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): May 9, 2019

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.)**

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(Address of principal executive offices, including zip code)

(415) 978-1200
(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:

☐ 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 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. ☐

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	FGEN	The Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 31, 2019. A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by FibroGen, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Reports First Quarter 2019 Financial Results," dated May 9, 2019

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.

Dated: May 9, 2019

By: /s/ Pat Cotroneo
Pat Cotroneo
Senior Vice President, Finance and Chief Financial Officer

Exhibit 99.1

FIBROGEN REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS

- *Positive topline results from pooled safety analyses of roxadustat Phase 3 global program*
- *Completed one year of treatment in Phase 2 trial evaluating pamrevlumab in treatment of non-ambulatory DMD patients*

Conference Call Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time

SAN FRANCISCO, May 09, 2019 -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter of 2019 and provided an update on the company's recent developments.

"The first quarter of 2019 saw critical execution across multiple programs. With respect to the global roxadustat anemia platform, we received positive topline results from analyses of pooled MACE and MACE+ data from our Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients. We and our partners continue to prepare for NDA submission to the FDA in the third quarter, with the EMA MAA submission to follow," said Thomas B. Neff, Chief Executive Officer. "In our anti-CTGF antibody program, we completed the analysis of the first year of treatment with pamrevlumab, our anti-CTGF antibody, for the 21 non-ambulatory subjects in a Phase 2 trial with favorable results in lung and cardiac functions and muscle strength from our administrative analysis suggesting promise for a new treatment option for DMD patients."

Recent Developments and Highlights

Roxadustat for Anemia in Chronic Kidney Disease (CKD) in the U.S. and EU

- In the pooled analyses of around 4,000 dialysis patients, the upper bound of the 95% confidence interval (CI) was below the pre-specified non-inferiority margin for the time to first MACE+ analyses. Based on the MACE safety analyses of this population, we believe there is no clinically meaningful difference in risk of MACE between roxadustat and epoetin alfa.
- In the pooled analyses of about 1,500 incident dialysis patients roxadustat demonstrated superiority to epoetin alfa in the time to first MACE+ in this subpopulation. In the MACE analysis, there is a trend toward reduced risk for patients on roxadustat, compared to epoetin alfa.
- In the non-dialysis pool of approximately 4,300 patients, non-inferiority was demonstrated for roxadustat compared to placebo in the time to first MACE+, based on the upper bound of the 95% CI being below the pre-specified non-inferiority margin. We believe there is no clinically meaningful difference in risk of MACE between roxadustat and placebo.
- Multiple MACE and MACE+ analyses in non-dialysis from the roxadustat global Phase 3 program are being performed in intent-to-treat (ITT) analyses that demonstrated comparability of roxadustat to placebo. ITT is among the several statistical methods that we will discuss with the FDA. In these ITT analyses, roxadustat was comparable based on a commonly applied non-inferiority margin of 1.3.
- Additional positive efficacy results from pooled analyses were observed in the areas of:
  - rate of kidney function decline, as measured by eGFR, as compared to placebo
  - quality of life, as measured by standard endpoints, as compared to placebo
  - efficacy in the presence of inflammation, as compared to epoetin alfa

FibroGen and AstraZeneca will begin discussions with the U.S. Food and Drug Administration (FDA) to prepare for regulatory submission of our New Drug Application (NDA), which is anticipated in September/October 2019, with the MAA for submission to the European Medicines Agency (EMA) to follow.

Roxadustat for Anemia in CKD in China

- Completed clinical site inspections by the China Food and Drug Inspection division of the National Medical Products Administration (NMPA) for Phase 3 study evaluating roxadustat for treatment of anemia in non-dialysis-dependent CKD patients.
- Anticipate NMPA approval decision on roxadustat for treatment of anemia in non-dialysis-dependent CKD mid-year 2019.

Roxadustat for Anemia in Myelodysplastic Syndromes (MDS)

- Completed enrollment of the open-label portion of our global multi-center Phase 3 study in transfusion-dependent, lower risk MDS patients.
- Initiated patient dosing in the double-blind, placebo-controlled portion of this Phase 3 study.
- Open-label portion of China Phase 2/3 MDS study is ongoing.

Pamrevlumab for Duchenne Muscular Dystrophy (DMD)

- Received Orphan Drug Designation from the FDA for treatment of Duchenne muscular dystrophy.
- Administrative analysis of the first year treatment in 21 non-ambulatory DMD patients shows favorable results in lung function, cardiac function, and muscle strength.

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- On track to initiate a randomized, double-blind, placebo-controlled Phase 3 clinical trial with a primary endpoint of change in forced vital capacity (FVC) from baseline in approximately 500 patients in Q2 2019.

Pamrevlumab for Pancreatic Cancer

- On track to initiate a randomized, double-blind, placebo-controlled Phase 3 study evaluating pamrevlumab in combination with gemcitabine and nab-paclitaxel as a neoadjuvant therapy versus placebo in combination with gemcitabine and nab-paclitaxel for unresectable locally advanced pancreatic cancer (LAPC) in approximately 260 patients in Q2 2019.

