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): November 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 November 9, 2021, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 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 Third Quarter 2021 Financial Results," dated November 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: November 9, 2021

By: /s/ Juan Graham
Juan Graham
Senior Vice President and Chief Financial Officer

Exhibit 99.1

FibroGen Reports Third Quarter 2021 Financial Results

• Roxadustat Receives EU approval for Patients with Anemia of CKD, triggering a $120M milestone payment from Astellas
• Roxadustat net product revenue in China of $13.4 million, on a US GAAP basis
• Total roxadustat net sales in China of $57.8 million[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca

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

"We and our partner Astellas are excited to be making Evrenzo available to patients in Europe," said Enrique Conterno, Chief Executive Officer, FibroGen. "In addition to continuously looking at opportunities to maximize the value of our portfolio of assets, following the complete response letter for roxadustat in the U.S., we are implementing a comprehensive plan which includes a cost reduction effort that will enable us to focus on our strategic priorities of development of pamrevlumab, roxadustat, and advancing our pipeline."

Recent Key Events and Other Developments

Regulatory:
- The European Commission approved EVRENZO® (roxadustat) for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD). Astellas has launched in Germany, the United Kingdom, Netherlands, and Austria.
- The U.S. Food and Drug Administration (FDA) issued a complete response letter regarding the New Drug Application (NDA) for roxadustat for the treatment of anemia of CKD.

Clinical:
- Announced positive topline results from WHITNEY, the Company's Phase 2 clinical study of roxadustat, for the treatment of chemotherapy-induced anemia (CIA). The results of the study will be presented at an upcoming medical meeting.

China:
- Roxadustat net transfer price from sales to the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $19.1 million for the third quarter. From the net transfer price, FibroGen defers a certain portion for revenue recognition purposes under US GAAP. FibroGen reported $13.4 million in roxadustat net product revenue for the quarter.
- Total roxadustat net sales in China of $57.8 million by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca, compared to $22.7 million in the third quarter of 2020.

Clinical Presentations / Publications:
- FibroGen and its partners presented 15 presentations at the American Society of Nephrology (ASN) Kidney Week 2021 Virtual Conference.
- One additional roxadustat Phase 3 manuscripts on the treatment of anemia of CKD was published in a peer-reviewed medical journal, bringing the total to 8:
  - Roxadustat for the Maintenance Treatment of Anemia in Patients with End-Stage Kidney Disease on Stable Dialysis: A European Phase 3, Randomized, Open-Label, Active-Controlled Study (PYRENEES) *Advances in Therapy*

[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.

Upcoming Data Milestones:

- Topline data from the Phase 3 MATTERHORN study of roxadustat in anemia of myelodysplastic syndromes (MDS) expected 2H 2022 / 1H 2023.
- Interim analysis of event free survival of Phase 3 LAPIS study of pamrevlumab in locally advanced pancreatic cancer (LAPC) expected in 2H 2022.
- Topline data from the Phase 3 LELANTOS-1 study of pamrevlumab in non-ambulatory Duchenne muscular dystrophy (DMD) expected 1H 2023.
- Topline data from the Phase 3 ZEPHYRUS-1 study of pamrevlumab in idiopathic pulmonary fibrosis (IPF) expected mid-2023.

Corporate

- Appointed Juan Graham as Chief Financial Officer.
- Implemented a plan to reduce our projected expenses by approximately $100 million per year, for each of the next 3 years.

Financial:

- Total revenue for the third quarter of 2021 was $156.0 million, as compared to $44.0 million for the third quarter of 2020. To highlight, current quarter revenue includes $120 million of milestone payments from Astellas related to the EU approval of roxadustat.
- Net income for the third quarter of 2021 was $49.8 million, or $0.54 net income per basic and diluted share, compared to a net income of $33.0 million, or $0.36 net income per basic and $0.35 per diluted share one year ago.
- At September 30, FibroGen had $665.0 million in cash, cash equivalents, investments, and accounts receivable.
- Based on our latest forecast, we estimate our 2021 ending balance of cash, cash equivalents, investments, and accounts receivable to be in the range of $580-610 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Tuesday, November 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 third quarter 2021 financial results conference call, and use confirmation number 1747879. A replay of the webcast will be available shortly after the call for a period of 7 days. To access the replay, please dial 1 (855) 859-2056 (domestic) or 1 (404) 537-3406 (international), and use passcode 1747879.

