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Zacks Small-Cap Research

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Brad Sorensen
312-265-9574
bsorensen@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Bone Biologics (BBLG-NASDAQ)

BBLG: Human Trials Begin

BBLG continues to pursue a way to make bone regeneration more efficient and with better outcomes for patients. We value BBLG at $19.50 per share using the discounted cash flow method.

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, or NB1.

The company announced that the first human patients have been treated with NB1, marking an important milestone for BBLG.

Current Price (06/19/24)	$1.49
Valuation	**$19.50**

SUMMARY DATA

52-Week High	**$14.08**
52-Week Low	**$1.42**
One-Year Return (%)	**-89.42**
Beta	**0.35**
Average Daily Volume (sh)	**57.469**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$2**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**34**
Insider Ownership (%)	**13**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 E	0 E	0 E	0 E
2025	0 E	0 E	0 E	0 E	0 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-0.07 A	-0.05 A	-0.12 A	-0.02 A	-0.13 A*
2023	-0.23 A	-1.69 A	-0.61 A	-5.89 A	-34.01 A
2024	-1.31 A	-1.39 E	-1.34 E	-1.29 E	-5.32 E
2025	-1.25 E	-1.20 E	-1.19 E	-1.20 E	-4.84 E

* Quarterly numbers don't add to annual due to share issuance and reverse split.

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COMPANY UPDATE

We have been discussing the promising initial results of the BBLG treatment known as NB1, and now the company has announced an important milestone—the first two human patients have been treated in the company's NB1 bone graft device. This marks the start of the pilot clinical study that will evaluate NB1 in 30 adult subjects who undergo transforaminal lumbar interbody fusion (TLIF) to treat degenerative disc disease (DDD) and will evaluate safety and effectiveness, fusion success, pain, function improvement and adverse events. According to the company, in order to be enrolled in the study, patients must have DDD at one level from L2-S1 and may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level. These two initial patients were treated in Australia. As we've noted before, the study design was previously reviewed and agreed upon by the U.S. Food and Drug Administration's Division of Orthopedic Devices in a Pre-submission to support progression to a pivotal clinical trial in the United States.

There are approximately 350,000 spinal fusion surgeries done in the US every year with varying degrees of success in alleviating often debilitating back pain. The existing dominant technology, known as rhBMP, has been quite successful in advancing the spinal fusion procedure but there are also challenges that can come along with using that technology. Patients can experience such impacts as rapid, uncontrolled bone growth that causes an unsound structure and unwanted bone formation where bone will grow where it is not intended. Back pain impacts 65 million Americans, with 16 million of those having what would be considered chronic back pain, leading to an estimated $12 billion per year in health care and indirect cost according to the Georgetown Policy Institute. While spinal fusion surgery isn't the appropriate treatment for every kind of back pain, it can help to relieve the pain associated with a variety of conditions.

The NELL-1 technology at the heart of NB1 is the centerpiece of what Bone Biologics is developing. It was developed by UCLA TDG and Bone holds the exclusive worldwide rights to that technology. NELL-1 has been reviewed positively in over 45 peer reviewed publications demonstrating technological viability. NELL-1 has shown spine fusion effectiveness across three animal species—rodent, sheep and nonhuman primate and has competed two clinically relevant sheep studies that demonstrated NELL-1 increases the fusion rate and quantity of bone compared to the control group.

Bone Biologics recently announced that it has received approval to begin pilot clinical trials with NB1 in spinal fusion patients. The approval was given by the Human Research Ethics Committee and the trials will take place in Australia. This is an important and exciting step for Bone as the study will evaluate the safety and effectiveness of the company's bone graft product—NB1. The study will include 30 adults who undergo transforaminal lumbar interbody fusion to treat degenerative disc disease. Importantly, this study design has been reviewed by the FDA's Division of Orthopedic Devices and is intended to support progression to a clinical study in the US.

