitride fusion device regulatory clearance
- Report 24-month SNAP clinical data for posterior lumbar interbody fusion procedure
- FDA clearance: porous fusion device for spinal fusion surgery
- FDA clearance: pedicle screw system for adjustment to spinal fusion system
- Sign four additional OEM or private label agreements
- Continue robust scientific publication strategy
- Additional product launches
  - Next generation of silicon nitride
  - New pedicle screw system
  - Expanded lateral lumbar implant sizes
## Silicon Nitride: The Ideal Biomaterial

<table>
<thead>
<tr>
<th></th>
<th>Silicon Nitride</th>
<th>Plastic</th>
<th>Allograft</th>
<th>Metals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibacterial</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Bone Growth</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Imaging Capability</td>
<td>✓</td>
<td>~</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Strength, Hardness, Fracture Resistance</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Stem Cell Stimulation</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Osteoconductive</td>
<td>✓</td>
<td>~</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Osteoinductive</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Bioactive Glass</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
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</tbody>
</table>

Silicon nitride is **Bioactive** in the patient healing process.
## Silicon Nitride: Anti-Infective & Osteopromotive

### Bacteria growth after implant

<table>
<thead>
<tr>
<th>Material</th>
<th>On implant</th>
<th>Growth in situ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon Nitride</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>PEEK</td>
<td>95%</td>
<td>88%</td>
</tr>
<tr>
<td>Titanium</td>
<td>67%</td>
<td>21%</td>
</tr>
</tbody>
</table>

### Bone growth in presence of bacteria

<table>
<thead>
<tr>
<th>Material</th>
<th>On implant</th>
<th>Growth in situ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon Nitride</td>
<td>23%</td>
<td>41%</td>
</tr>
<tr>
<td>PEEK</td>
<td>5%</td>
<td>21%</td>
</tr>
<tr>
<td>Titanium</td>
<td>9%</td>
<td>26%</td>
</tr>
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*In vivo Wistar Rat Calvarial Study: Histology at 3 months after implantation with inoculation S. epidermis*
Material Surface Topography Makes the Difference

Silicon nitride has **superior surface area** for an optimal bone friendly environment.
Silicon Nitride Encourages Bone Fusion

Details

- 58-year-old male
- Silicon nitride C3-C4; 10-month retrieval
- Revision unrelated to implant

Histology

- Mature, healthy, viable bone within graft hole
- Good connectivity between vertebrae
- **Appositional bone index of 19.1%** compared to 1.3% typical for PEEK
- New type of hydroxyapatite
  - Raman spectroscopic evidence
  - Material participates in bone fusion

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Case Study\textsuperscript{1} - Silicon Nitride vs. PEEK in Same Patient

Despite PEEK’s 3-year head start, silicon nitride experiences \textit{denser bone growth}.

\textsuperscript{1}Muhanna, Nabil, MD, “A Retrospective Radiographic Review of PEEK and Silicon Nitride Spinal Implants in the Same Patient”
Easier to see...

Silicon nitride provides greater visibility allowing for accurate device placement and post-op fusion detection.
Strength & Reliability from Crack Resistance

Zirconia & Alumina

Silicon Nitride

Brittle Crack Path

Fracture Resistant

Superior burst strength and fracture toughness vs. zirconia & alumina

Proprietary Silicon Nitride Types

**Solid: As-Fired and Polished**
- **As-fired** promotes bone growth
- **Polished** used for articulating applications

**Porous: Cancellous (CsC)**
- Biologic substitute allowing for bone in-growth

**Composite: Cortical-Cancellous**
- Synthetic bone for a variety of medical applications

**Composite: Articular-Bone Ingrowth**
- Joint arthroplasty/resurfacing applications
Valeo™ Interbody Spinal Fusion Devices

Full Line of FDA-cleared Si$_3$N$_4$ Products

- Cervical
- Lumbar
  - Anterior
  - Posterior
  - Oblique
  - Transforaminal
  - Lateral
- Corpectomy

Enhanced 2$^{nd}$ Generation Features

- Universal threaded instrumentation
- More implant sizes and approaches
- Improved safety & ease of use
Innovative Product Pipeline Key to Future Growth

**Pipeline Products**

- Composite cervical spinal fusion device
- Lateral lumbar product line expansion
- 2\(^{nd}\) generation Si\(_3\)N\(_4\)
- Modular & cannulated pedicle screw system
- 3D printed Si\(_3\)N\(_4\)
- All-porous Si\(_3\)N\(_4\) interbody
- Stand alone cervical interbody
- Si\(_3\)N\(_4\) coatings on metals
- Brazing of Si\(_3\)N\(_4\)
Product Pipeline: Next Generation of Silicon Nitride

Exposing osteoblast-like Saos-2 cells* to biomaterial surfaces in an *in vitro* experiment demonstrates modulation of hydroxyapatite production rate.

