

Regenerative Medicine for Bone

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Overview



Bone Biologics is redefining bone regeneration with Nell-1, a growth factor that has demonstrated to effectively increase the quantity and quality of bone across small and large animal models.

Healthcare Trends

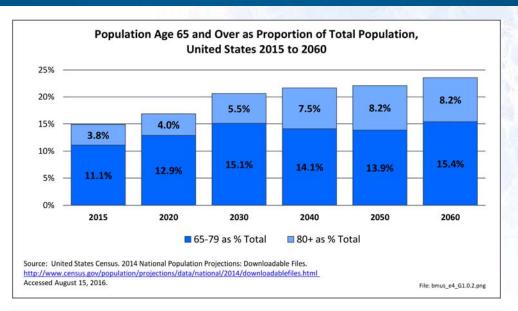


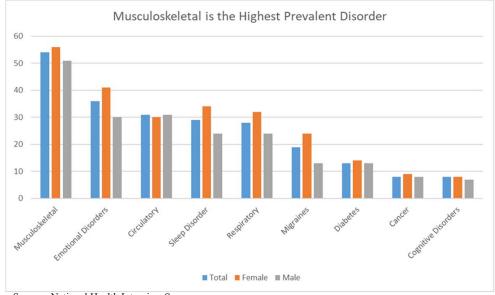
With an aging population, musculoskeletal diseases are becoming a greater burden as the cost of treating long-term pain and disability increases.

People are seeking a more active lifestyle, therefore "Quality of Life" is becoming more important.

Bone regeneration is a significant medical challenge impacting millions of people globally

The orthobiologics industry with its technology advancements will benefit patients and health systems through better outcomes, reduced surgical time, faster healing, and reduced costs.





Source: National Health Interview Survey

Bone Biologics Attractiveness



Opportunity

- 3 billion global market opportunity in spine fusion
- Additional indications in trauma and osteoporosis

Technology

- Strong technology discovered at UCLA
- Proprietary product platform with strong IP

Pre-clinical Data

 Pre-clinical studies have shown increases in fusion and quantity of bone

Business

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

Regulatory Path

- A device/drug combo product
- Following medical device PMA tract to FDA approval

Bone Biologic's Solution To Unmet Need 😼



A major challenge in orthopedic surgery is effective bone regeneration

Challenges w/ rhBMPs

- Rapid bone growth (egg shelling)
- Cysts & less dense bone formation
- Not target-specific will grow where bone is not present
- Swelling and intense inflammatory response in off label use

Proposed Nell-1 Solution

- Rapid / healthy bone growth
- Forms bone in target specific fashion without inducing inflammation and poor bone formation
- Does not initiate bone formation in muscle
- Can stimulate induced BMSCs to form bone in a rodent muscle pouch
- Exhibits specificity that BMPs lack

Nell-1 Product Pipeline



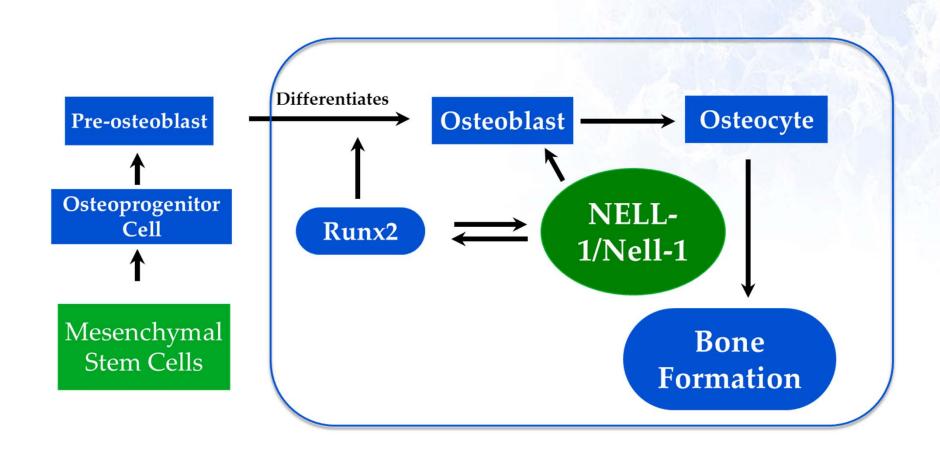


Clinical Indication	Discovery	Pre-Clinical	Phase I/II	Phase III	Market Size/ Leader
Spine Fusion					\$3.0 B InFuse (MDT) = >\$500 M
Trauma					
Osteoporosis					\$11.2 B Prolia(AMGN) = \$2.3 B Forteo (LLY) = \$1.6 B

Source: Company Reports, NOF

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



Novel Wnt Regulator NEL-Like Molecule-1 Antagonizes Adipogenesis and Augments Osteogenesis Induced by Bone Morphogenetic Protein-2.

