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 5, 2020

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 5, 2020, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 30, 2020. 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 2020 Financial Results," dated November 5, 2020
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 5, 2020

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

Exhibit 99.1

FIBROGEN REPORTS THIRD QUARTER 2020 FINANCIAL RESULTS

- Strong third Quarter China Roxadustat Net Sales of $22.7 million -
- Conference Call Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time -

SAN FRANCISCO, November 5, 2020 – FibroGen, Inc. (NASDAQ:FGEN) reported financial results for the third quarter of 2020 and provided an update on the company's recent developments.

"I am pleased with our progress with roxadustat across a number of fronts; including engagement with the FDA, commercial preparations in the U.S., and our impressive sales results in China." said Enrique Conterno, Chief Executive Officer, FibroGen. "As the world navigates the effects of the COVID-19 pandemic, we continue to advance our roxadustat and pamrevlumab clinical programs."

Key Events in Recent Months and Other Developments

Roxadustat

- FibroGen and its partners presented 42 abstracts, including 10 oral presentations and 2 late-breaker poster presentations, at the recent *American Society of Nephrology (ASN) Kidney Week 2020 Reimagined* conference:
  - Two late-breaking abstracts explored the cardiovascular outcomes of patients with anemia of chronic kidney disease (CKD) treated with roxadustat, including associations between achieved hemoglobin levels and risk of Major Adverse Cardiovascular Events (MACE) and MACE+.
  - New analyses showed the efficacy of roxadustat across the continuum of patients with anemia of CKD – both on dialysis and not on dialysis – including different dialysis modalities, iron repletion status, and comorbidities.
  - Presentations addressed the safety profile of roxadustat related to neoplasms, hypertension, and ophthalmological effects.
  - Additional presentations explored the increased risk of red blood cell transfusion at lower hemoglobin levels and the impact of roxadustat on rates of hospitalization due to heart failure.
- U.S. NDA for roxadustat for the treatment of anemia of chronic kidney disease, in dialysis-dependent and non-dialysis-dependent patients, is under review with a Prescription Drug User Fee Act (PDUFA) date of December 20, 2020.
- Marketing authorization application (MAA) for roxadustat for the treatment of anemia in adult patients with CKD, both on dialysis and not on dialysis, is under review by the European Medicines Agency (EMA).
- Japan sNDA for roxadustat for the treatment of anemia of CKD in non-dialysis-dependent patients is under review by the Pharmaceuticals and Medical Devices Agency (PMDA).
- Continued enrollment of the Phase 3 roxadustat clinical trial in anemia associated with myelodysplastic syndromes (MDS) and Phase 2 roxadustat clinical trial in chemotherapy-induced anemia (CIA).

Pamrevlumab

- Initiated LELANTOS, a Phase 3 trial of pamrevlumab in with non-ambulatory Duchenne muscular dystrophy (DMD).
- Continued enrollment of the ZEPHYRUS Phase 3 clinical trial of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF).
- Continued enrollment of the LAPIS Phase 3 clinical trial of pamrevlumab in patients with locally advanced unresectable pancreatic cancer (LAPC).

Upcoming Events

- Plan to initiate ZEPHYRUS-2, a Phase 3 trial of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF) as COVID-19 conditions improve.
- Plan to initiate LELANTOS-2, a Phase 3 trial of pamrevlumab in patients with ambulatory Duchenne muscular dystrophy (DMD) by year-end.

Corporate and Financial

- Total revenue for the third quarter of 2020 was $44.0 million, as compared to $33.2 million for the third quarter of 2019. The current quarter revenue consisted of $22.7 million in net roxadustat sales in China, $20.7 million in development revenue, $2.3 million for sales of bulk drug product, and a net reduction of $1.7 million for certain adjustments.
- Net income for the third quarter of 2020 was $33.0 million, or $0.36 net income per basic and $0.35 per diluted share, compared to a net loss of $49.4 million, or $0.57 net loss per basic and diluted share one year ago.
- Amended China Agreement with AstraZeneca in July 2020 such that both parties are optimally aligned to maximize the economic value of the roxadustat franchise, with more predictable economics and profitability for FibroGen. As a result, we reversed approximately $84.4 million of co-promotion expenses as a reduction to selling, general and administrative expenses in the third quarter of 2020.
- At September 30, 2020, FibroGen had $719.3 million in cash, cash equivalents, restricted time deposits, investments, and receivables.
- Based on our latest forecast, we now estimate our year-end 2020 balance for cash, cash equivalents, restricted time deposits, investments, and receivables to be in the range of $770 to $780 million.
- Appointed Percy Carter, MBA, PhD, to the newly-created position of Chief Scientific Officer.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Thursday, November 5, 2020, 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 2020 financial results conference call, and use passcode 5994243. A replay of the webcast will be available shortly after the call for a period of two weeks. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and use passcode 5994243.

