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 10, 2021

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))

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

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 2.02 Results of Operations and Financial Condition.

On May 10, 2021, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 31, 2021. 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, 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 2021 Financial Results," dated May 10, 2021
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.

Dated: May 10, 2021

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

Exhibit 99.1

FibroGen Reports First Quarter 2021 Financial Results

- *Roxadustat net product revenue in China of $15.4 million, on a US GAAP basis*
- *Total roxadustat net sales in China of $43.5 million[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca, compared to $29.2 million last quarter*
- *FDA to hold Advisory Committee Meeting on Roxadustat NDA - tentative date July 15, 2021*

SAN FRANCISCO, May 10, 2021 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter 2021 and provided an update on the Company's recent developments.

"We are pleased at the continued adoption and growth of roxadustat in China," said Enrique Conterno, Chief Executive Officer, FibroGen. "We are looking forward to the roxadustat FDA advisory committee meeting and the approval decision in Europe over the next few months, as well as advancing our late stage pamrevlumab and roxadustat clinical programs, focused on areas of high unmet need."

Recent Key Events and Other Developments

- **Regulatory:**
  - The Cardiovascular and Renal Drugs Advisory Committee (CRDAC) of the U.S. Food and Drug Administration (FDA) will hold an advisory committee (AdCom) meeting to review the new drug application (NDA) for roxadustat in the U.S. The tentative date for the meeting is July 15, 2021.
  - The Marketing Authorization Application (MAA) for roxadustat for the treatment of anemia in adult patients with chronic kidney disease (CKD) is under regulatory review by the European Medicines Agency (EMA) with an expected decision by mid-2021.
  - Pamrevlumab was granted Fast Track and Rare Pediatric Disease designations from the FDA for the treatment of Duchenne muscular dystrophy (DMD).

- **Clinical:**
  - Completed enrollment in the ASPEN and DENALI Phase 3b roxadustat clinical trials with dialysis organizations in dialysis patients with anemia of CKD.
  - Initiated the LELANTOS-2 Phase 3 clinical trial of pamrevlumab in ambulatory patients with DMD.

- **China:**
  - Reported roxadustat net product revenue in China of $15.4 million, on a US GAAP basis, including revenue generated from our sales to the distribution entity and FibroGen China's direct sales.
  - Total roxadustat net sales in China of $43.5 million by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca, compared to $29.2 million last quarter.
  - Hospital listings at the end of the first quarter represented approximately 74% of the CKD anemia market opportunity in China.

- **Presentations / Publications:**
  - Roxadustat data was presented at the following scientific meetings in 2021:
    - FibroGen and its partners presented four posters at the recent National Kidney Foundation Virtual Spring Clinical Meetings.

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[1] Total roxadustat net sales in China includes sales made by the distribution entity as well as FibroGen China's direct sales, each to its own distributors. The distribution entity jointly owned by AstraZeneca and FibroGen is not consolidated into FibroGen's financial statements.

        - FibroGen and its partners presented eight posters at International Society of Nephrology (ISN) World Congress of Nephrology 2021.
    - Roxadustat Phase 3 manuscripts on the treatment of anemia of CKD were published in peer-reviewed medical journals:
        - Pooled Analysis of Roxadustat for Anemia in Patients with Kidney Failure Incident to Dialysis (clarifying and updating Pooled ROCKIES/ SIERRAS/HIMALAYAS with journal) - *Kidney International Reports*
        - Roxadustat for the Treatment of Anemia in Chronic Kidney Disease (CKD) Patients Not on Dialysis: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study (ALPS) - *Nephrology Dialysis Transplantation*
        - Roxadustat for Chronic Kidney Disease-related Anemia in Non-dialysis Patients (ANDES) - *Kidney International Reports*
        - Roxadustat for Treating Anemia in Patients with CKD Not on Dialysis: Results from a Randomized Phase 3 Study (OLYMPUS) - *Journal of the American Society of Nephrology*
        - Roxadustat for anemia in patients with end-stage renal disease incident to dialysis (HIMALAYAS) - *Nephrology Dialysis Transplantation*
        - A Randomized Trial of Roxadustat in Anemia of Kidney Failure: SIERRAS Study - *Kidney International Reports*

Upcoming Data Catalysts

- Data from the Phase 2 WHITNEY study of roxadustat in chemotherapy-induced anemia (CIA) expected 2H 2021.
- Data from the Phase 3 MATTERHORN study of roxadustat in anemia of MDS expected 1H 2022.
- Resection data from the Phase 3 LAPIS study of pamrevlumab in locally advanced pancreatic cancer (LAPC) expected 2H 2022.
- Data from the Phase 3 LELANTOS study of pamrevlumab in DMD expected 2H 2022.