• Am J Pathol 186(2): 2016 Nfatc2 is a primary response gene of NELL-1 regulating chondrogenesis in ATDC5 cells.

• *J.Bone Miner.Res.* 26(6):1230-41, 2011

NELL-1 protein promotes bone formation in a sheep spinal fusion model.

• Tissue Eng Part A, 17(7-8):1123-35.2011

The effect of NELL-1 and bone morphogenetic protein-2 on calvarial bone regeneration.

• J Oral Maxillofac Surg 68(2):300-308 2010 "The study of NELL-1 gene modified goat bone marrow stromal cells in promoting new bone formation".

• Mol Therapy 15(10):1872-1880, 2007 NELL-1 induced bone regeneration in calvarial defects.

• Am J Pathol 169(3):903-15, 2006 "Human *NELL*-1 Expressed in Unilateral Coronal Synostosis."

• <u>I Bone Mineral Res.</u> 14: 80-89, 1999

Pilot Large-Animal Study



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

Result	Fusion Rate	New Bone Vol	New Bone Area	Bone Strength	
	(uCT)	(uCT)	(Histo Morph)	(Biomech)	
rhNELL-1 Better than Control (sDBX)	✓	✓	✓	✓	

Strong IP Barrier



***** 13 issued patents with more than 200 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

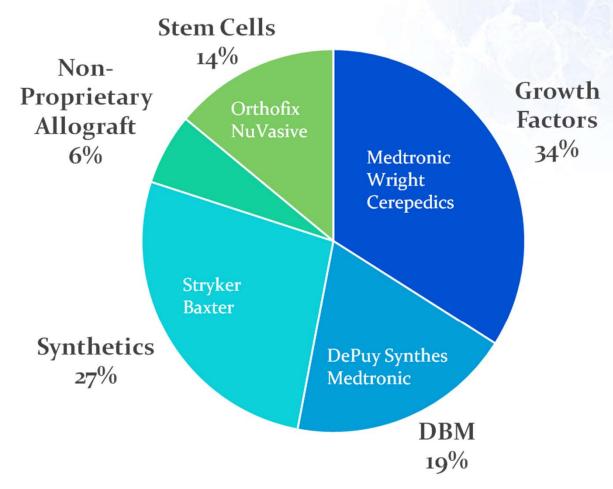
Patent No.	Title	Issued
U.S. Patent No. 9,511,115	Pharmaceutical compositions for treating or preventing bone conditions	12/6/2016
U.S. Patent No. 7,052,856	NELL-1 enhanced bone mineralization	5/30/2006
U.S. Patent No. 7,544,486	NELL peptide expression systems and bone formation activity of NELL peptide	6/9/2009
U.S. Patent No. 7,687,462	Composition for promoting cartilage formation or repair comprising a NELL gene product and method of treating cartilage-related conditions using such composition	3/30/2010
U.S. Patent No. 7,691,607	Expression system of NELL peptide	4/6/2010
U.S. Patent No. 7,776,361	NELL-1 enhanced bone mineralization	8/17/2010
U.S. Patent No. 7,807,787	NELL-1 Peptide	10/5/2010
U.S. Patent No. 7,833,968	Pharmaceutical compositions for treating or preventing bone conditions	11/16/2010
U.S. Patent No. 7,884,066	NELL-1 enhanced bone mineralization	2/8/2011
U.S. Patent No. 9,598,480	Recombinant NEL-like (NELL) protein production	3/21/2017
U.S. Patent No. 9,447,155	Isoform NELL-1 peptide	9/20/2016
U.S. Patent No. 9,974,828	Isoform NELL-1 peptide	5/22/2018
U.S. Patent No. 10,335,458	Pharmaceutical compositions for treating or preventing bone conditions	7/2/2019

Large Addressable Market



\$3 Billion Global Bone Graft Substitute Market

We estimate about 13% market share for BBC ~5 years after commercialization



Sources: Orthopedic Network News

Revenue Estimates for Spine Indication



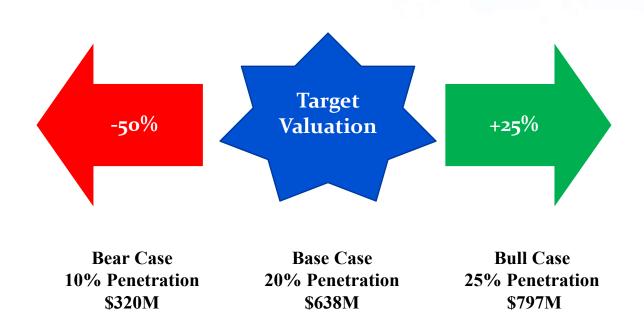
We assume reasonable penetration rates of NELL-1 due to an attractive safety and efficacy profile, at a reasonable price.

