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 9, 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 August 9, 2021, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 30, 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 Second Quarter 2021 Financial Results," dated August 9, 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: August 9, 2021

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

Exhibit 99.1

FibroGen Reports Second Quarter 2021 Financial Results

• Roxadustat net product revenue in China of $13.4 million, on a US GAAP basis.
• Total roxadustat net sales in China of $52.8 million[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca
• Roxadustat Receives Positive Opinion from the CHMP of EMA for Patients with Anemia of CKD
• Roxadustat Receives Negative Vote from FDA Advisory Committee for Patients with Anemia of CKD

SAN FRANCISCO, August 9, 2021 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the second quarter 2021 and provided an update on the Company's recent developments.

"We continue to be energized by the performance of roxadustat in China, where we are seeing impressive adoption of roxadustat in a rapidly expanding anemia of CKD market. In addition, the positive CHMP opinion in Europe brings roxadustat one step closer to patients in this important region," said Enrique Conterno, Chief Executive Officer, FibroGen. "We look forward to the European Commission decision following the positive CHMP opinion. On the other hand, we are disappointed with the FDA Cardiovascular and Renal Drugs Advisory Committee negative vote, and we will continue to work with our partner AstraZeneca and the FDA on a path forward."

Recent Key Events and Other Developments
Regulatory:
- In June, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion relating to the use of roxadustat for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD). A European Commission decision is expected in August 2021.
- In July, the U.S. Food and Drug Administration (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC) voted to recommend not approving roxadustat for the treatment of anemia due to CKD. An FDA action on the new drug application is expected in the near future.

Clinical:
- Pamrevlumab included in the Pancreatic Cancer Action Network's (PanCAN) Precision Promise[SM] adaptive trial platform evaluating pamrevlumab for patients with metastatic pancreatic cancer.

China:
- Roxadustat net product revenue in China of $13.4 million, on a US GAAP basis, including revenue generated from our sales to the distribution entity and FibroGen China's direct sales, compared to $15.4 million last quarter.
- Total roxadustat net sales in China of $52.8 million by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca, compared to $43.5 million last quarter.
- Hospital listings at the end of the second quarter represented approximately 81% of the CKD anemia market opportunity in China versus 74% last quarter.

---

[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.

Clinical Presentations / Publications:

- FibroGen and its partners presented three roxadustat oral presentations and ten mini-oral presentations at the recent 58th European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress.
- Two additional roxadustat Phase 3 manuscripts on the treatment of anemia of CKD were published in a peer-reviewed medical journal, bringing the total to 7:
  - Roxadustat for the treatment of anaemia in chronic kidney disease patients not on dialysis: a phase 3, randomised, open-label, active-controlled study (DOLOMITES) *Nephrology Dialysis Transplantation*.
  - Efficacy and Cardiovascular Safety of Roxadustat for Treatment of Anemia in Patients with Non–Dialysis-Dependent CKD (NDD Pooled) *Clinical Journal of the American Society of Nephrology*.
- FibroGen presented one oral presentation and one poster presentation of two-year data from a Phase 2 trial of pamrevlumab in non-ambulatory DMD patients at the recent Parent Project Muscular Dystrophy (PPMD) Annual Conference.

Upcoming Data Milestones:

- Data from the Phase 2 WHITNEY study of roxadustat in chemotherapy-induced anemia (CIA) expected 3Q 2021 versus prior 2H 2021.
- Topline data from the Phase 3 MATTERHORN study of roxadustat in anemia of myelodysplastic syndromes (MDS) now expected 2H 2022 / 1H 2023 versus prior 1H 2022.
- Interim analysis of event free survival for potential accelerated approval of Phase 3 LAPIS study of pamrevlumab in locally advanced pancreatic cancer (LAPC) will be completed in 2H 2022.
- Topline data from the Phase 3 LELANTOS-1 study of pamrevlumab in Duchenne muscular dystrophy (DMD) now expected 1H 2023 versus prior 2H 2022.
- Topline data from the Phase 3 ZEPHYRUS-1 study of pamrevlumab in idiopathic pulmonary fibrosis (IPF) expected mid-2023

Corporate

- Appointed John Hunter, Ph.D. as Chief Scientific Officer.
- FibroGen and HiFiBiO announced partnership to advance next-generation therapies for patients with cancer and autoimmune disease. FibroGen exclusively licensed HiFiBiO's Galectin-9 program, and obtained an exclusive option to their CXCR5 and CCR8 programs.
- Eluminex Biosciences exclusively licensed worldwide rights to develop and commercialize FibroGen's investigational biosynthetic cornea program and the underlying recombinant human collagen Type III technology.
- The Company has completed its internal review of the events leading to our April 6, 2021 disclosures in which we clarified that certain cardiovascular safety analyses from the roxadustat Phase 3 program for the treatment of anemia of chronic kidney disease included post-hoc changes to the stratification factors.