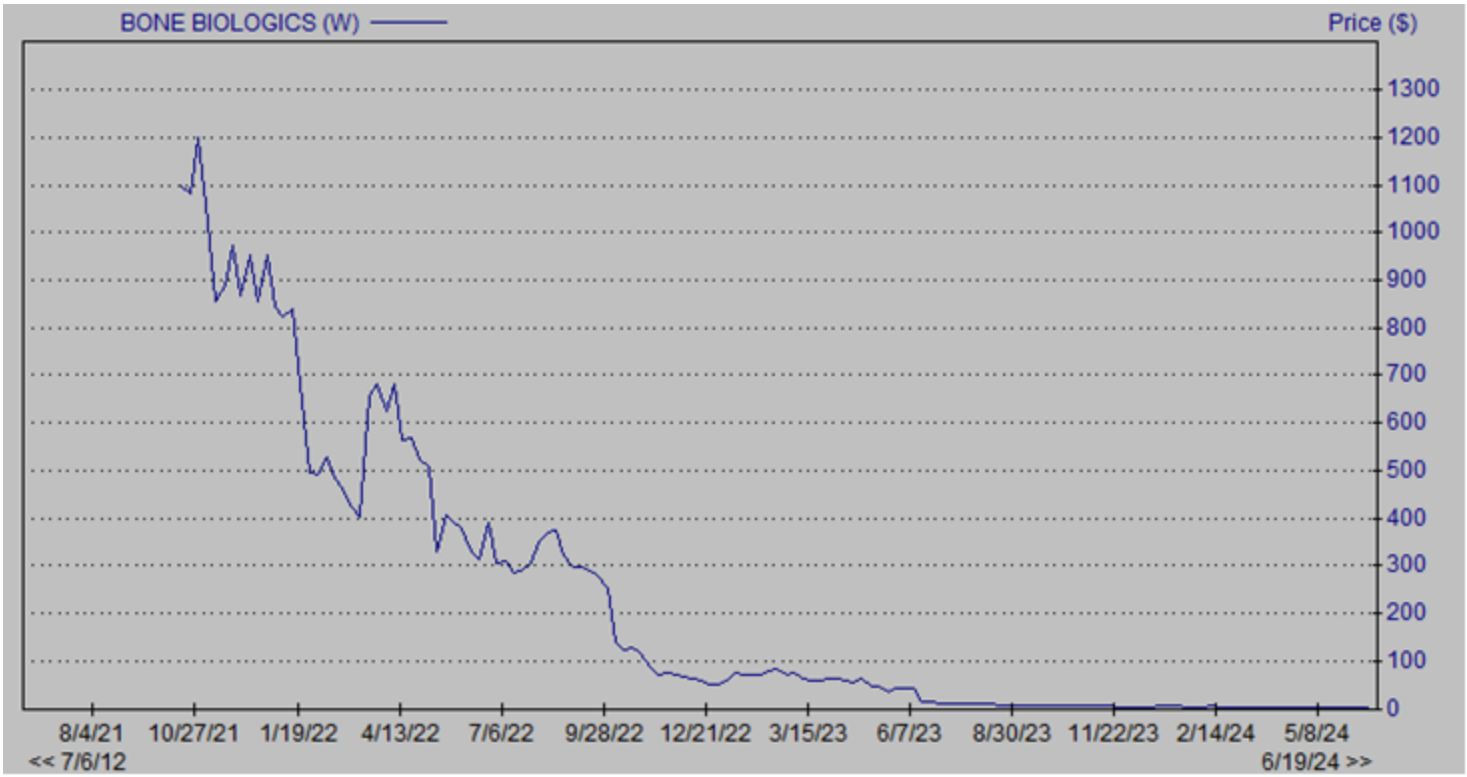
Summary

We have written before about the market opportunity that BBLG has, and it continues to grow. Investors have been slow to recognize the potential in our view but now, as human trials begin, is the opportunity to get in at what we view as a discounted price. If trial results are positive, as we believe they will be, the positive reaction in the investing community will likely be swift. We continue to be excited about the opportunity and the science behind NELL-1 and are looking forward to the results from the human trials ongoing this year. BBLG has what we believe is a product with great potential, addressing a market with seemingly insatiable demand and a solid funding situation, which is vital in this environment. As such, we believe investors with a longer-term investing horizon should take a look at BBLG.

INCOME STATEMENT AND BALANCE SHEET

Bone Biologics Income Statement and Balance Sheet								
		4Q2023A	1Q2024A	2Q2024E	3Q2024E	4Q2024E	2025E	2026E
Revenues		0	0	0	0	0	0	0
Cost of Good Sold		0	0	0	0	0	0	0
Gross Profit		0	0	0	0	0	0	0
Operating Expenses								
	Research and Dev.	447,078	245,625	257,906	270,802	284,342	1,083,206	1,159,031
	Gen. and Admin.	712,930	657,911	744,617	744,617	744,617	2,978,468	3,127,391
Total Operating Expenses		1,160,008	903,536	1,002,523	1,015,419	1,028,959	4,061,674	4,286,422
Loss From Operations		(1,160,008)	(903,536)	(1,002,523)	(1,015,419)	(1,028,959)	(4,061,674)	(4,286,422)
	Interest income (expense)	348	255	428	536	649	2,596	2,648
	Other income/(expenses)	(390,225)	37,311	39,177	41,135	43,192	172,769	176,224
Loss before provision for income taxes		(1,549,885)	(865,970)	(962,919)	(973,747)	(985,117)	(3,886,310)	(4,107,550)
Provision for Income taxes		0	0	0	0	0	0	0
Net loss		(1,549,885)	(865,970)	(962,919)	(973,747)	(985,117)	(3,886,310)	(4,107,550)
Net loss per share		($5.89)	($1.31)	($1.39)	($1.34)	($1.29)	($4.84)	($4.87)
Wtd Avg Shares Outstanding		263,137	660,928	693,974	728,673	765,107	803,362	843,530
Assets								
Current Assets								
	Cash	3,026,569	3,227,634	2,904,871	2,614,384	2,352,945	2,117,651	1,905,886
	Advances on R&D contract services	328,844	328,844	328,844	328,844	328,844	328,844	328,844
	Prepaid Expenses	382,350	283,096	297,251	312,113	327,719	344,105	361,310
Total Assets		3,737,763	3,839,574	3,530,965	3,255,341	3,009,508	2,790,600	2,596,040
Liabilities and Stockholders Equity								
Current Liabilities								
	Accounts Payable	360,662	146,186	153,495	161,170	169,229	177,690	186,574
	Notes Payable	0	0	0	0	0	5,000,000	15,000,000
	Other liabilities	470,740	18,440	241,160	80,514	470,740	494,277	518,991
Total Liabilities		831,402	164,626	394,655	241,684	639,969	5,671,967	15,705,565
Stockholders Equity								
	Common Stock	534	1,016	1,016	1,016	1,016	1,016	1,016
	Additional Paid-in Capital	83,814,785	85,448,860	83,129,021	83,149,047	83,814,785	85,448,860	85,448,860
	Accumulated Deficit	(80,908,958)	(81,774,928)	(79,993,727)	(80,136,406)	(81,446,261)	(88,331,244)	(98,559,402)
Total Stockholders Equity		2,906,361	3,674,948	3,136,310	3,013,657	2,369,540	(2,881,368)	(13,109,526)
Total Liabilities and Stockholders Equity		3,737,763	3,839,574	3,530,965	3,255,341	3,009,508	2,790,600	2,596,040

HISTORICAL STOCK PRICE



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