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Zacks Small-Cap Research

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Bone Biologics (BBLG-NASDAQ)

BBLG: Important Trial Gains Approval

BBLG continues to pursue a way to make bone regeneration more efficient and with better outcomes for patients. The company just received approval for human trials, which is a vital step toward FDA approval.

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 knows as NELL-1/DBX.

The company announced that it has received approval for a pilot human trial for its NB1 bone graft. This is an extremely important step and an important milestone for the company.

Current Price (04/10/23)	$0.26
Valuation	**$7.55**

SUMMARY DATA

52-Week High	**$2.84**
52-Week Low	**$0.19**
One-Year Return (%)	**-90.03**
Beta	**0.75**
Average Daily Volume (sh)	**56,482**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8%**
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 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 E	0 E	0 E	0 E	0 E
2024	0 E	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	-0.05 E	-0.10 E	-0.12 E	-0.07 E	-0.34 E
2024	-0.10 E	-0.11 E	-0.12 E	-0.14 E	-0.47 E
2025	-0.15 E	-0.20 E	-0.21 E	-0.20 E	-0.76 E

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

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COMPANY UPDATE

Bone Biologics 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.

After the announcement, the CEO of Bone Biologics, Mr. Jeffrey Frelick, said, "We believe NB1 is poised to address the problems with existing bone growth products by providing rapid, controlled and guided bone growth only in the presence of existing bone, not elsewhere in the body. Our longer-term goal is to capture a meaningful portion of the $3 billion annual global market for spine fusion products."

We have previously gone through the science behind the NB1 technology and the very promising results seen in animal trials. We are excited that this important product is now able to undergo human testing and are confident that positive results will follow based on the animal studies we have cited before. This is an important step in what we believe will be the eventual commercialization of the NB1 product.

Additionally, the company recently released its 2022 annual report and the following are the highlights:

- Cash on the balance sheet rose to $7.5 million at the end of 2022 from $6.7 million at the end of the previous year.
- Liabilities remain low compared to the cash on hand.
- The company is in the clinical stage and has no revenues but continues to manage expenses well, resulting in a lower-than-expected 2022 loss of $0.13 per share.

The annual report confirms what we have written about previously—that the company is in solid financial shape in order to shepherd this potentially very important treatment known as NB1 through the process, toward commercialization. Combined with the announcement that human trials are also beginning, this is a very exciting time for Bone Biologics and remain quite positive on the prospects for BBLG in the coming months and years.

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, ahead of the human trials, 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 human trials beginning 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						
		2022E	2023E	2024E	2025E	2026E
Revenues		0	0	0	0	0
Cost of Good Sold		0	0	0	0	0
Gross Profit		0	0	0	0	0
Operating Expenses						
	Research and Dev.	1,579,298	1,737,228	3,474,456	6,948,911	13,897,822
	Gen. and Admin.	2,085,875	2,294,463	2,409,186	2,529,645	2,656,127
Total Operating Expenses		3,665,173	4,031,690	5,883,641	9,478,556	16,553,950
Loss From Operations		(3,665,173)	(4,031,690)	(5,883,641)	(9,478,556)	(16,553,950)
	Interest Expense	0	0	0	600,000	900,000
	Other income/(expenses)	2,180,553	0	0	1	2
Loss before provision for income taxes		(1,484,620)	(4,031,690)	(5,883,641)	(10,078,555)	(17,453,948)
Provision for Income taxes		0	0	0	1	2
Net loss		(1,484,620)	(4,031,690)	(5,883,641)	(10,078,556)	(17,453,950)
Net loss per share		($0.13)	($0.34)	($0.47)	($0.76)	($1.26)
Wtd Avg Shares Outstanding		11,423,074	11,994,228	12,593,939	13,223,636	13,884,818
Assets						
Current Assets						
	Cash	7,538,312	7,689,078	7,842,860	7,999,717	8,159,711
	Prepaid Expenses	956,925	0	0	0	0
Total Assets		8,495,237	7,689,078	7,842,860	7,999,717	8,159,711
Liabilities and Stockholders Equity						
Current Liabilities						
	Accounts Payable	888,461	932,884	979,528	1,028,505	1,079,930
	Notes Payable	0	0	0	10,000,000	15,000,000
	Other liabilities	1,659,468	0	0	0	0
Total Liabilities		2,547,929	932,884	979,528	11,028,505	16,079,930
Stockholders Equity						
	Common Stock	15,300	15,300	15,300	15,300	15,300
	Additional Paid-in Capital	77,892,235	82,732,811	88,723,590	88,910,027	101,472,546
	Accumulated Deficit	(71,960,227)	(75,991,917)	(81,875,559)	(91,954,115)	(109,408,064)
Total Stockholders Equity		5,947,308	6,756,194	6,863,332	(3,028,787)	(7,920,219)
Total Liabilities and Stockholders Equity		8,495,237	7,689,078	7,842,860	7,999,717	8,159,711

HISTORICAL STOCK PRICE



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