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 27, 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. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2019, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter and full year ended December 31, 2018. 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 Fourth Quarter and Full Year 2018 Financial Results," dated February 27, 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: February 27, 2019

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

FIBROGEN REPORTS FOURTH QUARTER AND FULL YEAR 2018 FINANCIAL RESULTS

——Roxadustat Approved in China for Anemia in Dialysis-Dependent CKD Patients—
—Primary Efficacy Endpoints Met in Seven Phase 3 Roxadustat Studies for U.S./EU—

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

SAN FRANCISCO, February 27, 2019 – FibroGen, Inc. (NASDAQ: FGEN), a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics, today reported financial results for the fourth quarter and full year 2018 and provided an update on the company's recent developments.

"FibroGen achieved a number of remarkable clinical and regulatory milestones in 2018. We received approval in China for roxadustat, a first-in-class treatment for anemia associated with chronic kidney disease for patients on dialysis in December 2018. Roxadustat will be the first HIF-PH inhibitor to be made available to CKD dialysis patients in need of anemia treatment.

Following the release of positive efficacy data from our Phase 3 program, our team is now preparing for the submission of our U.S. NDA to the FDA in 2019," said Thomas B. Neff, FibroGen's Chief Executive Officer. "In addition, we were granted Fast Track designation from the FDA for pamrevlumab in idiopathic pulmonary fibrosis and in pancreatic cancer in 2018. Our team is focused on commencing Phase 3 clinical studies in both of these indications."

Recent Developments and Highlights
Roxadustat for CKD Anemia in U.S./ROW

- FibroGen announced positive topline results from three U.S./EU Phase 3 trials of roxadustat for the treatment of anemia in patients with chronic kidney disease (CKD)
- Our partner AstraZeneca announced positive topline results from two global Phase 3 trials of roxadustat for the treatment of anemia in patients with CKD
- Our partner Astellas announced that roxadustat met its primary endpoint in its three Phase 3 trials of roxadustat for the treatment of anemia in patients with CKD

Roxadustat for CKD Anemia in China

- Received marketing authorization from the National Medical Products Administration (NMPA) for roxadustat for the treatment of anemia caused by CKD in patients who are dialysis-dependent, including hemodialysis and peritoneal dialysis, triggering a total of $12 million in related milestone payments to FibroGen
- Clinical results from two Phase 3 studies conducted in China were presented at the American Society of Nephrology (ASN) Kidney Week 2018 in a clinical late-breaking poster session

Roxadustat for CKD Anemia in Japan

- Astellas announced positive topline results from the four Phase 3 dialysis-dependent studies
- Astellas filed a New Drug Application (NDA) for roxadustat for anemia associated with dialysis-dependent CKD with the Pharmaceuticals and Medical Devices Agency (PMDA), triggering a $15 million milestone payment to FibroGen
- Clinical results from two of the four Japan Phase 3 trials in dialysis-dependent patients were presented at the ASN Kidney Week 2018:
    - Phase 3 trial results in peritoneal dialysis patients presented in an oral session
    - Results of a Phase 3 darbepoetin alfa-controlled study in stable hemodialysis patients previously treated with ESA presented in a clinical late-breaking poster session

Roxadustat for MDS Anemia

- Patient dosing ongoing in both a U.S./Europe Phase 3 study and a China Phase 2/3 study

Pamrevlumab for Idiopathic Pulmonary Fibrosis (IPF)

- Granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with idiopathic pulmonary fibrosis (IPF)
- Presented positive Phase 2b efficacy and safety results (improvements in lung function (FVC), quantitative measure of fibrosis (HRCT) and quality of life (SGRQ)) in multiple poster presentations at the American Thoracic Society (ATS) 2018 Conference
- Clinical and preclinical data presented at the European Respiratory Society International Congress (ERS) 2018 and 20th International Colloquium on Lung and Airway Fibrosis (ICLAF) 2018

Pamrevlumab for Pancreatic Cancer

- Granted Fast Track designation by the FDA for the treatment of patients with unresectable locally advanced pancreatic cancer (LAPC)
- Positive Phase 2 clinical trial results presented for presentation at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

Pamrevlumab for Duchenne Muscular Dystrophy

- Completed Phase 2 clinical trial enrollment in the first quarter of 2018

Corporate and Financial

- Net income for the fourth quarter of 2018 was $21.0 million, or $0.25 per basic share and $0.23 per diluted share, compared to a net loss of $33.9 million, or $0.41 net loss per basic and diluted share one year ago
- Net loss for the year ended December 31, 2018, was $86.4 million, or $1.03 per share, compared to $120.9 million, or $1.66 per share one year ago
- At December 31, 2018, FibroGen had $747.2 million in cash, restricted time deposits, cash equivalents, investments, and receivables, compared to $762.2 million at year-end 2017
- The weighted average number of common shares used to calculate net loss per share was 84.1 million shares and 73.0 million shares for the years of 2018 and 2017, respectively
- Total shares outstanding as of December 31, 2018 were 85.4 million shares