About Roxadustat

Roxadustat is a first-in-class, oral small molecule HIF-PH inhibitor that promotes erythropoiesis through increased endogenous production of erythropoietin; improved iron absorption, transport, and mobilization; and downregulation of hepcidin, which helps to overcome the negative impact of inflammation on hemoglobin synthesis and red blood cell production. Roxadustat is approved in China for the treatment of anemia of adult patients with CKD, both on dialysis and not on dialysis. In Japan, roxadustat is approved for the treatment of anemia of CKD patients on dialysis, and a supplemental NDA for the treatment of anemia of CKD patients not on dialysis is under regulatory review. The roxadustat NDA for the treatment of anemia of CKD in patients both on dialysis and not on dialysis is under review by the U.S. Food and Drug Administration with a Prescription Drug User Fee Act date of December 20, 2020. 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 21, 2020. Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and chemotherapy-induced anemia (CIA).

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 that inhibits the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and locally advanced unresectable pancreatic cancer (LAPC), and in Phase 2 clinical development for the treatment of Duchenne muscular dystrophy (DMD) and coronavirus (COVID-19). 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 idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and coronavirus (COVID-19). 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, our financial results, 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, 2019 and our Quarterly Report on Form 10-Q for quarter ended September 30, 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)

	September 30, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 532,468	$ 126,266
Short-term investments	155,398	407,491
Accounts receivable, net	26,252	28,455
Inventory	11,803	6,887
Prepaid expenses and other current assets	11,563	133,391
Total current assets	737,484	702,490
Restricted time deposits	2,072	2,072
Long-term investments	247	61,118
Property and equipment, net	36,153	42,743
Finance lease right-of-use assets	32,028	39,602
Other assets	4,031	9,372
Total assets	$ 812,015	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 7,553	$ 6,088
Accrued and other liabilities	90,572	83,816
Deferred revenue	7,912	490
Finance lease liabilities, current	12,311	12,351
Total current liabilities	118,348	102,745
Long-term portion of lease obligations	839	1,141
Product development obligations	17,790	16,780
Deferred revenue, net of current	137,954	99,449
Finance lease liabilities, non-current	28,514	37,610
Other long-term liabilities	37,639	64,266
Total liabilities	341,084	321,991
Total stockholders' equity	451,660	516,135
Non-controlling interests	19,271	19,271
Total equity	470,931	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 812,015	$ 857,397

(1) The condensed consolidated balance sheet amounts at December 31, 2019 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,	
	2020	2019	2020	2019
	(Unaudited)			
Revenue:				
License revenue	$ —	$ 11,935	$ —	$ 162,517
Development and other revenue	20,663	20,660	59,065	85,507
Product revenue, net	22,683	579	43,331	579
Drug product revenue	686	—	8,924	—
Total revenue	44,032	33,174	111,320	248,603
Operating costs and expenses:				
Cost of goods sold	2,207	242	6,253	242
Research and development	58,476	49,963	174,792	152,467
Selling, general and administrative	(48,981)	35,823	64,157	84,772
Total operating costs and expenses	11,702	86,028	245,202	237,481
Income (loss) from operations	32,330	(52,854)	(133,882)	11,122
Interest and other, net:				
Interest expense	(580)	(702)	(1,864)	(2,209)
Interest income and other, net	1,469	4,193	5,279	12,496
Total interest and other, net	889	3,491	3,415	10,287
Income (loss) before income taxes	33,219	(49,363)	(130,467)	21,409
Provision for income taxes	215	76	190	256
Net income (loss)	$ 33,004	$ (49,439)	$ (130,657)	$ 21,153
Net income (loss) per share				
Basic	$ 0.36	$ (0.57)	$ (1.46)	$ 0.24
Diluted	$ 0.35	$ (0.57)	$ (1.46)	$ 0.23
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	90,558	87,007	89,414	86,390
Diluted	93,678	87,007	89,414	91,995

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