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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 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 known 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. Additionally, the company announced some capital moves to solidify the company's financial situation.

Current Price (06/19/23)	$1.57
Valuation	**$8.00**

SUMMARY DATA

52-Week High	**$51.95**
52-Week Low	**$1.57**
One-Year Return (%)	**-96.01**
Beta	**0.76**
Average Daily Volume (sh)	**226.827**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8%**
Insider Ownership (%)	**43%**
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 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	-0.23 A	-1.50 E	-1.55 E	-0.95 E	-4.00 E
2024	-1.50 E	-1.55 E	-1.60 E	-1.70 E	-6.35 E
2025	-1.80 E	-2.00 E	-2.10 E	-2.00 E	-7.90 E

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

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COMPANY UPDATE

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.

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 announced some financial transactions that helped to stabilize the company's share price, while also announcing a plan offering of shares to further fund operations and solidify capital for the approval process. The details are as follow:

- The company announced a reverse 1 for 30 share split to reduce the overall share count and bring the price of BBLG to a more acceptable range.

- The company issued, including the potential overallotment to the underwriter that we believe will be exercised, 2,918,781 shares in order to fund the clinical trials, bolster the company's patent portfolio, and other corporate endeavors.

- As a result of these capital changes, we are adjusting our price target to account for the reverse split, the dilution from the additional shares, and the changing market conditions that includes tightening credit availability and the perception that acquisitions may be harder to come by in the coming year. We remain optimistic on the prospects for BBLG and the new price target of $8.00 per share represents a substantial premium over the current price.

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.

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