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FibroBiologics Reports Third Quarter 2024 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 second quarter of 2025

HOUSTON, Nov. 12, 2024 (GLOBE NEWSWIRE) -- FibroBiologics, Inc. (Nasdaq: FBLG) ("FibroBiologics"), a clinical-stage biotechnology company with 160+ patents issued and pending for the development of therapeutics and potential cures for chronic diseases using fibroblasts and fibroblast-derived materials, today announced third quarter 2024 financial results and provided a corporate update.

Third Quarter 2024 and Recent Highlights

- Joined the Russell 2000® Index effective at the open of US equity markets on Monday, July 1, 2024.
- Presented at a number of investor conferences including: the 2024 ThinkEquity Conference, BIO-Europe 2024, H.C. Wainwright 26th Annual Global Investment Summit, 2024 Maxim Virtual Summit, and the JonesTrading Healthcare Summit.
- Engaged Southern Star Research to provide clinical research organization (CRO) services in Australia. Initial CRO services will include preparatory work for a Phase 1/2 clinical trial utilizing FibroBiologics' fibroblast-based spheroids product candidate, CYWC628, to treat diabetic foot ulcers (DFUs).
- 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 the DFU clinical trial.
- Expanded FibroBiologics' intellectual property portfolio with the issuance of: (i) three patents by the United States Patent Office ("USPTO"), (ii) three patents from the Japan Patent Office, (iii) a patent from the European Patent Office, and (iv) a patent from the Australian Patent Office, and the filing of patent applications with the USPTO covering the use of FibroBiologics' fibroblast cell-based technology for the potential treatment of Lupus, instant blood-mediated inflammatory reaction (IBMIR), splenomegaly, generating three-dimensional hemopoietic organoids that can give rise to immune cells, insulin-secreting pancreatic organoids, and fibroblast-derived product containing adhesive bandage for wound healing.
- Moved discovery phase project, CYPS317, to the product candidate pipeline for the treatment of psoriasis.

- 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.

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.
- Complete pre-clinical IND-enabling studies for the treatment of psoriasis with FibroBiologics' fibroblast spheroid product candidate, CYPS317, by the end of 2025.

"We continue to experience strong momentum in our clinical programs and are making significant breakthroughs in our core science," said Pete O'Heeron, Founder and Chief Executive Officer. "We are enthusiastic about the progress of our preclinical research and our product candidates, particularly our wound care product candidate, CYWC628, which is on track to enter a phase 1/2 clinical trial to treat diabetic foot ulcers in the second quarter of 2025. I am also enthused by our human longevity program and pleased to report that, to date, we have demonstrated over 60 days of T-cell generation, vascularization, and durable fixation at the transplantation site in animal models using transplanted artificial organoids. This momentum not only reflects our commitment to innovation but also positions us strategically for future advancements in cell therapy."

Financial Highlights for the Nine Months Ended September 30, 2024

- Research and development expenses were approximately $3.1 million for the nine months ended September 30, 2024, compared to approximately $1.6 million for the same period in 2023. The increase was primarily due to hiring additional research personnel and increased tissue acquisition and CDMO expenses for cell manufacturing.
- General and administrative expenses were approximately $6.9 million for the nine months ended September 30, 2024, compared to approximately $4.8 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 nine months ended September 30, 2024, FibroBiologics reported a net loss of approximately $8.1 million compared to a net loss of approximately $6.8 million for the same period in 2023. The increase in net loss for the nine months ended September 30, 2024, was primarily due to the increases in research and development expenses and general and administrative expenses, noted previously, and the commitment fee expense and change in fair value of the forward contract liability, partially offset by the change in the fair value of the warrant liability.
- Cash and cash equivalents totaled approximately $7.8 million at September 30, 2024.

For more information, please visit FibroBiologics' website or email FibroBiologics

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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 and momentum of FibroBiologics' research and development program, being positioned strategically for future advancements in cell therapy, and 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. 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) expectations regarding the initiation, progress and expected results of FibroBiologics' R&D efforts and preclinical studies; (b) the unpredictable relationship between R&D and preclinical results and clinical study results; (c) risks related to FibroBiologics' liquidity and its ability to maintain capital resources sufficient to conduct its business; and (d) the ability of FibroBiologics to successfully prosecute its patent applications. 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 160+ US and internationally issued patents/patents pending across various clinical pathways, including disc degeneration, orthopedics, multiple sclerosis, wound healing, reversing organ involution, and cancer. FibroBiologics represents the next generation of medical advancement in cell therapy and tissue regeneration. For more information, visit www.FibroBiologics.com.

Source: Fibrobiologics, Inc.