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): June 26, 2023

FIBROGEN, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36740**	**77-0357827**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
409 Illinois Street **San Francisco, California**		**94158**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 415 978-1200

(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:

☐ 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))

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, $0.01 par value	FGEN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Events.

On June 26, 2023, FibroGen, Inc. issued a press release in which it reported topline results from its Phase 3 study of pamrevlumab for the treatment of idiopathic pulmonary fibrosis.

A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces Topline Results from Phase 3 ZEPHYRUS-1 Study of Pamrevlumab for the Treatment of Idiopathic Pulmonary Fibrosis" dated June 26, 2023
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 hereunto duly authorized.

FIBROGEN, INC.

Date: June 26, 2023

By: /s/ Michael Lowenstein

Michael Lowenstein
Chief Legal Officer

FibroGen Announces Topline Results from Phase 3 ZEPHYRUS-1 Study of Pamrevlumab for the Treatment of Idiopathic Pulmonary Fibrosis

Study did not meet the primary endpoint
Pamrevlumab was generally safe and well tolerated
ZEPHYRUS-2 Phase 3 study will be discontinued
Company to implement plan to extend cash runway into 2026

SAN FRANCISCO, June 26, 2023 -- FibroGen, Inc. (NASDAQ: FGEN) today announced topline results from its Phase 3 ZEPHYRUS-1 trial evaluating the safety and efficacy of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF). The study compared treatment with pamrevlumab to placebo and did not meet the primary endpoint of change from baseline in forced vital capacity (FVC) at week 48 (p=0.29). The mean decline in FVC from baseline to week 48 was 260 ml in the pamrevlumab arm compared to 330 ml in the placebo arm (placebo-corrected difference of 70 ml; 95% CI -60 to 190 ml). The secondary endpoint of time to disease progression (FVC percent predicted decline of ≥10% or death) was also not met (HR= 0.78; 95% CI 0.52 to 1.15).

In the safety analysis, pamrevlumab was generally safe and well tolerated and the majority of treatment emergent adverse events were mild or moderate. Treatment-emergent serious adverse events were observed in 28.2% of patients in the pamrevlumab group and 34.3% of patients in the placebo group.

Based on the results of ZEPHYRUS-1, ZEPHYRUS-2, the second Phase 3 clinical trial, will be discontinued. FibroGen plans to communicate the results of the ZEPHYRUS-1 study at an upcoming medical forum.

“We are deeply disappointed that these results do not support pamrevlumab as a new treatment for IPF,” said Mark D. Eisner, MD, MPH, Chief Medical Officer, FibroGen. “FibroGen would like to thank the patients and clinical trial investigators for their dedication to participating in this study.”

FibroGen anticipates reporting topline data from Phase 3 studies with pamrevlumab for the treatment of ambulatory DMD patients (LELANTOS-2) in

3Q 2023, locally advanced pancreatic cancer (LAPIS) in 1H 2024, and metastatic pancreatic cancer (Precision Promise).

“FibroGen’s focus will be on reporting the additional pamrevlumab studies, advancing our pipeline, and continuing commercialization of roxadustat in China and in countries where approved,” said Enrique Conterno, Chief Executive Officer, FibroGen.

Upcoming Milestones:

- Topline data from the LELANTOS-2 Phase 3 study of pamrevlumab in ambulatory DMD patients expected 3Q 2023.
- Topline data from the LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer (LAPC) expected 1H 2024.
- Topline data from the Pancreatic Cancer Action Network (PanCAN) Precision Promise^{SM} Phase 3 study of pamrevlumab in metastatic pancreatic cancer.
- Anticipate the filing of up to two INDs: FG-3165 (anti-Gal9 antibody) 1Q 2024 and FG-3163 (anti-CCR8 antibody) 4Q 2023.
- Anticipate the initiation of a Phase 2 trial of FG-3246, a first-in-class antibody-drug conjugate (ADC) targeting a novel epitope on CD46 for metastatic castration-resistant prostate cancer (mCRPC) in 2H 2024.

Cash Runway:

FibroGen plans to implement a significant cost reduction effort in the U.S. with the intent to extend our cash runway into 2026.

About ZEPHYRUS

A total of 356 patients with IPF were enrolled into ZEPHYRUS-1, a randomized, double-blind, placebo-controlled, multi-center Phase 3 trial designed to evaluate the efficacy and safety of pamrevlumab in patients with IPF. Patients were randomized (1:1) to receive either pamrevlumab or placebo for 48 weeks.

The Phase 3 clinical development program evaluating pamrevlumab for the treatment of IPF consists of two studies, ZEPHYRUS-1 and ZEPHYRUS-2. These trials are randomized, double-blind, placebo-controlled, multi-center Phase 3 trials designed to evaluate the efficacy and safety of pamrevlumab in patients with IPF. For more information about ZEPHYRUS-1 and ZEPHYRUS-2, please visit www.clinicaltrials.gov (NCT03955146 and NCT04419558).

About Idiopathic Pulmonary Fibrosis (IPF)
Idiopathic pulmonary fibrosis is a chronic lung disease characterized by a progressive and irreversible decline in lung function in which lung tissue becomes damaged, stiff, and scarred. As tissue scarring progresses, transfer of oxygen into the bloodstream is increasingly impaired, leading to irreversible loss of lung function, as well as high morbidity and mortality.

About Pamrevlumab
Pamrevlumab is a potential first-in-class antibody being developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), and ambulatory Duchenne muscular dystrophy (DMD), and in Phase 2/3 for the treatment of metastatic pancreatic cancer. The U.S. Food and Drug Administration has granted Orphan Drug Designation, and Fast Track designation to pamrevlumab for the treatment of patients with DMD, and LAPC. The U.S. Food and Drug Administration has also granted Rare Pediatric Disease Designation to pamrevlumab for the treatment of patients with DMD. Pamrevlumab has demonstrated a safety and tolerability profile that has supported ongoing clinical investigation in IPF, DMD, and LAPC. Pamrevlumab is an investigational drug and not approved for marketing by any regulatory authority. For information about our pamrevlumab studies please visit www.clinicaltrials.gov.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing, and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in connective tissue growth factor (CTGF) biology and hypoxia-inducible factor (HIF) to advance innovative medicines for the treatment of unmet needs. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), metastatic pancreatic cancer, and ambulatory Duchenne muscular dystrophy (DMD). Roxadustat (®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in CKD patients on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) in China. FibroGen recently expanded its research and development portfolio to include product candidates in the

immuno-oncology space along with an exclusive license for FOR46. For more information, please visit www.fibrogen.com.

Forward-Looking Statements
This release contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, and the development and commercialization of the company's product candidates. These forward-looking statements include, but are not limited to, statements about FibroGen's plans and objectives and typically are identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. FibroGen's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, each as filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and FibroGen undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

Contacts:
FibroGen, Inc.

Investors:
Meichiel Keenan
Investor Relations and Corporate Communications
mkeenan@fibrogen.com

Media:
Michael Szumera
mszumera@fibrogen.com