Regenerative Medicine for Bone
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Bone Biologics is **redefining bone regeneration** with **NELL-1**, a secreted, osteopromotive protein whose expression controls skeletal ossification.

**NELL-1** effectively increases the quantity and quality of bone across small and large animal models either via local implantation or intravenous delivery.
A Potential Breakthrough in Bone Regeneration

We are developing a next-gen osteopromotive product (NELL-1 + DBX) that is selective to bone.

Discovered through understanding craniosynostosis.

Platform technology with initial focus on spine fusion, followed by trauma and osteoporosis.

Preclinical studies have shown equivalent efficacy and superior safety compared to rhBMP-2.
## Bone Biologic’s Solution To Unmet Need

A major challenge in orthopedic surgery is effective bone regeneration

<table>
<thead>
<tr>
<th>Challenges w/ rhBMPs</th>
<th>NELL-1 Solution</th>
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<tbody>
<tr>
<td>Rapid bone growth (egg shedding)</td>
<td>Rapid / healthy bone growth</td>
</tr>
<tr>
<td>Cysts &amp; less dense bone formation</td>
<td>Forms bone in target specific fashion without inducing inflammation and poor bone formation</td>
</tr>
<tr>
<td>Not target-specific – will grow where bone is not present</td>
<td>Cannot initiate bone formation in muscle</td>
</tr>
<tr>
<td>Swelling and intense inflammatory response in off label use</td>
<td>Can stimulate induced BMSCs to form bone in a rodent muscle pouch</td>
</tr>
<tr>
<td></td>
<td>Exhibits specificity that BMPs lack</td>
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Source: Scientific publications
## NELL-1 Product Pipeline

<table>
<thead>
<tr>
<th>Clinical Indication</th>
<th>Discovery</th>
<th>Pre-Clinical</th>
<th>Phase I/II</th>
<th>Phase III</th>
</tr>
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<tbody>
<tr>
<td>Spine Fusion</td>
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<td></td>
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<tr>
<td>Trauma</td>
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<tr>
<td>Osteoporosis</td>
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NELL-1 Mechanism of Action

- Runx2 Protein is known as the “Master Switch” responsible for bone formation
- BBC’s NELL-1 Protein helps committed cells grow better bone or cartilage (depending upon cell type)
- rhBMP-2 targets many cells ---- May lead to tissue formation in undesirable anatomical locations
More Than 45 Publications on NELL-1


Pilot Large-Animal Study

Clinically relevant sheep study demonstrated that rhNELL-1 increases the fusion rate and quantity of bone compared to sDBX

<table>
<thead>
<tr>
<th>Result</th>
<th>Fusion Rate (uCT)</th>
<th>New Bone Vol (uCT)</th>
<th>New Bone Area (Histo Morph)</th>
<th>Bone Strength (Biomech)</th>
</tr>
</thead>
<tbody>
<tr>
<td>rhNELL-1 Better than Control (sDBX)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
Strong IP Barrier

- **15 issued patents with more than 175 claims covering:**
  - Molecular Structure - Composition
  - Manufacturing Process - NELL-1 protein expressed in mammalian & other systems
  - Field of Use – Use for promoting bone growth

- **Exclusive license to NELL-1 technology from UCLA for spine, trauma, and osteoporosis**

<table>
<thead>
<tr>
<th>Patent No.</th>
<th>Title</th>
<th>Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Patent No. 9,511,115</td>
<td>Pharmaceutical compositions for treating or preventing bone conditions</td>
<td>12/6/2016</td>
</tr>
<tr>
<td>U.S. Patent No. 7,052,856</td>
<td>NELL-1 enhanced bone mineralization</td>
<td>5/30/2006</td>
</tr>
<tr>
<td>U.S. Patent No. 7,687,462</td>
<td>Composition for promoting cartilage formation or repair comprising a NELL gene product and method of treating cartilage-related conditions using such composition</td>
<td>3/30/2010</td>
</tr>
<tr>
<td>U.S. Patent No. 7,776,361</td>
<td>NELL-1 enhanced bone mineralization</td>
<td>8/17/2010</td>
</tr>
<tr>
<td>U.S. Patent No. 7,833,968</td>
<td>Pharmaceutical compositions for treating or preventing bone conditions</td>
<td>11/16/2010</td>
</tr>
<tr>
<td>U.S. Patent No. 8,044,026</td>
<td>Composition for promoting cartilage formation or repair comprising a NELL gene product and method of treating cartilage related conditions using such composition</td>
<td>10/25/2011</td>
</tr>
<tr>
<td>U.S. Patent No. 8,048,646</td>
<td>NELL peptide expression systems and bone formation activity of NELL peptide</td>
<td>11/1/2011</td>
</tr>
<tr>
<td>U.S. Patent No. 8,207,120</td>
<td>NELL-1 enhanced bone mineralization</td>
<td>6/26/2012</td>
</tr>
<tr>
<td>U.S. Patent No. 9,598,480</td>
<td>Recombinant NEL-like (NELL) protein production</td>
<td>3/21/2017</td>
</tr>
<tr>
<td>U.S. Patent No. 9,447,155</td>
<td>Isoform NELL-1 peptide</td>
<td>9/20/2016</td>
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</table>
The global orthobiologic bone replacement market is approximately $3 billion ($1.7B of which is U.S. based), and is expected to grow roughly 6% a year over the next five years.
Key Metrics