2019 Outlook

Roxadustat

- Approval to treat non-dialysis-dependent CKD patients in China is expected in mid-2019
- Regulatory decision on the treatment of dialysis-dependent CKD patients in Japan is expected in the second half of 2019
- Full MACE adjudication procedures from our roxadustat Phase 3 studies for the NDA and MAA are expected to be completed in the first half of 2019
- Submission of our U.S. NDA for the treatment of anemia associated with CKD to the FDA is anticipated in the third quarter of 2019; and we expect our partner Astellas to submit a marketing authorization application (MAA) to the European Medicines Agency (EMA) thereafter
- In MDS, we plan to advance roxadustat into the double-blind, placebo-controlled pivotal portion of our U.S./EU Phase 3 study
- In chemotherapy-induced anemia, we expect to start enrolling patients in our Phase 2 clinical study in the U.S. in 2019

Pamrevlumab

- On track to start a randomized, double-blind, placebo-controlled pivotal Phase 3 study evaluating pamrevlumab in combination with gemcitabine and nab-paclitaxel as a neoadjuvant therapy for LAPC in approximately 260 patients in the second quarter of 2019
- Expect to commence a randomized, double-blind, placebo-controlled Phase 3 clinical trial in IPF with a primary endpoint of change in forced vital capacity (FVC) from baseline in approximately 500 patients in the second quarter of 2019
- Expect to complete the first year of treatment for all 21 non-ambulatory DMD patients in our Phase 2 trial in the first quarter of 2019

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Wednesday, February 27, 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 (888) 771-4371 (U.S. and Canada) or (847) 585-4405 (international), reference the FibroGen fourth quarter and full year 2018 financial results conference call, and use passcode 48309188. 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 48309188#.

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.

FibroGen and its collaboration partners are pursuing four approval pathways in major jurisdictions to prepare for commercialization worldwide:

- 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, 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 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)

	December 31, 2018	December 31, 2017 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 89,258	$ 673,658
Short-term investments	532,144	62,060
Accounts receivable	63,684	8,452
Prepaid expenses and other current assets	4,929	4,800
Total current assets	690,015	748,970
Restricted time deposits	4,145	5,181
Long-term investments	55,820	10,506
Property and equipment, net	127,198	129,476
Other assets	3,420	4,517
Total assets	$ 880,598	$ 898,650
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 9,139	$ 5,509
Accrued liabilities	66,123	63,781
Deferred revenue	13,771	16,670
Total current liabilities	89,033	85,960
Long-term portion of lease financing obligations	97,157	97,763
Product development obligations	16,798	17,244
Deferred rent	3,038	3,657
Deferred revenue, net of current	136,109	138,241
Other long-term liabilities	9,993	8,047
Total liabilities	352,128	350,912
Total stockholders' equity	509,199	528,467
Non-controlling interests	19,271	19,271
Total equity	528,470	547,738
Total liabilities, stockholders' equity and non-controlling interests	$ 880,598	$ 898,650

(1) The condensed consolidated balance sheet amounts at December 31, 2017 are recast from audited financial statements to reflect the adoption of the new revenue standards as of January 1, 2018.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2018	2017 (1)	2018	2017 (1)
	(Unaudited)			
Revenue:				
License revenue	$ 7,947	$ —	$ 22,269	$ 9,933
Development and other revenue	35,331	30,736	125,913	121,063
Product revenue	64,776	—	64,776	—
Total revenue	108,054	30,736	212,958	130,996
Operating expenses:				
Research and development	70,284	52,469	235,839	196,517
General and administrative	17,851	13,851	63,812	51,760
Total operating expenses	88,135	66,320	299,651	248,277
Income (loss) from operations	19,919	(35,584)	(86,693)	(117,281)
Interest and other, net:				
Interest expense	(2,734)	(1,805)	(10,991)	(9,706)
Interest income and other, net	3,772	3,651	11,568	6,433
Total interest and other, net	1,038	1,846	577	(3,273)
Loss before income taxes	20,957	(33,738)	(86,116)	(120,554)
Provision for income taxes	5	156	304	321
Net income (loss)	$ 20,952	$ (33,894)	$ (86,420)	$ (120,875)
Net income (loss) per share				
Basic	$ 0.25	$ (0.41)	$ (1.03)	$ (1.66)
Diluted	$ 0.23	$ (0.41)	$ (1.03)	$ (1.66)
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	85,096	82,151	84,062	72,987
Diluted	91,260	82,151	84,062	72,987

(1) The condensed consolidated statements of operations amounts for the three months and year ended December 31, 2017 are recast from unaudited financial statements to reflect the adoption of the new revenue standards as of January 1, 2018.

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Contact
FibroGen, Inc.
Karen L. Bergman
Vice President, Investor Relations and Corporate Communications
1 (415) 978-1433
kbergman@fibrogen.com