

Zacks Small-Cap Research

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Bone Biologics

(BBLG-NASDAQ)

BBLG: Market opportunity for Bone continues to grow.

BBLG continues to report a solid cash position that furthers our confidence in the company's ability to continue along the path toward FDA approval of potential game-changing bone regeneration technology.

Outlook

Bone Biologics is pursuing a better and more effective way of dealing with back pain requiring surgery by developing bone regeneration in spinal fusion using the recombinant human protein known as NELL-1/DBX.

The company's 2Q release showed that the company's cash position remains solid and the process toward the ultimate goal of FDA approval remains on track.

Current Price (09/14/22) **\$1.19**
Valuation **\$7.75**

SUMMARY DATA

52-Week High **\$5.48**
52-Week Low **\$1.19**
One-Year Return (%) **N/A**
Beta **N/A**
Average Daily Volume (sh) **142,937**

Shares Outstanding (mil) **10**
Market Capitalization (\$mil) **\$12**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **0%**
Insider Ownership (%) **72%**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **N/A**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2022 Estimate **-2.2**
P/E using 2023 Estimate **-1.9**

Risk Level

Type of Stock
Industry

High
Medical Device
Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 E	0 E	0 E
2023	0 E	0 E	0 E	0 E	0 E
2024	0 E	0 E	0 E	0 E	0 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-0.15 A	-0.13 A	-0.49 A	-0.35 A	-1.12 A
2022	-0.07 A	-0.05 A	-0.25 E	-0.29 E	-0.66 E
2023	-0.15 E	-0.20 E	-0.22 E	-0.15 E	-0.72 E
2024	-0.30 A	-0.45 E	-0.50 E	-0.53 E	-1.78 E

COMPANY UPDATE

Bone Biologics (BBLG) is a company advancing a technology, known as NELL-1, that could positively impact millions of Americans suffering with back pain, and stands to be in the middle of the increasing demand for treatment of such conditions as osteoporosis, which is estimated to be valued at \$14 billion by Coherent Market Insights and growing at close to 4% a year. Additionally, the company also has the potential to be heavily involved in the orthobiologics market, with a recently updated estimate by MR Accuracy Report of close to \$7 billion by 2028.

It is these issues, and other back-related problems, that continue to make us optimistic about the prospects for Bone Biologics. BBLG stock has had a bit of a rough run but it appears to us to have found support and we see the potential for decent sized gains ahead. Investors may have to be patient but stocks such as BBLG can have sudden, sharp movements on such events such as testing announcements or regulatory decisions, leading to the belief that getting an established position in a stock like BBLG for investors with a higher risk tolerance may be better to be done sooner rather than later.

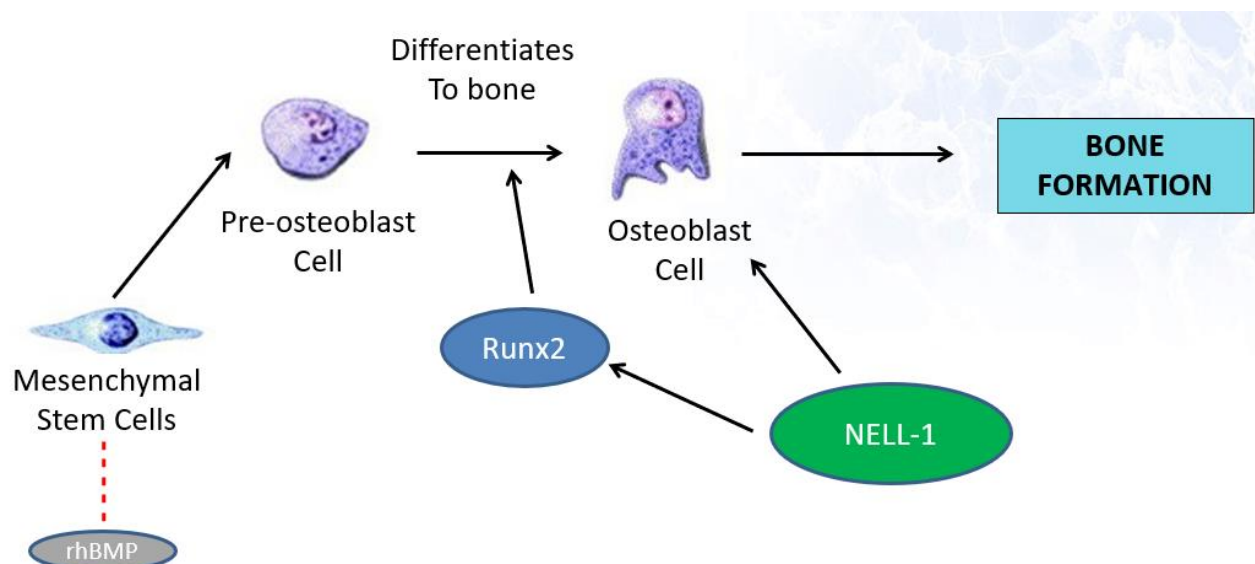
Bone recently announced their 2Q earnings and there were no real surprises. The company continues to make progress toward getting NELL-1 into the testing process by completing preparations for a first-in-man clinical study scheduled to commence in Australia in 2023. The study has been accepted by both the FDA and Australia's Human Research Ethics Committee. The company's balance sheet, which is important to pay attention to for a medical company at this stage of development, continues to look good in our view. Cash remains solid at almost \$5.5 million, while expenses in 2Q2022 were just under \$470,000. Additionally, the company holds no long-term debt at the present time—all leaving the company in a good position in our view to shepherd NELL-1 through the testing process. The company estimates it will take approximately \$10 million to complete first-in-man studies—money we believe the company's pristine balance sheet will help the company's management raise.

