

May 14, 2025



FibroBiologics Reports First Quarter 2025 Financial Results and Provides Corporate Update

Preparations for Phase 1/2 clinical trial in Australia utilizing fibroblast-based spheroids product candidate, CYWC628, to treat diabetic foot ulcers are proceeding with plans to initiate in the third quarter of 2025

HOUSTON, May 14, 2025 (GLOBE NEWSWIRE) -- FibroBiologics, Inc. (Nasdaq: FBLG) ("FibroBiologics"), a clinical-stage biotechnology company with 240+ patents issued and pending for the development of therapeutics and potential cures for chronic diseases using fibroblasts and fibroblast-derived materials, today announced first quarter 2025 financial results and provided a corporate update.

Recent Highlights

- Announced the completion of FibroBiologics' proprietary master cell bank that will support upcoming clinical trials. Manufactured in accordance with FDA Good Manufacturing Practices (cGMP), the cell bank has successfully passed all required safety testing.
- Announced the opening of a new laboratory facility in Houston that will expand the company's ability to pioneer additional candidates for chronic disease-focused indications leveraging its novel fibroblast-based technology.
- Announced a significant advancement in neurodegenerative disease research. Leveraging the well-established Cuprizone animal model, FibroBiologics has demonstrated that intravenous fibroblasts can facilitate remyelination. FibroBiologics' Cuprizone animal model study demonstrated a statistically significant increase in myelin expression within seven and nine weeks after both single and multiple dose fibroblast treatments. This confirms FibroBiologics' previous report of remyelination with the Experimental Autoimmune Encephalomyelitis (EAE) animal model.
- Presented at a number of investor and science conferences including the ThymUS 2025 Meeting, The Cell & Gene Meeting on the Mediterranean, and The German-Nordic Joint Extracellular Matrix Meeting.
- Announced the filing of a patent application with the United States Patent and Trademark Office covering methods employing fibroblasts to improve mitochondrial performance in cells.

Upcoming Milestones

- Initiate Phase 1/2 clinical trial in Australia utilizing fibroblast-based spheroids product

candidate, CYWC628, in diabetic foot ulcer (DFU) patients in the third quarter of 2025.

- Complete Phase 1/2 clinical trial in Australia in DFU patients in the first quarter of 2026.
- Determine the potential of using the CYWC628 master cell bank for use with the manufacturing of CybroCell™, FibroBiologics' investigational intradiscal administered allogeneic fibroblast cell-based therapy in development for degenerative disc disease.
- Complete pre-clinical IND-enabling studies for the treatment of psoriasis with FibroBiologics' fibroblast spheroid product candidate, CYPS317, by the end of 2025.

"In the first quarter of 2025, we achieved a major operational milestone: the completion of the CYWC628 master cell bank with Charles River. This sets the foundation for our upcoming Phase 1/2 clinical trial in DFU wound healing, which we're on track to launch in the second half of the year," said Pete O'Heeron, Founder & CEO. "We've also made a strategic move to strengthen our competitive advantage by filing a new patent that leverages our fibroblast platform to target mitochondrial activity—a key driver in a range of diseases. We believe the increasing visibility we're gaining across investor and scientific forums reflects not just interest, but belief in the disruptive potential of our platform and the velocity building across our pipeline."

Financial Highlights for the Quarter Ended March 31, 2025

- Research and development expenses were approximately \$1.8 million for the quarter ended March 31, 2025, compared to approximately \$1.0 million for the same period in 2024. The increase was primarily due to increased drug product expenses and other expenses to prepare for the Phase 1/2 clinical trial in DFU patients, and the hiring of additional research personnel.
- General and administrative expenses were approximately \$2.8 million for the quarter ended March 31, 2025, compared to approximately \$2.5 million for the same period in 2024. The increase was primarily due additional personnel.
- For the quarter ended March 31, 2025, FibroBiologics reported a net loss of approximately \$5.0 million compared to a net loss of approximately \$8.5 million for the same period in 2024. The decrease in net loss for the quarter ended March 31, 2025, was primarily due to the change in the fair value of the warrant liability, partially offset by increases in research and development expenses and general and administrative expenses.
- Cash and cash equivalents totaled approximately \$8.7 million at March 31, 2025.

For more information, please visit FibroBiologics' [website](#) or email FibroBiologics at info@fibrobiologics.com.

Cautionary Statement Regarding Forward-Looking Statements

This communication contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements include information concerning the benefits of the new laboratory facility, plans for, and the anticipated timing of the initiation of, FibroBiologics' clinical trials, and the robustness, progress, timing, and momentum of FibroBiologics' research and development program. These forward-looking statements are based on FibroBiologics' management's current expectations, estimates,

projections, and beliefs, as well as a number of assumptions concerning future events. When used in this communication, the words "estimates," "projected," "expects," "anticipates," "forecasts," "plans," "intends," "believes," "seeks," "may," "will," "should," "future," "propose" and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside FibroBiologics' management's control, that could cause actual results to differ materially from the results discussed in the forward-looking statements, including those set forth under the caption "Risk Factors" and elsewhere in FibroBiologics' annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the SEC and any subsequent public filings. Copies are available on the SEC's website, www.sec.gov. These risks, uncertainties, assumptions and other important factors include, but are not limited to: (a) risks related to FibroBiologics' liquidity and its ability to maintain capital resources sufficient to conduct its business; (b) expectations regarding the initiation, progress and expected results of FibroBiologics' R&D efforts and preclinical studies; (c) the unpredictable relationship between R&D and preclinical results and clinical study results; (d) the ability of FibroBiologics to successfully prosecute its patent applications; (e) FibroBiologics' ability to maintain the master services agreement with Charles River and enter into statements of work for CDMO services; and (f) FibroBiologics' ability to maintain the master services agreement with Southern Star Research. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and FibroBiologics assumes no obligation and, except as required by law, does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. FibroBiologics gives no assurance that it will achieve its expectations.

About FibroBiologics

Based in Houston, FibroBiologics is a clinical-stage biotechnology company developing a pipeline of treatments and seeking potential cures for chronic diseases using fibroblast cells and fibroblast-derived materials. FibroBiologics holds 240+ US and internationally issued patents/patents pending across various clinical pathways, including wound healing, multiple sclerosis, disc degeneration, psoriasis, orthopedics, human longevity, and cancer. FibroBiologics represents the next generation of medical advancement in cell therapy and tissue regeneration. For more information, visit www.FibroBiologics.com.

General Inquiries:

info@fibrobiologics.com

Investor Relations:

Nic Johnson

Russo Partners

(212) 845-4242

fibrobiologicsIR@russopr.com

Media Contact:

Liz Phillips

Russo Partners

(347) 956-7697

Elizabeth.phillips@russopartnersllc.com



Source: Fibrobiologics, Inc.