History
- September 19, 2014 – Reversed merge into shell corp.
- March 31, 2016 – Commenced trading on OTC QB
- July 16, 2018 Reverse stock split

Financial Metrics
- ~26M shares o/s
- Raised $23M to date
- Company needs ~$20M to complete First in Man Trial

Market Metrics
- ~500,000 lumbar spine fusions WW
- Multibillion market opportunity for spine indication
- BBC 5yr revenue estimate >$400M (40% market penetration)
Product Development Milestones

- **2016**: Final Nell-1 cell line selected and synthesized
- **2017**: Commence Pivotal animal study
- **2018**: Pilot data from large animal
- **2019**: Commence OUS Phase I/II Clinical
- **2020**: Commence US Phase III Clinical
- **2021**: FDA Approval
Value Proposition to Stakeholders

**Payors**

- 15,000 people turn 65 everyday in America
- More ortho procedures and therapy increase costs
- Safer treatment --- less complications
- Fewer reoperations

**Patients**

- More companies offering high-deductible health insurance
- Consumers becoming more selective
- Demand better care

**Physicians**

- Improved clinical outcomes will see physicians/health systems drive utilization
- Established market and reimbursement
Management Team

**Jeffrey Frelick, CEO and President**
- COO Life Science Enterprises
- 15 yrs. Med-Tech analyst, Canaccord, ThinkEquity, Lazard, Leerink
- Consultant, Boston Biomedical Consultants
- Regional Sales Mgr., Becton Dickinson PCD
- Laboratory Technologist, Clinical Pathology Facility

**Deina Walsh, CPA, Chief Financial Officer**
- Former partner in EFP Rotenberg LLP.
- Certified Public Accountant
- Accounting and financial functions, SEC reporting, pre and post-IPO compliance, SOX, regulatory compliance, internal controls. Debt and equity financings, and M&A.

**Dr. Scott Boden, Chief Medical Advisor**
- Professor of Orthopedic Surgery at Emory University School of Medicine
- Director of Emory Orthopedics & Spine Center
- Vice Chair of Orthopedics, CMO/CQO of The Emory University Orthopedics & Spine Hospital
- Emory Healthcare Physician Director of Strategy and Development for Orthopedics & Spine Programs
Board of Directors

Don Hankey
*Chairman of the Board Bone Biologics / CEO Hankey Group*
Mr. Hankey holds his BA and post-graduate work from University of Southern California. He started his career at what became known as USB Paine Weber. Mr. Hankey acquired Midway Ford in 1972 and founded Hankey Investment Company in 1982 where he grew its portfolio in the financial services industry. The Hankey Group today is comprised of seven operating companies across the automotive, finance, technology, real estate and insurance industries.

Bruce Stroever
*Former CEO Musculoskeletal Transplant Foundation*
Mr. Stroever served as Chairman of Bone Biologics from 2012 - 2018 and was the President and CEO of MTF until 2018, where he joined in 1988 as General Manager. He previously held several positions at Johnson & Johnson’s Ethicon division. He received his B.E. in Mechanical/Chemical Engineering from Stevens Institute of Technology and Masters of Science in Bioengineering from Columbia University.

Bret Hankey
*President of Hankey Group*
Mr. Hankey brings more than 15 years of operating and board director experience to the BBLG board. Since 2000, Mr. Hankey has served in various capacities within the Hankey Group where he currently serves as President and is a member of the board of directors on all seven operating companies specializing primarily in the automotive, finance, technology, real estate and insurance industries.

Steve La Neve
*Former CEO and President of Bone Biologics*
Mr. La Neve brings 30 years of health care experience and leadership to Bone Biologics. Previously Mr. La Neve was CEO of Bone Biologics, Life Science Enterprises, and ETEX Corp. while holding divisional president roles at Medtronic and Becton Dickinson. He holds a B.S. in Health Planning from Penn State University and an MBA West Chester University.
Building an Orthobiologic Leader

Opportunity
- A multibillion market opportunity with very good growth characteristics

Technology
- Nell-1 functions specifically and selectively on target cells in the osteochondrogenic lineage

Pipeline
- Additional products beyond spine, that include hard tissue local & systemic

Business
- A lean, virtual business model with leading strategic partners, vendors, and contractors

Foundation
- Strong technology discovered at UCLA coupled with seasoned Med-Tech management team
2 Burlington Woods Dr, Suite 100
Burlington, MA 01803
781-552-4452

www.bonebiologics.com