In short, 2Q2022 earnings from BBLG produced no surprises and confirmed that the process for getting NELL-1 into the commercial market remains on progress. There are obviously risks with a company such as Bone, such as speed bumps on the way to approval that the company is unable to overcome or being unable to fund further needed testing, but the initial studies we've seen give us confidence that BBLG will be able to navigate those potential challenges successfully and has the potential to be a good investment for investors with a higher risk tolerance.

THE SCIENCE

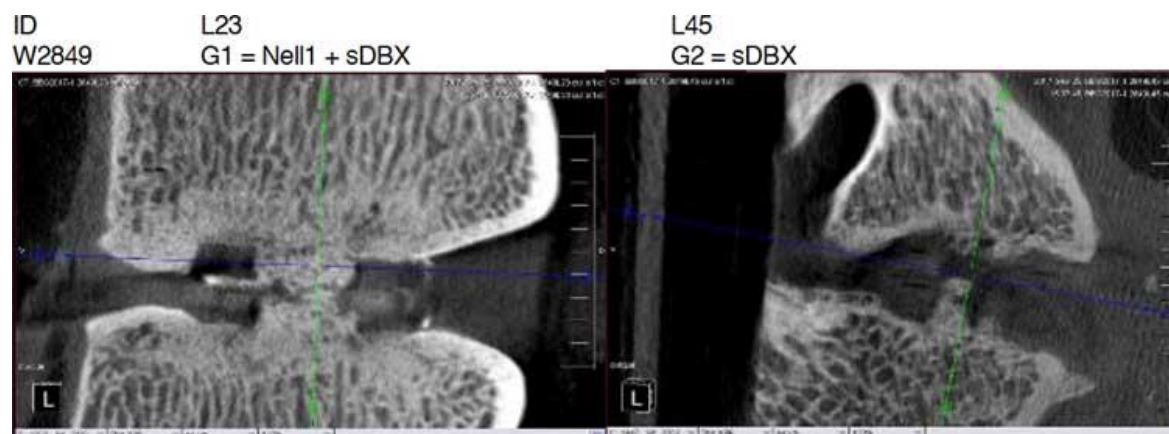
NELL-1 is a novel secreted protein that has been shown that by administering that protein intravenously stimulates significant bone formation through the regenerative ability of stem cells. There have been various studies showing the effectiveness of the NELL-1 protein in bone regeneration in rats, a couple of which can be found here [The osteoinductive properties of Nell-1 in a rat spinal fusion model - PubMed \(nih.gov\)](#) and here [Nell-1 Enhances Bone Regeneration in a Rat Critical-Sized Femoral Segmental Defect Model \(nih.gov\)](#). The diagram below demonstrates/illustrates that NELL-1 acts later in the pathway of bone formation and only grows bone in the presence of bone, which improves the safety of the procedure. The Runx2 protein is a transcription factor, meaning it attaches to specific regions of DNA and helps control the activity of particular genes, in this case activating NELL-1 and being responsible for bone growth. Contrasting,

the existing process using rhBMP induces a molecular cascade early in the pathway, targeting many cells, which could lead to tissue formation in undesirable anatomical locations.