Financial:

- Total revenue for the second quarter of 2021 was $24.4 million, as compared to $42.9 million for the second quarter of 2020. The current quarter revenue includes $13.4 million net product revenue for roxadustat sales in China, and $19.6 million in development revenue. The current quarter also includes $(8.6) million drug product revenue as a result of the recent unfavorable CRDAC vote.
- Operating costs and expenses for the second quarter of 2021 included a one-time charge of $25 million related to our partnership with HiFiBio, and an increase of approximately $20 million driven primarily by pamrevlumab development expenses compared to one year ago.
- Net loss for the second quarter of 2021 was $134.0 million, or $1.45 net loss per basic and diluted share, compared to a net loss of $85.3 million, or $0.95 net loss per basic and diluted share one year ago.

Conference Call and Webcast Details
FibroGen will host a conference call and webcast today, Monday, August 9, 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 second quarter 2021 financial results conference call, and use confirmation number 4951789. 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 4951789.

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, Chile, and South Korea for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). In Europe, the Marketing Authorisation Application is under review by the European Medicines Agency (EMA). In the U.S., the New Drug Application is under review by the U.S. Food and Drug Administration. 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, 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, 2020 and our Quarterly Report on Form 10-Q for quarter ended June 30, 2021 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)

	June 30, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 353,361	$ 678,393
Short-term investments	153,851	8,144
Accounts receivable, net	24,266	41,883
Inventory	24,530	16,530
Prepaid expenses and other current assets	8,458	10,160
Total current assets	564,466	755,110
Restricted time deposits	2,072	2,072
Long-term investments	105,758	244
Property and equipment, net	30,670	33,647
Finance lease right-of-use assets	861	29,606
Equity method investment in unconsolidated variable interest entity	3,083	2,728
Operating lease right-of-use assets	97,091	2,043
Other assets	4,617	1,390
Total assets	$ 808,618	$ 826,840
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 48,988	$ 24,789
Accrued and other liabilities	147,801	118,333
Deferred revenue	25,234	6,547
Finance lease liabilities, current	23	12,330
Operating lease liabilities, current	10,718	1,188
Total current liabilities	232,764	163,187
Product development obligations	18,277	18,697
Deferred revenue, net of current	152,865	138,474
Finance lease liabilities, non-current	6	25,391
Operating lease liabilities, non-current	94,196	853
Other long-term liabilities	30,659	38,789
Total liabilities	528,767	385,391
Total stockholders' equity	260,580	422,178
Non-controlling interests	19,271	19,271
Total equity	279,851	441,449
Total liabilities, stockholders' equity and non-controlling interests	$ 808,618	$ 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)			
Revenue:				
License revenue	$ —	$ —	$ —	$ —
Development and other revenue	19,641	18,957	34,228	38,402
Product revenue, net	13,371	15,693	28,733	20,648
Drug product revenue	(8,648)	8,238	(168)	8,238
Total revenue	24,364	42,888	62,793	67,288
Operating costs and expenses:				
Cost of goods sold	3,078	3,076	6,479	4,047
Research and development	122,567	61,414	197,243	116,315
Selling, general and administrative	32,554	63,535	63,334	113,138
Total operating costs and expenses	158,199	128,025	267,056	233,500
Loss from operations	(133,835)	(85,137)	(204,263)	(166,212)
Interest and other, net:				
Interest expense	(355)	(651)	(856)	(1,284)
Interest income and other income (expenses), net	(363)	644	(817)	3,810
Total interest and other, net	(718)	(7)	(1,673)	2,526
Loss before income taxes	(134,553)	(85,144)	(205,936)	(163,686)
Provision for income taxes	(3)	169	130	(25)
Investment income in unconsolidated variable interest entity	562	—	323	—
Net loss	$ (133,988)	$ (85,313)	$ (206,066)	$ (163,661)
Net loss per share - basic and diluted	$ (1.45)	$ (0.95)	$ (2.24)	$ (1.84)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	92,276	89,451	91,983	88,835

# # #

Contacts:
FibroGen, Inc.

Investors:
Michael Tung, M.D.
Corporate Strategy / Investor Relations
415.978.1434
mtung@fibrogen.com

Media:
GCI Health
FibroGenMedia@gcihealth.com