Zacks Small-Cap Research

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FibroBiologics, Inc. (FBLG-NASDAQ)

FBLG: On Target to Initiate Phase 1/2 Trial in 2025…

Based on our probability adjusted DCF model that takes into account potential future revenues of CybroCell, CYMS101, CYWC628, and psoriasis treatment FBLG is valued at $11.00 per share. This model is highly dependent upon the continued clinical success of the company's development candidates and will be adjusted accordingly based upon future clinical results.

Current Price (11/21/24)	$2.24
Valuation	**$11.00**

OUTLOOK

On November 12, 2024, FibroBiologics, Inc. (FBLG) announced financial results for the third quarter of 2024 and provided a business update. The company is continuing preparations for a Phase 1/2 clinical trial in Australia to test its fibroblast-based spheroid product as a therapy for diabetic foot ulcers. We anticipate the trial initiating in the second quarter of 2025 and completing by the end of 2025. FibroBiologics recently announced filing two patent applications covering cell-based therapy for splenomegaly and reduction of blood clots associated with instant blood-mediated inflammatory reaction (IBMIR) in cell-based therapeutics. These add to the company's already large intellectual property portfolio and show its commitment to scientific discoveries on its path to developing fibroblast-based therapies.

SUMMARY DATA

52-Week High	**$29.10**
52-Week Low	**$1.11**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**203,901**
Shares Outstanding (mil)	**35**
Market Capitalization ($mil)	**$78**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**21**
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 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2024	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2025					0.0 E
2026					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.17 A	-$0.17 A	-$0.17 A	-$0.17 A	-$0.68 A
2024	-$0.27 A	$0.03 A	-$0.01 A	-$0.09 E	-$0.33 E
2025					-$0.29 E
2026					$0.29 E

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WHAT'S NEW

Business Update

On Track to Initiate Phase 1/2 Trial in Diabetic Foot Ulcers

FibroBiologics, Inc. (FBLG) is on track to initiate a Phase 1/2 trial of CYWC628, a fibroblast-based spheroid product candidate, in patients suffering from diabetic foot ulcers (DFU) in the second quarter of 2025. We anticipate the trial being completed by the end of 2025.

DFUs affect approximately 19 million individuals worldwide, with approximately 1.6 million of them in the U.S. The company previously performed preclinical experiments in a diabetic mouse model. The results showed that fibroblast-based spheroid-treated wounds had a greater percent change in wound closure post-treatment compared to wounds treated with an approved DFU therapy (Grafix®) or control. In addition, wound closure occurred faster for fibroblast spheroid-treated wounds, which is critically important since worse outcomes for patients are associated with wounds that do not heal in a timely manner.

Pre-IND Studies for Psoriasis Treatment to Complete by End of 2025

The company has plans to complete pre-IND studies for its intravenously-administered fibroblast cell-based psoriasis treatment candidate CYPS317. The company has conducted studies in a mouse model of psoriasis (induced with 5% imiquimod [IMQ]), with results showing that a single treatment significantly reduced psoriatic skin lesion severity. It also ameliorated IMQ-induced changes in spleen size and blood cell counts along with reducing epidermal thickening and immune cell infiltration in psoriatic lesions. There were no adverse events seen with the respiratory, circulatory, hepatic, and renal organ systems. The IND-enabling studies should be completed before the end of 2025.

Expands Intellectual Property Portfolio

The company has recently filed the following patent applications:

- A patent application has been filed that covers methods of treatment of splenomegaly using a cell-based therapeutic approach. As mentioned above, treatment with a fibroblast-based treatment ameliorated changes in spleen size induced by IMQ in a mouse model of psoriasis. Enlarged spleen (known as splenomegaly) can occur in a variety of conditions, including autoimmune disorders, chronic infections, chemotherapy, and depression treatment drugs. Enlarged spleens can lead to discomfort, anemia, and a weakened immune system.

- A patent was filed that covers methods employing fibroblasts or other Tissue Factor (TF)-expressing cells for the prevention of Instant Blood-Mediated Inflammatory Reaction (IBMIR). One of the most pressing challenges in cell therapy is IBMIR, which is a nonspecific response mediated by the innate immune system that is characterized by coagulation, complement activation, and platelet adhesion that ultimately endangers the effectiveness and safety of cell-based therapies. This novel approach to minimizing the risk of IBMIR could help make cell therapy treatment safer and more effective.

Update on Artificial Thymus Organoid Technology

In October 2024, FibroBiologics announced new findings from its artificial thymus organoid program. The company has continued to evaluate the technology in animal models and recently disclosed that fibroblasts and thymus-derived cell organoids can persist and function for over 50 days post-transplantation. The organoids show evidence of vascularization and additional analysis showed that they are capable of generating a diverse array of fully mature T cells that express T cell receptors (TCR). These T cells can then further differentiate into CD4, CD8, regulatory, and gamma delta T cells, which are vital for a fully functioning immune response. The T cells also express a very diverse set of TCR-beta chains that are capable of

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recognizing an array of antigens. While very early in development, this technology may one day be used to treat patients with immune deficiencies due to age-related immune decline or who have been treated with chemotherapy. We anticipate the company publishing its findings in 2025.

Financial Update

On November 12, 2024, FibroBiologics announced financial results for the third quarter of 2024. As expected, the company did not record any revenues for the third quarter of 2024. R&D expenses for the third quarter of 2024 were $1.2 million compared to $0.6 million for the third quarter of 2023. The increase was primarily due to increased CDMO costs, research materials and supplies, and personnel related expenses. G&A expenses for the third quarter of 2024 were $2.1 million compared to $1.5 million in the third quarter of 2023. The increase was primarily due to higher regulatory, legal, accounting, insurance, and personnel costs. The company reported a $1.9 million gain during the three months ending September 30, 2024 resulting from the mark to market of the company's warrant liability, which will occur at the end of each reporting period as long as the warrants are outstanding and classified as a liability.