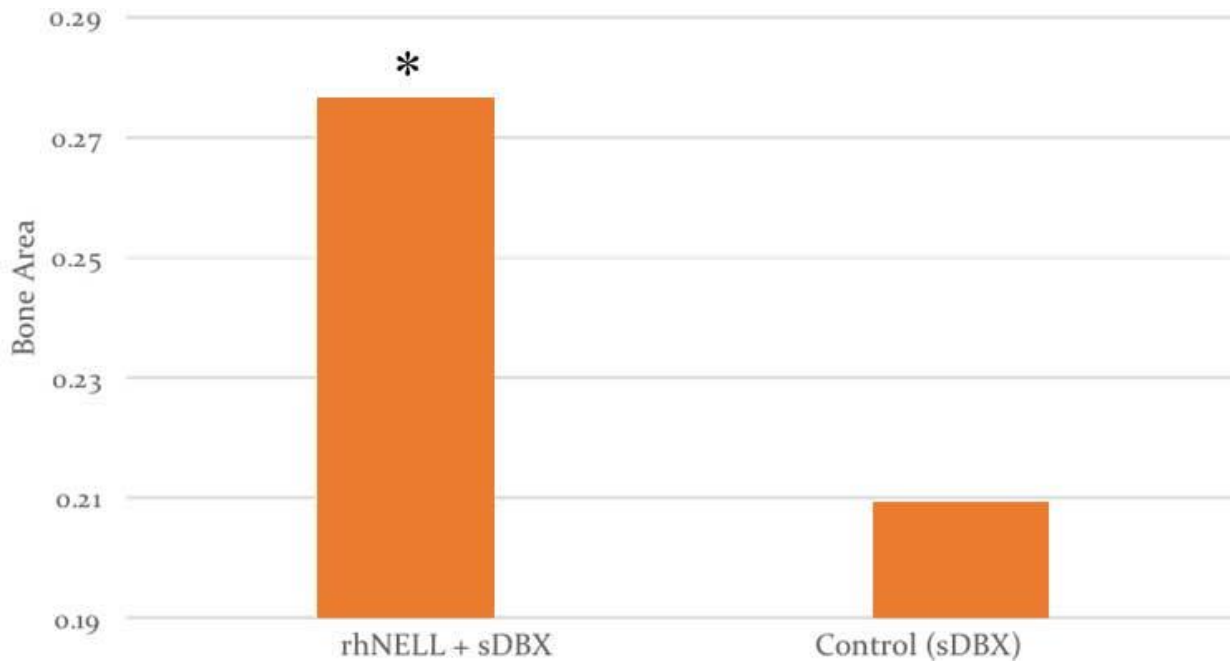
Source: Bone Biologics-Accessed-2/25/2022 <https://www.bonebiologics.com/>

Tests have shown some impressive results in sheep, which are used in studies like this because of their greater body weight and stresses on their bones. For example, NELL-1 increases the fusion rate 37.5 points—seen on the left below:



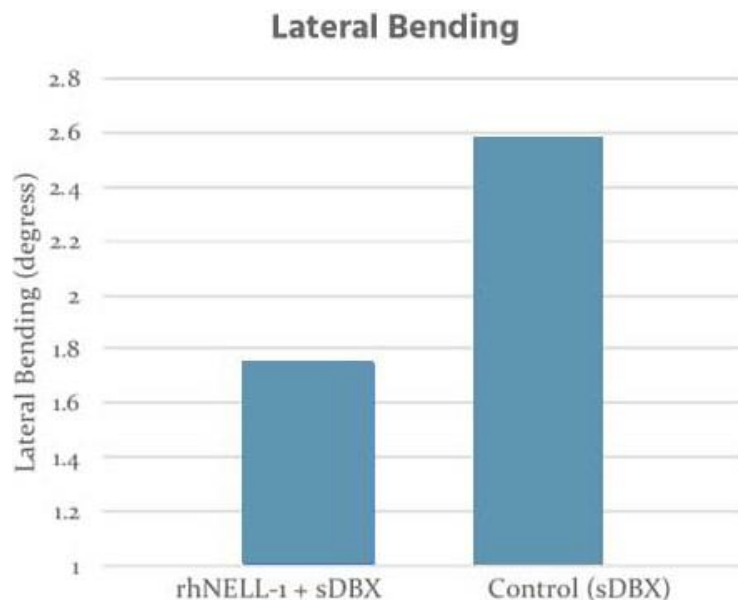
Source: Bone Biologics-Accessed-2/25/2022 <https://www.bonebiologics.com/>

It also showed significantly increased bone quality:



Source: Bone Biologics-Accessed-2/25/2022 <https://www.bonebiologics.com/> * = 30% increase in bone area

And while growing bone faster and with more area, the growth occurring is of a higher quality, which in the case of spinal fusion means more rigid bone formation and less bending:



