UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 20, 2024

FibroBiologics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41934**	**86-3329066**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

455 E. Medical Center Blvd.
Suite 300
Houston, Texas 77598
(Address of principal executive offices and Zip Code)

(281) 671-5150
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.00001 per share	FBLG	Nasdaq Global Market

Item 8.01. Other Events.

On February 20, 2024, FibroBiologics, Inc. issued a press release announcing its Presentation of Preclinical and Clinical Data at the 2024 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum. A copy of the press release is attached as Exhibit 99.1 and is incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1	Press Release dated February 20, 2024
Exhibit 104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: February 20, 2024

FibroBiologics, Inc.

By: */s/ Pete O'Heeron*
Name: Pete O'Heeron
Title: Chief Executive Officer

Exhibit 99.1

FibroBiologics to Present Preclinical and Clinical Data at the 2024 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum

HOUSTON, February 20, 2024 – FibroBiologics (Nasdaq: FBLG) ("FibroBiologics") is a clinical-stage biotechnology company with 150+ patents issued and pending with a focus on the development of therapeutics and potential cures for chronic diseases using fibroblasts and fibroblast-derived materials. FibroBiologics will present in vitro and in vivo preclinical data using allogeneic human dermal fibroblasts (HDFs) and HDF spheroids as well as primary safety phase 0/1 clinical trial data for the single-dose infusion of HDFs during the poster sessions at the upcoming Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2024 on Thursday, February 29, at the Palm Beach County Convention Center and the Hilton West Palm Beach in West Palm Beach, Florida.

The National Institutes of Health describes multiple sclerosis (MS) as a T-cell-mediated autoimmune disorder in which the immune system targets and destroys the myelin sheath of axons in the central nervous system, leading to severe and progressive cognitive impairment, sensory deprivation, and weakened coordination. FibroBiologics is investigating the therapeutic potential of using HDFs as a treatment for MS through immune modulation and stimulation of myelin expression by oligodendrocytes to rebuild the damaged myelin sheath.

Extensive preclinical studies were conducted using allogeneic HDFs in the experimental autoimmune encephalomyelitis (EAE) animal model of MS. In vivo results indicated that HDFs significantly suppressed Th17 cell activation, stimulated T regulatory (Treg) cell expansion, inhibited dendritic cell maturation, reduced microglial activation, and stimulated oligodendrocyte expansion and remyelination. The results also demonstrated that administration of HDFs in the EAE model significantly enhanced Treg-dependent disease inhibition in a manner superior to adipose or bone marrow-derived MSCs.

The phase 0/1 primary-safety clinical trial studied a single-dose infusion of allogeneic HDFs into four relapsing-remitting and one secondary progressive MS patients. The primary outcome of the safety clinical trial indicated a strong correlation for CBC, blood chemistry, and electrocardiogram data for all patients compared with pre-infusion test results, and no adverse events were reported.

"Our in vivo animal studies provided evidence that allogeneic HDFs are capable of suppressing pathogenic T cell activation, stimulating T regulatory (Treg) cell expansion, inhibiting dendritic cell maturation, and stimulating oligodendrocyte expansion and myelin protein expression," said Dr. Hamid Khoja, Chief Scientific Officer at FibroBiologics. "Based on our results to date, we are enthusiastic about the promise of HDFs for the treatment of MS, although we understand that further study is required. In pursuit of that goal, FibroBiologics is designing a phase II clinical trial to study the safety and efficacy profile of various concentrations of HDF spheroids and the effect of multiple-dose treatments over an eighteen-month study period."

Abstract Information:

Title: The Potential of Using Allogeneic Human Dermal Fibroblast Spheroids as a Biological Extended-Release Therapy for the Treatment of Multiple Sclerosis: Preclinical and Phase 0/1 Clinical Trial Results
Authors: H. Khoja, B. Jiang, P. O'Heeron
Session Title: PS1-Poster Session 1
Session Date and Time: February 29, 2024, 6:00 PM - 7:30 PM
Poster Number: P341

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

Cautionary Statement Regarding Forward-Looking Statements

This communication may contain "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements include information concerning FibroBiologics' possible or assumed future results of operations, business strategies, debt levels, competitive position, industry environment, potential growth opportunities and the effects of regulation, including whether FibroBiologics will generate returns for stockholders. 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 in the Risk Factors section of FibroBiologics' Registration Statement for the Direct Offering filed with the SEC. 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) the occurrence of any event, change or other circumstances that could cause the Registration Statement to not become effective; (b) the ability of FibroBiologics to continue to meet Nasdaq listing requirements; (c) the ability to effectively manage the business as a result of the super-voting proxy given to the Board of Directors. 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 cell therapy, regenerative medicine company developing a pipeline of treatments and potential cures for chronic diseases using fibroblast cells and fibroblast-derived materials. FibroBiologics holds 150+ US and internationally issued patents/patents pending across various clinical pathways, including disc degeneration, orthopedics, multiple sclerosis, psoriasis, wound healing, reversing organ involution, and cancer. FibroBiologics represents the next generation of medical advancement in cell therapy. For more information, visit www.FibroBiologics.com.

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