Corporate and Financial

- Net loss for the first quarter of 2019 was $45.4 million, or $0.53 net loss per basic and diluted share, compared to a net loss of $41.4 million, or $0.53 net loss per basic and diluted share one year ago.
- At March 31, 2019, FibroGen had $712.7 million in cash, restricted time deposits, cash equivalents, investments, and receivables, compared to $747.2 million at year-end 2018.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Thursday, May 9, 2019, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) to discuss financial results and provide a business update. A live audio webcast of the call may be accessed in the investor section of the company's website, www.fibrogen.com. To participate in the conference call by telephone, please dial 1 (888) 771-4371 (U.S. and Canada) or 1 (847) 585-4405 (international), reference the FibroGen first quarter 2019 financial results conference call, and use passcode 48545313. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (888) 843-7419 (domestic) or (630) 652-3042 (international), and use passcode 48545313#.

About Roxadustat

Roxadustat (FG-4592), discovered by FibroGen, is a first-in-class, orally administered small molecule currently approved in China for the treatment of anemia in CKD patients on dialysis. Roxadustat is a HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients, including in the presence of inflammation and without a need for supplemental intravenous iron.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. AstraZeneca and FibroGen are collaborating on the development and commercialization of roxadustat for the treatment of anemia in the U.S., China, and other markets in the Americas and in Australia/New Zealand as well as Southeast Asia.

About Pamrevlumab

Pamrevlumab is a first-in-class antibody 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 advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, has been granted Orphan Drug Designation (ODD) in each of these indications. Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and for patients with locally advanced unresectable pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). Across all trials, pamrevlumab has consistently demonstrated a good safety and tolerability profile to date. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF), connective tissue growth factor (CTGF) biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase (HIF-PH) activity, completing Phase 3 clinical development worldwide for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) now approved by the National Medical Products Administration (NMPA) in China. Our partner Astellas submitted a NDA for the treatment of anemia in CKD patients on dialysis in Japan in September 2018, which is currently under review by the Pharmaceuticals and Medical Devices Agency (PMDA). Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, an anti-CTGF human monoclonal antibody, is advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. For more information, please visit www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the development of the company's product candidates pamrevlumab and roxadustat, our interpretation of the pooled safety analyses and other analyses of the global Phase 3 program for roxadustat, the expected endpoints and potential standards for safety assessments of such data by the FDA and the EMA, the potential for and timing of an NDA submission to the FDA and an MAA submission to the EMA for potential marketing approval for roxadustat, the potential safety and efficacy profile of our product candidates, and our clinical, regulatory plans, and those of our partners. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts 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. Our 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 our 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, 2018 and our quarterly report on 10-Q for the fiscal quarter ended March 31, 2019 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 we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2019	December 31, 2018 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 81,673	$ 89,258
Short-term investments	483,726	532,144
Accounts receivable	6,023	63,684
Prepaid expenses and other current assets	7,578	4,929
Total current assets	579,000	690,015
Restricted time deposits	4,145	4,145
Long-term investments	132,203	55,820
Property and equipment, net	45,828	127,198
Finance lease right-of-use assets	47,029	—
Other assets	4,192	3,420
Total assets	$ 812,397	$ 880,598
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 3,772	$ 9,139
Accrued and other liabilities	66,278	66,123
Deferred revenue	12,104	13,771
Finance lease liabilities, current	11,766	—
Total current liabilities	93,920	89,033
Long-term portion of lease obligations	1,443	97,157
Product development obligations	16,545	16,798
Deferred rent	—	3,038
Deferred revenue, net of current	135,196	136,109
Finance lease liabilities, non-current	46,818	—
Other long-term liabilities	9,981	9,993
Total liabilities	303,903	352,128
Total stockholders' equity	489,223	509,199
Non-controlling interests	19,271	19,271
Total equity	508,494	528,470
Total liabilities, stockholders' equity and non-controlling interests	$ 812,397	$ 880,598

(1) The condensed consolidated balance sheet amounts at December 31, 2018 are derived from audited financial statements.

Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended March 31,	
	2019	2018
	(Unaudited)	
Revenue:		
License revenue	$ —	$ —
Development and other revenue	23,863	31,925
Total revenue	23,863	31,925
Operating expenses:		
Research and development	50,496	56,974
Selling, general and administrative	22,210	15,550
Total operating expenses	72,706	72,524
Loss from operations	(48,843)	(40,599)
Interest and other, net:		
Interest expense	(770)	(2,769)
Interest income and other, net	4,177	2,071
Total interest and other, net	3,407	(698)
Loss before income taxes	(45,436)	(41,297)
Provision for (benefit from) income taxes	(25)	99
Net loss	$ (45,411)	$ (41,396)
Net loss per share - basic and diluted	$ (0.53)	$ (0.50)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	85,704	82,863

# # #

Contact
FibroGen, Inc.
Karen L. Bergman
Vice President, Investor Relations and Corporate Communications
1.415.978.1433
ir@fibrogen.com