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Annual WW Lumbar spine fusion procedures	500,000	500,000	500,000	500,000	500,000
Revenues	\$46,875,000	\$133,875,000	\$191,250,000	\$292,500,000	\$397,500,000
% Growth		186%	43%	53%	36%

Future Valuation Estimates

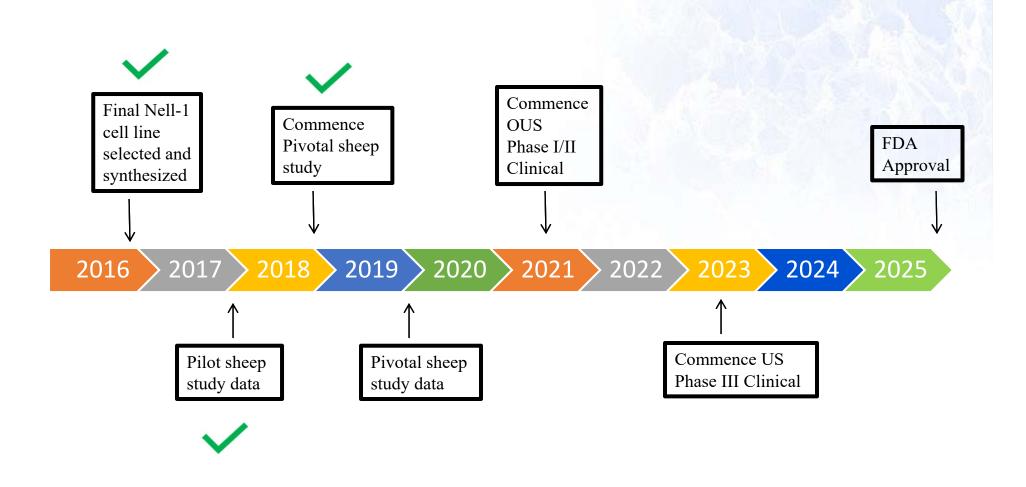


We assume approximately \$191M of revenues in second full year of commercialization, resulting in approximately 20% penetration in lumbar spine fusion procedures.



Product Development Milestones





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

- ~18M Diluted shares o/s **
- Raised \$23M to date
- Company needs ~\$20M to complete First in Man Trial

** 30M shares outstanding – 23M collateral shares + 11M convertible notes = 18M Diluted shares

Market Metrics

- ~500,000 lumbar spine fusions WW
- Multibillion market opportunity for spine indication
- BBC 5yr revenue estimate ~\$400M

Ortho M&A



		PURCHASE		PRICE/SALES	F William
TARGET	ACQUIRER	PRICE (\$-m)	TTM REVENUES	MULTIPLE	DATE
Paragon Medical	NN Inc	\$375	\$138	2.7	Apr-18
Spinal Kinetics	OrthoFix	\$105	\$30	3.5	Mar-18
Exactech	TPG Capital	\$625	\$260	2.4	Oct-17
Dfine	Merit Medical	\$98	\$32	3.0	Jul-16
LDR Spine	Medtronic	\$1,000	\$166	6.0	Jun-16
Cayenne Medical	Zimmer Biomet	\$150	\$20	7.5	Apr-16
Ellipse Technologies	NuVasi	\$410	\$41	10.0	Jan-16
X-Spine	Xtant Medical	\$86	\$42	2.0	Jul-15
TEI Biosciences	Integra	\$312	\$63	4.9	Jul-15
OrthoView	Materialise	\$12	\$5	2.3	Oct-14
Tornier	Wright Medical	\$1,500	NA	NA	Oct-14
Small Bone Innovations	Stryker	\$375	\$48	7.8	Jun-14
Biomet	Zimmer	\$13,350	\$3,200	4.2	Apr-14
ArthroCare	Smith & Nephew	\$1,700	\$368	4.6	Feb-14
Solana Surgical	Wright Medical	\$90	\$15	6.0	Jan-14
OrthoPro	Wright Medical	\$36	\$6	6.0	Jan-14
Confluent Surgical	Integra	\$265	\$65	4.1	Jan-14
Aldagen	Cytomedix	\$40	\$5	8.0	Feb-12
Orthovita	Stryker	\$316	\$95	3.3	Jun-11
Osteotech	Medtronic	\$123	\$96	1.3	Nov-10
ApaTech	Baxter	\$240	\$60	4.0	Mar-10
AVERAGE MULTIPLE				4.7	
Source: SEC documents and Company reports					

Value Proposition to Stakeholders



Payors

- Reduced costs
- Safer treatment --- less complications
- Fewer reoperations

Patients

- Consumers more selective, demand better care
- Better safety profile
- Improved fusions and healing

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.

John Booth

CEO Spineology Inc.

Mr. Booth has been CEO of Spineology since 2004. He previously held executive level positions at Phillips Plastic Corp, and INCSTAR Corp. as well as various financial and general management roles in the medical technology industry. Mr. Booth received a B.S. in accounting from Villanova and a MBA from Seton Hall.

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.





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