As of September 30, 2024, FibroBiologics had approximately $7.8 million in cash and cash equivalents. As of November 11, 2024, FibroBiologics had approximately 34.7 million shares outstanding and, when factoring in options and warrants, a fully diluted share count of 40.0 million.

Conclusion

The company remains on track with its business plan and we look forward to the initiation of the Phase 1/2 clinical trial of CYWC628, the company's lead asset targeting diabetic foot ulcers, in the second quarter of 2025 and completion of the trial before the end of 2025. We are also encouraged by how the company continues to expand its intellectual property portfolio covering cell-based therapeutic approaches. With no changes to our model our valuation remains at $11 per share.

PROJECTED FINANCIALS

FibroBiologics, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
CybroCell	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
CYMS101	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
CYWC628	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Psoriasis	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
License and other revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & development	$2.4	$1.0	$1.0	$1.2	$1.0	$4.1	$6.0	$8.0
General & administrative	$6.5	$2.5	$2.2	$2.1	$1.9	$8.8	$7.5	$7.7
Operating Income	($8.9)	($3.5)	($3.2)	($3.4)	($2.9)	($12.9)	($13.5)	($15.7)
Non-Operating Expenses (Net)	($7.6)	($5.0)	$4.1	$2.9	$0.0	$2.0	$0.0	$0.0
Pre-Tax Income	($16.5)	($8.5)	$0.9	($0.5)	($2.9)	($11.0)	($13.5)	($15.7)
Deemed Dividend	$2.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($19.1)**	**($8.5)**	**$0.9**	**($0.5)**	**($2.9)**	**($11.0)**	**($13.5)**	**($15.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.68)**	**($0.27)**	**$0.03**	**($0.01)**	**($0.09)**	**($0.33)**	**($0.29)**	**($0.29)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	28.2	31.1	32.7	33.5	34.0	32.8	47.0	55.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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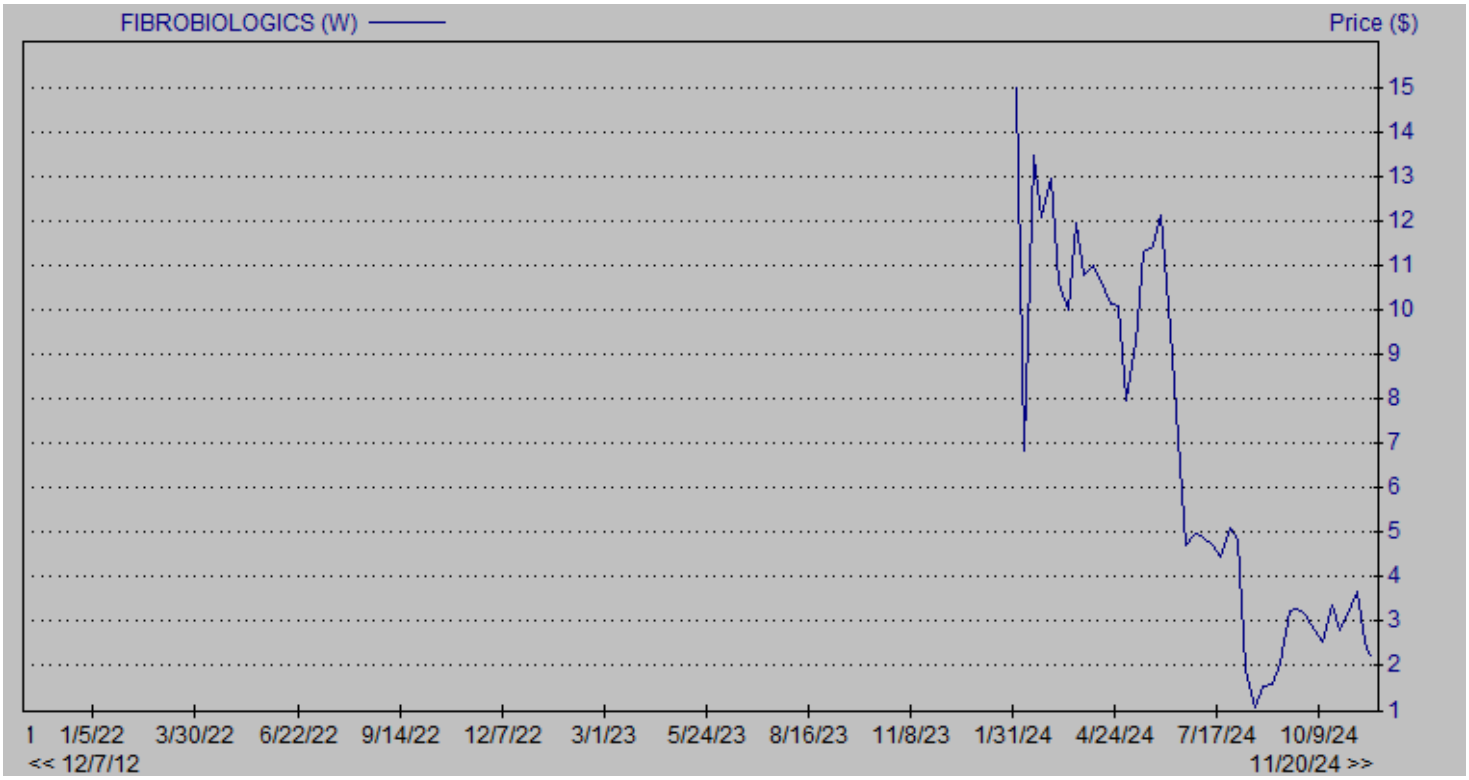

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