About Roxadustat

Roxadustat, an oral medication, is the first in a new class of medicines comprising 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 of chronic kidney disease (CKD) and anemia associated with myelodysplastic syndromes (MDS), and for chemotherapy-induced anemia (CIA).

Roxadustat is approved in European Union (EU) member states, including the European Economic Area (EEA) countries, as well as in Japan, China, Chile, and South Korea for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). Several other licensing applications for roxadustat have been submitted by partners, Astellas and AstraZeneca to regulatory authorities across the globe, and are currently under 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 idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), and Duchenne muscular dystrophy (DMD. 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), 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 idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), and Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF).). FibroGen recently expanded its research and development portfolio to include product candidates in the immuno-oncology and autoimmune space. 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 September 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.

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Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 274,527	$ 678,393
Short-term investments	211,875	8,144
Accounts receivable, net	35,994	41,883
Inventory	29,315	16,530
Prepaid expenses and other current assets	21,688	10,160
Total current assets	573,399	755,110
Restricted time deposits	2,072	2,072
Long-term investments	142,636	244
Property and equipment, net	29,052	33,647
Finance lease right-of-use assets	771	29,606
Equity method investment in unconsolidated variable interest entity	3,421	2,728
Operating lease right-of-use assets	94,055	2,043
Other assets	5,107	1,390
Total assets	$ 850,513	$ 826,840
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 23,868	$ 24,789
Accrued and other liabilities	151,346	118,333
Deferred revenue	23,256	6,547
Finance lease liabilities, current	15	12,330
Operating lease liabilities, current	10,831	1,188
Total current liabilities	209,316	163,187
Product development obligations	17,914	18,697
Deferred revenue, net of current	162,415	138,474
Finance lease liabilities, non-current	5	25,391
Operating lease liabilities, non-current	91,478	853
Other long-term liabilities	24,322	38,789
Total liabilities	505,450	385,391
Total stockholders' equity	325,792	422,178
Non-controlling interests	19,271	19,271
Total equity	345,063	441,449
Total liabilities, stockholders' equity and non-controlling interests	$ 850,513	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(Unaudited)			
Revenue:				
License revenue	$ 116,434	$ —	$ 116,434	$ —
Development and other revenue	26,097	20,663	60,325	59,065
Product revenue, net	13,442	22,683	42,175	43,331
Drug product revenue	—	686	(168)	8,924
Total revenue	155,973	44,032	218,766	111,320
Operating costs and expenses:				
Cost of goods sold	3,266	2,207	9,746	6,253
Research and development	75,880	58,476	273,123	174,792
Selling, general and administrative	25,853	(48,981)	89,186	64,157
Total operating costs and expenses	104,999	11,702	372,055	245,202
Income (loss) from operations	50,974	32,330	(153,289)	(133,882)
Interest and other, net:				
Interest expense	(109)	(580)	(965)	(1,864)
Interest income and other income (expenses), net	(1,303)	1,482	(2,120)	5,292
Total interest and other, net	(1,412)	902	(3,085)	3,428
Income (loss) before income taxes	49,562	33,232	(156,374)	(130,454)
Provision for income taxes	106	215	235	190
Investment income (loss) in unconsolidated variable interest entity	342	(13)	664	(13)
Net income (loss)	$ 49,798	$ 33,004	$ (155,945)	$ (130,657)
Net income (loss) per share				
Basic	$ 0.54	$ 0.36	$ (1.69)	$ (1.46)
Diluted	$ 0.54	$ 0.35	$ (1.69)	$ (1.46)
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	92,644	90,558	92,206	89,414
Diluted	92,808	93,678	92,206	89,414

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