Osteoconductivity increased **190%** over current silicon nitride composition.


*Apatite deposition: 5x10⁵ cell/mL, DMEM medium w/ 50μg/mL ascorbic acid, 10mM β-glycerol phosphate, 100nM dexamethasone, 10% FBS, 7 day incubation*
Product Pipeline: Composite Spinal Fusion Device

Pending FDA 510(k) Clearance

- Disruptive technology offering silicon nitride benefits
  - Super hydrophilic; orthobiologic alternative
  - Avoids possible use of cadaveric or autograft bone
  - Additional applications outside of spine

Silicon Nitride Statistically Equivalent to Industry Gold Standard

- Blinded, randomized clinical trial comparing Si$_3$N$_4$ to PEEK filled with autograft
- Statistically equivalent clinical improvement and fusion rates
- 24-month data submitted to FDA for anticipated composite device clearance
- Re-designed implant submission to FDA during Q1 2017
Product Pipeline: Porous Fusion Device

**Scanning Electron Microscope**

- **Time = 0**
- **12 Weeks**
- **24 Weeks**

Bone In-growth = >3mm

Bone In-growth = 5.5mm

In-vivo Ovine Medial Femoral Condyle Study
Product Pipeline: Taurus Pedicle Screw System

• Modular
  - Can be implanted without the head – ability to distract of screws
  - Lends well to MIS system

• Tension head
  - Screw head is adjustable and will hold a specific angle or position

• Triple lead
  - Cortical trajectory approach
  - Aggressive option for those not using power

• Cannulated
  - Navigation and MIS friendly
Product Pipeline: Dental Implants

• Signed joint development agreement
  - Biomechanical and material testing to be completed in Q3 2016

• JDA to provide additional basis for FDA clearance process

• Recent peer-reviewed publication shows silicon nitride holds promise as a therapeutic aid for treating severe gum disease

Langmuir, 2016, 32 (12), pp 3024–3035
Product Pipeline: Hip & Knee Replacement

- No corrosion; no metal ion release

- Articulating and bone growth properties on a single device

- Additional testing\(^1\) of the femoral head to further validate:
  - Reduced oxidization of poly surfaces
  - Superior burst strength and fracture toughness
  - Resistance to corrosion and fretting
  - Superior wear

\(^1\) Femoral head testing to be done in partnership with Kyocera, Kyoto University and the University of Nebraska
Intellectual Property

- **60 patents issued**
  - 49 U.S.
  - 11 International

- **30 patent applications**
  - 19 U.S.
  - 11 International
Unique Manufacturing Technique

- 30,000 sq. ft. manufacturing facility in Salt Lake City, UT
  - Only FDA & CE cleared $\text{Si}_3\text{N}_4$ medical device manufacturing facility
  - Vertically integrated for rapid prototyping and development
  - Dedicated R&D and Product Development laboratories

- Production of powder and green compact preparation
- Ability to manufacture complex designs and shapes
- Rigorous quality control process for each implant
Hybrid Sales Strategy

**AMDA Spine**
- Generate sales through independent domestic distributors
- Future growth through additional distributors & surgeons, while introducing new & innovative products
- Updating pedicle screw system to on-board additional new surgeons

**Private Label**
- Sell Amedica products with partner’s logo and through their channels
- Near-term sales w/ limited selling expense and no CapEx
- Validates $Si_3N_4$ benefits AND penetrates market faster

**OEM**
- Convert existing partner’s metal or plastic device to $Si_3N_4$
- Prototype, testing and FDA clearance in-house
- Longer-term revenue impact w/ limited additional spend
- Enhance body of scientific data to position $Si_3N_4$ as the standard of care
Operating Contribution Margin by Department

*Before overhead allocation*

<table>
<thead>
<tr>
<th></th>
<th>COGS</th>
<th>Commission</th>
<th>S&amp;M</th>
<th>Contribution</th>
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<tr>
<td><strong>Existing Business</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>25%</td>
<td>40%</td>
<td>25%</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Private Label/ OEM</strong></td>
<td>60%</td>
<td>0%</td>
<td>0%</td>
<td>40%</td>
</tr>
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</table>
Key Partnerships

Current Partnerships

- Spinal Kinetics
  - First private label and OEM partner

- Weigao Orthopedics
  - 10 year exclusive distribution agreement with largest orthopedic company in China
  - 6 years of minimum purchase requirements totaling 225,000 units
  - Finalizing CFDA clearance submission strategy

- Kyocera
  - Secondary supplier source – Vancouver, WA

Potential Partnerships

- Other Global Spine Partners
  - Assessing regulatory clearance path with several potential partners in Japan, Taiwan and Australia

- Key Arthroplasty Discussions
  - Current material testing agreements lead to clearer path toward additional OEM partners

- Non-medical Applications