March 31, 2025

FibroBiologics Reports Full Year 2024 Financial Results and Provides Corporate Update

Proprietary master cell bank of fibroblast-based spheroids product candidate, CYWC628, completed in accordance with Good Manufacturing Practices after successfully passing all required safety testing

Preparations for Phase 1/2 clinical trial in Australia utilizing CYWC628 to treat diabetic foot ulcers are proceeding with plans to initiate in the second quarter of 2025

Cash and cash equivalents of approximately $14.0 million at December 31, 2024

HOUSTON, March 31, 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 full year 2024 financial results and provided a corporate update.

Recent Highlights

- Established a master services agreement with Charles River Laboratories to develop and manufacture FibroBiologics' therapeutic master cell bank, working cell bank, and fibroblast-based spheroids product, CYWC628, for utilization in a Phase 1/2 clinical trial to treat diabetic foot ulcers (DFUs).
- Completed 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.
- Engaged Southern Star Research to provide clinical research organization (CRO) services in Australia in connection with FibroBiologics' planned Phase 1/2 clinical trial utilizing CYWC628 to treat DFUs.
- Presented at a number of investor and science conferences including the 2024 Jones Healthcare and Innovation Conference, HC Wainright Global Investment Conference, 2024 Maxim Virtual Summit, BIO San Diego, Cell and Gene Meeting on the Mesa, ThinkEquity Conference, BIO CEO Conference, and The Extracellular Matrix Pharmacology Congress, Copenhagen, Denmark.
- Announced early-stage research and development efforts in FibroBiologics' human longevity program covering potential extension of life applications including recovery of lost thymic functionality by using transplanted artificial thymic organoids in animal models, which has demonstrated the generation of a diverse array of mature T-cells, and 60+ days of vascularization and persistence at the transplantation site.

- Moved discovery phase project, CYPS317, to the product candidate pipeline for the treatment of psoriasis.
- Entered into a Standby Equity Purchase Agreement (SEPA) with YA II PN LTD. (Yorkville), an investment fund managed by Yorkville Advisors Global, LP. The agreement allows FibroBiologics, subject to customary conditions, to sell up to $25.0 million in the aggregate of its common stock to Yorkville over the course of two years. Yorkville advanced FibroBiologics the first $10.0 million available under the agreement in December 2024 and FibroBiologics expects Yorkville to advance another $5.0 million available under the agreement following receipt of shareholder approval in satisfaction of Nasdaq rules at FibroBiologics' 2025 annual meeting of stockholders in June 2025. FibroBiologics can sell an additional $10.0 million of its common stock to Yorkville under the agreement, subject to Yorkville's consent and other conditions.
- Expanded patent portfolio in the area of manufacturing and manipulation of the cellular microenvironment and with: (i) the issuance of a patent from the European Patent Office covering methods and compositions for the treatment of cancer utilizing fibroblasts that have been modified to enhance their ability to deliver one or more anti-cancer agents to an individual, (ii) the filing of a patent application with the United States Patent and Trademark Office covering methods employing fibroblasts or other Tissue Factor (TF)-expressing cells to prevent IBMIR-mediated blood clotting, (iii) the filing of a patent application covering methods for treatment of splenomegaly using a cell-based therapeutic approach, and (iv) the filing of a patent application with the USPTO 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 DFU patients in the second quarter of 2025.
- Complete Phase 1/2 clinical trial in Australia in DFU patients by the end of 2025.
- Determine timeline for Phase 1 clinical trial for CybroCell™, FibroBiologics' investigational allogeneic fibroblast cell-based therapy in development for degenerative disc disease, through discussion with the U.S. Food and Drug Administration (FDA). FibroBiologics received IND clearance from the FDA in 2018, conditional upon approval of our master cell bank, to evaluate this candidate in a planned clinical trial.
- Complete pre-clinical IND-enabling studies for the treatment of psoriasis with FibroBiologics' fibroblast spheroid product candidate, CYPS317, by the end of 2025.

"We entered 2025 with $14 million in cash and cash equivalents and access to additional financing, which enables us to continue to push forward our clinical programs and explore new opportunities," said Pete O'Heeron, CEO and Co-founder of FibroBiologics. "We are focused on starting our Phase 1/2 clinical trial in Australia utilizing CYWC628 in DFU patients in the second quarter of 2025 and expect to have early results by year-end. Our team will continue its ongoing efforts to tackle diseases at their root causes rather than just managing symptoms, which should create real value for patients and our shareholders alike."

Financial Highlights for the Year Ended December 31, 2024

- Research and development expenses were approximately $4.5 million for the year ended December 31, 2024, compared to approximately $2.4 million for the same period in 2023. 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 $9.2 million for the year ended December 31, 2024, compared to approximately $6.5 million for the same period in 2023. The increase was primarily due to the costs associated with FibroBiologics' Direct Listing and operating as a public company and additional personnel.
- For the year ended December 31, 2024, FibroBiologics reported a net loss of approximately $11.2 million compared to a net loss of approximately $16.5 million for the same period in 2023. The decrease in net loss for the year ended December 31, 2024, 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 $14.0 million at December 31, 2024.

For more information, please visit FibroBiologics' website or email FibroBiologics at info@fibrobiologics.com.

This communication shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of the securities discussed herein, in any jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

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 plans for, and the anticipated timing of the initiation of, FibroBiologics' clinical trials, the robustness, progress, timing, and momentum of FibroBiologics' research and development program and our positioning to accelerate progress in delivering treatments to patients, CDMO services to be provided under the master services agreement with Charles River, our relationship with Charles River, CRO services to be provided under the master services agreement with Southern Star Research, our relationship with Southern Star Research, the funding of the advances under the SEPA, FibroBiologics' ability to sell additional shares under the SEPA, FibroBiologics' ability to complete clinical trials and IND-enabling studies and to develop its other programs and indications, potential discussions with the FDA, the potential and capabilities of fibroblasts and artificial thymus organoids to persist and function post-transplantation, with vascularization and the generation of a diverse array of mature T cells, and potential value creation of ongoing efforts. 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.

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