

FibroBiologics Reports Third Quarter 2025 Financial Results and Provides Corporate Update

Advancing preparations to begin manufacturing of fibroblast-based spheroids product candidate, CYWC628, for the Phase 1/2 clinical trial evaluating CYWC628 in diabetic foot ulcers (DFU) patients

Preparing to submit Investigational New Drug applications for the treatment of psoriasis with CYPS317 and the treatment of multiple sclerosis with CYMS101

HOUSTON, Oct. 31, 2025 (GLOBE NEWSWIRE) -- FibroBiologics, Inc. (Nasdaq: FBLG) ("FibroBiologics"), a clinical-stage biotechnology company with 270+ patents issued and pending with a focus on the development of therapeutics and potential cures for chronic diseases using fibroblasts and fibroblast-derived materials, today announced third quarter 2025 financial results and provided a corporate update.

Recent Highlights

- Announced positive IND-enabling updates from the psoriasis research program demonstrating the potential of human dermal fibroblast spheroids as a novel therapeutic approach for chronic-relapse psoriasis.
- Advanced the Bone Marrow Organoid platform, offering promising new treatment options for hematopoietic cancers and age-related immune decline.
- Filed patent application with the United States Patent and Trademark Office covering methods of generating multipotent cells from fibroblasts found in donor tissue for clinical applications.
- Published a leadership-authored article in the *Opinion Pages* presenting the scientific case for fibroblast cells' therapeutic advantages compared to stem cell therapies.
- Presented recent updates on fibroblast-based therapies for chronic disease treatments at the Cell & Gene Meeting on the Mesa, H.C. Wainwright 27th Annual Global Investment Conference, and the 2025 ThinkEquity Conference.
- Implemented cost efficient measures to reduce operating expenses and focus resources on near-term pipeline priorities.

Upcoming Milestones

- Complete manufacturing training runs for CYWC628 and confirm sterility of the manufacturing process by the end of 2025.
- Complete the manufacturing of CYWC628 in accordance with FDA Good

Manufacturing Practices (cGMP).

- Initiate Phase 1/2 clinical trial in Australia evaluating fibroblast-based spheroids product candidate, CYWC628, in diabetic foot ulcers (DFU) patients in the first quarter of 2026.
- Complete Phase 1/2 clinical trial in Australia in DFU patients in the third quarter of 2026.
- Complete pre-clinical IND-enabling studies for the treatment of psoriasis with CYP317, FibroBiologics' fibroblast spheroid product candidate, and submit IND.
- Complete pre-clinical IND-enabling studies for the treatment of multiple sclerosis with CYMS101, FibroBiologics' fibroblast spheroid product candidate, and submit IND.

"This quarter brought our strategy into greater focus," said Pete O'Heeron, Founder and Chief Executive Officer of FibroBiologics. "We are efficiently moving our most advanced product candidates towards the clinic while laying the groundwork to demonstrate that fibroblasts can be a scalable platform and not simply a single-asset bet. Our fibroblast platform will enter the clinic with our Phase 1/2 trial in diabetic foot ulcer patients in the first quarter next year, as we execute against defined milestones to validate its biology, the technology, and the regulatory and commercial path forward."

Financial Highlights for the Nine Months Ended September 30, 2025

- Research and development expenses were approximately \$6.6 million for the nine months ended September 30, 2025, compared to approximately \$3.1 million for the same period in 2024. The increase was primarily due to increased contract research costs of \$0.4 million for cell manufacturing activities; increased CRO costs of \$2.1 million to prepare for a clinical trial; increased lab facilities expense of \$0.2 million for lab rent; increased personnel related expenses of \$0.3 million due to hiring additional research scientists; and increased research materials and supplies expenses of \$0.5 million due to increased laboratory personnel and preclinical studies.
- General and administrative expenses were approximately \$7.4 million for the nine months ended September 30, 2025, compared to approximately \$6.9 million for the same period in 2024. The increase was primarily due to increased expenses of \$0.7 million for added personnel in 2025, which includes stock-based compensation expense; increased professional fees of \$0.2 million for accounting, legal and marketing expenses; increased travel expenses of \$0.1 million; and decreased Direct Listing related expenses of \$0.4 million.
- For the nine months ended September 30, 2025, FibroBiologics reported a net loss of approximately \$15.4 million compared to a net loss of approximately \$8.1 million for the same period in 2024. The net loss for the nine months ended September 30, 2025, was primarily due to the increase in both research and development expenses and general and administrative expenses discussed above.
- Cash and cash equivalents totaled approximately \$4.9 million at September 30, 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 status, timing and plans for manufacturing FibroBiologics' product candidates, the potential clinical benefits of fibroblasts and fibroblast-derived materials, plans for, and the anticipated timing of the initiation and completion of, FibroBiologics' current and future preclinical studies, clinical trials, and research and development programs, the robustness, progress, and momentum of FibroBiologics' research and development program, the potential of product candidates as scalable platform technologies, the potential indications for FibroBiologics' programs, and plans for, and the timing of, regulatory filings. 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 manufacture its product candidates; and (f) FibroBiologics' ability to conduct clinical trials. 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 270+ 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



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