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): August 29, 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 August 29, 2023, FibroGen, Inc. issued a press release in which it reported topline results from its Phase 3 study of pamrevlumab for the treatment of Duchenne muscular dystrophy in ambulatory patients.

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 LELANTOS-2, a Phase 3 Clinical Study of Pamrevlumab in Ambulatory Duchenne Muscular Dystrophy" dated August 29, 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: August 29, 2023

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Officer

FibroGen Announces Topline Results from LELANTOS-2, a Phase 3 Clinical Study of Pamrevlumab in Ambulatory Duchenne Muscular Dystrophy

– Study did not meet the primary endpoint –

– Pamrevlumab was generally safe and well tolerated –

SAN FRANCISCO, August 29, 2023 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today announced topline data from the Phase 3 LELANTOS-2 trial of pamrevlumab for the treatment of ambulatory patients with Duchenne muscular dystrophy (DMD) on background systemic corticosteroids. The study did not meet the primary endpoint of change in the North Star Ambulatory Assessment (NSAA) total score from baseline to week 52 (placebo-corrected mean difference -0.528 points; 95% CI -2.308 to 1.251; p=0.5553). Secondary endpoints measured by change from baseline at week 52 in 4-stair climb velocity, 10-meter walk/run test, time to stand, time to loss of ambulation, and proportion of patients with greater than 10 seconds in the 10-meter walk/run test were also not met.

“We are deeply disappointed that the LELANTOS-2 study did not meet its primary endpoint,” said Thane Wettig, Interim Chief Executive Officer, FibroGen. “We are grateful for the courageous efforts of patients, their caregivers, the advocacy community, and the trial investigators who have contributed to this important clinical study. We are committed to sharing all learnings from this trial with the Duchenne community and hope that there are insights that may help future efforts to develop treatments for this devastating disease.”

Preliminary safety data showed that pamrevlumab was generally safe and well tolerated. The majority of treatment emergent adverse events were mild or moderate. Treatment-emergent serious adverse events were observed in 8.3% of patients in the pamrevlumab group and 2.8% of patients in the placebo group.

FibroGen is in the process of evaluating the totality of the data, including other pre-specified endpoints, to determine the next steps for the program. The Company plans to communicate the full results of the LELANTOS-2 study at an upcoming medical forum.

About LELANTOS-2
A total of 73 boys with ambulatory DMD ages 6 to <12 years were enrolled in LELANTOS-2, a global, Phase 3, randomized, double-blind trial of pamrevlumab or placebo in combination with systemic corticosteroids. The primary endpoint of the study was ambulatory function measured by change in the North Star Ambulatory Assessment (NSAA) total score from baseline to Week 52. Secondary endpoints assessed from baseline to Week 52 included changes in 4-stair climb velocity, 10-meter walk/run test, time to stand, time to loss of ambulation, and proportion of patients with greater than 10 seconds in the 10-meter walk/run

test. In LELANTOS-2, patients were dosed with pamrevlumab (35 mg/kg IV on Day 1 and every two weeks thereafter with last dose at Week 52) or placebo.

About Duchenne Muscular Dystrophy
Duchenne muscular dystrophy (DMD) is a rare and debilitating neuromuscular disease that affects approximately 1 in every 5,000 newborn boys. About 20,000 children are diagnosed with DMD globally each year. The fatal disease is caused by a genetic mutation leading to the absence or defect of dystrophin, a protein necessary for normal muscle function. The absence of dystrophin results in muscle weakness, muscle loss, fibrosis, and inflammation. Patients with DMD are often wheelchair-bound before the age of 12, and their progressive muscle weakness may lead to serious medical problems relating to respiratory and cardiac muscle.

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 ambulatory Duchenne muscular dystrophy (DMD), and locally advanced unresectable pancreatic cancer (LAPC), and in Phase 2/3 for the treatment of metastatic pancreatic cancer. The U.S. Food and Drug Administration has granted Orphan Drug Designation to pamrevlumab for treatment of patients with DMD and pancreatic cancer, 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 DMD, LAPC, and metastatic pancreatic cancer. 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, a fully human anti-CTGF 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 FG-3246. 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, the development and commercialization of the company's product candidates, the potential safety and efficacy profile of its product candidates, and the potential impact of clinical data. 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 June 30, 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:
David DeLucia, CFA
Vice President, Corporate FP&A and Investor Relations
ddelucia@fibrogen.com

Media:
Michael Szumera
External Communications
mszumera@fibrogen.com