Corporate

- Appointed Tricia Stewart as Chief People Officer

Financial

- Total revenue for the first quarter of 2021 was $38.4 million, as compared to $24.4 million for the first quarter of 2020. The current quarter revenue consists of $15.4 million net product revenue for roxadustat sales in China, $14.6 million in development revenue, and $8.5 million drug product revenue for roxadustat bulk drug or active pharmaceutical ingredient.
- Net loss for the first quarter of 2021 was $71.8 million, or $0.78 net loss per basic and diluted share, compared to a net loss of $78.3 million, or $0.89 net loss per basic and diluted share one year ago.
- As of March 31, 2021, FibroGen had $682.6 million in cash, restricted time deposits, cash equivalents, investments, and receivables.
- Based on our latest forecast, we estimate our 2021 ending cash to be in the range of $660 to $670 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, May 10, 2021, 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 (877) 658-9081 (U.S. and Canada) or 1 (602) 563-8732 (international), reference the FibroGen first quarter 2021 financial results conference call, and use confirmation number 2036817. A replay of the webcast will be available shortly after the call for a period of four weeks. To access the replay, please dial 1 (855) 859-2056 (domestic) or 1 (404) 537-3406 (international), and use passcode 2036817.

About Roxadustat
Roxadustat, an oral medicine, is the first in a new class of medicines, HIF-PH inhibitors, that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin; improved iron absorption and mobilization; and downregulation of hepcidin. Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA).

Roxadustat is approved in China, Japan, and Chile for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). In the U.S., the New Drug Application is under review by the U.S. Food and Drug Administration. In Europe, the Marketing Authorization Application for roxadustat for the treatment of anemia of CKD in patients both on dialysis and not on dialysis was filed by our partner Astellas and accepted by the European Medicines Agency for review on May 2020. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe, and are currently in review.

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

About Pamrevlumab
Pamrevlumab is a first-in-class antibody developed by FibroGen that inhibits the activity of connective tissue growth factor (CTGF), an important biological mediator in fibrotic and proliferative disorders. Pamrevlumab is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For information about pamrevlumab studies currently recruiting patients, 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 hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). 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 and commercialization of the Company's product candidates, the potential safety and efficacy profile of our product candidates, our clinical programs and regulatory events. 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, 2020 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.

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Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 433,508	$ 678,393
Short-term investments	110,724	8,144
Accounts receivable, net	40,543	41,883
Inventory	20,764	16,530
Prepaid expenses and other current assets	16,155	10,160
Total current assets	621,694	755,110
Restricted time deposits	2,072	2,072
Long-term investments	93,679	244
Property and equipment, net	30,933	33,647
Finance lease right-of-use assets	27,311	29,606
Equity method investment in unconsolidated variable interest entity	2,483	2,728
Other assets	9,129	3,433
Total assets	$ 787,301	$ 826,840
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 24,061	$ 24,789
Accrued and other liabilities	119,781	119,521
Deferred revenue	10,725	6,547
Finance lease liabilities, current	12,480	12,330
Total current liabilities	167,047	163,187
Product development obligations	17,962	18,697
Deferred revenue, net of current	151,491	138,474
Finance lease liabilities, non-current	22,193	25,391
Other long-term liabilities	38,335	39,642
Total liabilities	397,028	385,391
Total stockholders' equity	371,002	422,178
Non-controlling interests	19,271	19,271
Total equity	390,273	441,449
Total liabilities, stockholders' equity and non-controlling interests	$ 787,301	$ 826,840

(1) The condensed consolidated balance sheet amounts at December 31, 2020 are derived from audited financial statements.

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

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Revenue:		
License revenue	$ —	$ —
Development and other revenue	14,587	19,446
Product revenue, net	15,362	4,955
Drug product revenue	8,480	—
Total revenue	38,429	24,401
Operating costs and expenses:		
Cost of goods sold	3,401	970
Research and development	74,676	54,902
Selling, general and administrative	30,779	49,603
Total operating costs and expenses	108,856	105,475
Loss from operations	(70,427)	(81,074)
Interest and other, net:		
Interest expense	(501)	(633)
Interest income and other income (expenses), net	(453)	3,165
Total interest and other, net	(954)	2,532
Loss before income taxes	(71,381)	(78,542)
Provision for income taxes	134	(194)
Investment loss in unconsolidated variable interest entity	(240)	—
Net loss	$ (71,755)	$ (78,348)
Net loss per share - basic and diluted	$ (0.78)	$ (0.89)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	91,688	88,219

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