Source: Bone Biologics-Accessed-02/25/2022 <https://www.bonebiologics.com/>

Finally, the NELL-1 technology has been reviewed by more than 45 Peer Reviewed Publications and has been tested in three animal species (rodent, sheep and nonhuman primates) and has shown to be effective and addresses some of the challenges involved in spinal fusion by:

- Inducing rapid, controlled, guided bone growth that avoids abnormal bone formation
- Forming bone in a target specific fashion later in the cascade without inducing inflammation
- Not initiating bone formation in surrounding tissue

The combination product, NELL-1/DBM is expected to be purified NELL-1 mixed with 510(k) cleared Demineralized Bone Putty recommended for use in conjunction with the applicable hardware consistent with the indication. The NELL-1/DBM Device will be comprised of a single dose vial of NELL-1 recombinant protein mixed with DBM putty in the operating room. A vial of NELL-1 plus DBM will be sold in a convenience kit with a diluent and a syringe of 510(k) cleared demineralized bone (DBM putty) produced by MTF. A delivery device will allow the surgeon to mix the reconstituted NELL-1 with the appropriate quantity of DBM Putty just prior to implantation. Since committing to this process and bring in new leadership Bone Biologics has already surpassed four milestones:

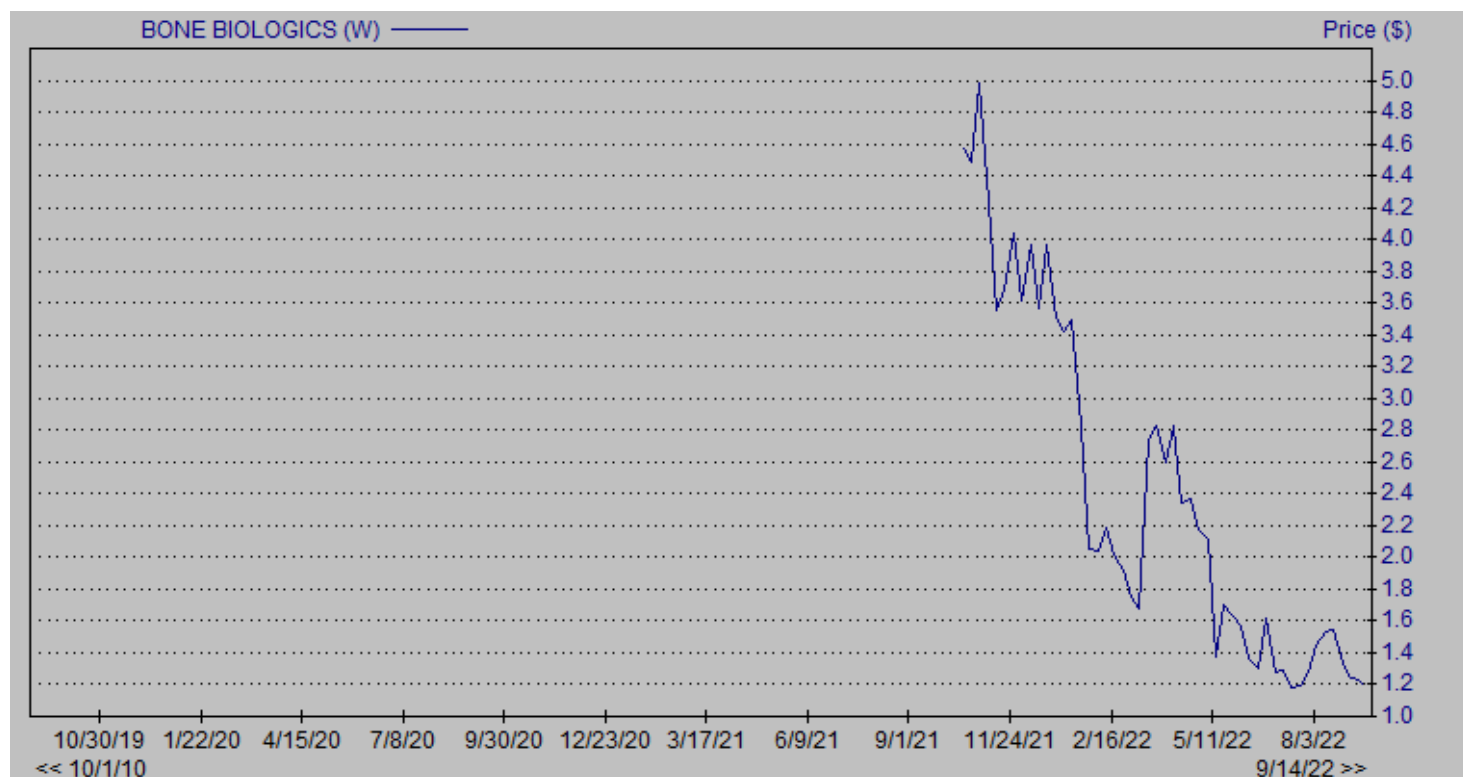
- Demonstrating a successful small laboratory scale pilot run for the manufacturing of the recombinant NELL-1 protein in Chinese hamster ovary cells
- Validation of protein dosing and efficacy in established large animal sheep models pilot study
- Completed pivotal animal study
- Filed for a Pilot clinical trial outside the US

