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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 and released 1Q earnings results.

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. Additionally, the company released 1Q 2023 earnings results showing good cash on the balance sheet.

Current Price (05/15/23)	$0.19
Valuation	**$6.75**

SUMMARY DATA

52-Week High	**$1.73**
52-Week Low	**$0.19**
One-Year Return (%)	**-90.03**
Beta	**0.75**
Average Daily Volume (sh)	**56,482**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$3**
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	-0.10 E	-0.12 E	-0.07 E	-0.62 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 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 recently released its 1Q 2023 earnings and the following are the highlights:

- Cash on the balance sheet was $6.2 million as of March 31, 2023, down from $7.5 million at the end of 2022. The company noted that it estimates it will need approximately $15 million to complete first in man studies and an additional $27 million for FDA approval.

- Bone Biologics will have to raise more funds through the equity or debt markets, but we believe as test results come in, those funds will become easier to obtain.

- 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. Expenses went up during the first quarter compared to the last quarter, but we are happy to see that development as the vast majority of the increase was in the research area as the company continues to develop its Nell-1 product.

- We reduced our price target to $6.75 to account for the additional share count. The reduction should not be viewed in any way as a negative view on BBLG, simply an accounting issue.

The quarterly 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 recent announcement that human trials are also beginning, this is a very exciting time for Bone Biologics and we 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.

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