Additionally, Bone Biologics has received Human Research Ethics Committee (HREC) approval for a multicenter pilot clinical trial that will commence in 2023 to evaluate NELL-1/DBM in 30 patients in Australia with degenerative disc disease. Additionally, UCLA TDG and Bone Biologics received guidance from the FDA that NELL-1/DBM will be classified as a combination product with a device lead—meaning the PMA approval process will likely be less onerous than if it was a pure drug or classified as a drug lead.

PROJECTED INCOME STATEMENT AND BALANCE SHEET

Bone Biologics Income Statement and Balance Sheet									
		2Q2021A	3Q2021A	4Q2021A	1Q2022A	2Q2022A	2022E	2023E	2024E
Revenues		0	0	0	0	0	0	0	0
Cost of Good Sold		0	0	0	0	0	0	0	0
Gross Profit		0	0	0	0	0	0	0	0
Operating Expenses									
	Research and Dev.	47,516	47,516	82,044	36,400	17,600	4,100,000	4,510,000	15,800,000
	Gen. and Admin.	365,289	595,078	1,019,432	620,022	451,704	2,500,000	2,750,000	2,887,500
Total Operating Expenses		412,805	642,594	1,101,476	656,422	469,304	6,600,000	7,260,000	18,687,500
Loss From Operations		(412,805)	(642,594)	(1,101,476)	(656,422)	(469,304)	(6,600,000)	(7,260,000)	(18,687,500)
	Interest Expense	(510,840)	(790,354)	(805,109)	0	0	300,000	600,000	1,800,000
	Gain on forgives of Def Comp	0	0	297,500	0	0	0	0	0
Loss before provision for income taxes		(923,645)	(1,432,948)	(1,609,085)	(656,422)	(469,304)	(6,900,000)	(7,860,000)	(20,487,500)
Provision for Income taxes		0	0	1,600	33,077	0	0	0	0
Net loss		(923,645)	(1,432,948)	(1,610,685)	(689,499)	(469,304)	(6,900,000)	(7,860,000)	(20,487,500)
Net loss per share		(\$0.13)	(\$0.49)	(\$0.35)	(\$0.07)	(\$0.05)	(\$0.66)	(\$0.72)	(\$1.78)
Wtd Avg Shares Outstanding		7,278,334	2,911,333	4,541,861	10,350,579	10,350,579	10,454,085	10,976,789	11,525,628
Assets									
Current Assets									
	Cash	4,438	3,374	6,675,365	5,814,586	5,454,522	5,284,525	3,835,296	5,888,002
	Prepaid Expenses	0	49,019	0	279,128	204,359	0	0	0
Total Assets		4,438	52,393	6,675,365	6,093,714	5,658,881	5,284,525	3,835,296	5,888,002
Liabilities and Stockholders Equity									
Current Liabilities									
	Accounts Payable	84,237	70,275	99,909	54,913	70,636	73,789	104,904	57,659
	Notes Payable	12,491,190	14,809,876	0	0	0	5,000,000	10,000,000	30,000,000
	Other liabilities	2,044,966	297,500	0	0	0	0	0	0
Total Liabilities		14,620,393	15,177,651	99,909	54,913	70,636	5,073,789	10,104,904	30,057,659
Stockholders Equity									
	Preferred Stock	30,682	12,273	10,350	10,350	10,350	10,350	10,350	10,350
	Additional Paid-in Capital	55,141,930	55,160,339	77,040,713	77,193,557	77,212,305	77,965,493	78,745,147	79,532,599
	Accumulated Deficit	(69,788,567)	(70,297,870)	(70,475,607)	(71,165,106)	(71,634,410)	(78,065,106)	(85,925,106)	(106,412,606)
Total Stockholders Equity		(14,615,955)	(15,125,258)	6,575,456	6,038,801	5,588,245	(89,263)	(7,169,609)	(26,869,657)
Total Liabilities and Stockholders Equity		4,438	52,393	6,675,365	6,093,714	5,658,881	4,984,525	2,935,296	3,188,002

HISTORICAL STOCK PRICE



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