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 6, 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 August 6, 2020, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 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 Second Quarter 2020 Financial Results," dated August 6, 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: August 6, 2020

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

Exhibit 99.1

FIBROGEN REPORTS SECOND QUARTER 2020 FINANCIAL RESULTS

- Strong Second Quarter China Roxadustat Net Sales of $15.7 million -
- Conference Call Today at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time -

August 6, 2020 -- FibroGen, Inc. (NASDAQ: FGEN) reported financial results for the second quarter of 2020 and provided an update on the company's recent developments.

"Despite this difficult time, we continue to be inspired by our unique opportunity to leverage world-class science to benefit patients," said Enrique Conterno, Chief Executive Officer, FibroGen. "I am pleased with the progress we are making with roxadustat across a number of fronts; including our engagement with the FDA, the European submission, and our impressive sales in China. Additionally, we recently initiated three new trials with pamrevlumab: our Phase 3 study with DMD and two trials in patients hospitalized with COVID-19."

Key Events in Recent Months and Other Developments

Roxadustat

- U.S. NDA for roxadustat for the treatment of anemia of chronic kidney disease (CKD), 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, accepted by the European Medicines Agency (EMA) for regulatory review in May.
- Japan sNDA for roxadustat for the treatment of anemia of CKD in non-dialysis-dependent patients is under review.
- Presented results from the DOLOMITES Phase 3 study at the 57th ERA-EDTA Virtual Congress in which roxadustat demonstrated non-inferiority to darbepoetin alfa in achievement of hemoglobin correction in non-dialysis-dependent patients with CKD.
- Continued enrollment of 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 a randomized, double-blind, placebo-controlled Phase 2 study investigating the efficacy and safety of pamrevlumab in approximately 130 hospitalized patients with acute COVID-19 infection in the U.S.
- Initiated BOREA, a Phase 2/3 investigator-initiated clinical trial investigating the efficacy and safety of pamrevlumab in approximately 68 patients hospitalized with COVID-19 in Italy.
- Reopened enrollment of the ZEPHYRUS Phase 3 clinical trial of pamrevlumab in patients with IPF after pausing for two months to minimize the risk of exposure to COVID-19.
- 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 second IPF Phase 3 clinical trial similar in size and design to ZEPHYRUS, as COVID-19 conditions improve.
- Plan to initiate LELANTOS, a Phase 3, randomized, double-blind, placebo-controlled trial of pamrevlumab in approximately 90 patients with non-ambulatory Duchenne muscular dystrophy (DMD).

Corporate and Financial

- Total revenue for the second quarter of 2020 was $42.9 million, as compared to $191.6 million for the second quarter of 2019. The current quarter revenue consisted of $15.7 million in net roxadustat sales in China, $19.0 million in development revenue, and $8.2 million in roxadustat API sales to Astellas in Japan.
- Net loss for the second quarter of 2020 was $85.3 million, or $0.95 net loss per basic and diluted share, compared to a net income of $116.0 million, or $1.34 net income per basic share and $1.26 per diluted share one year ago.
- At June 30, 2020, FibroGen had $716.0 million in cash, cash equivalents, restricted time deposits, investments, and receivables.
- Based on our latest forecast, we reiterate our year-end 2020 estimate to be in the range of $720 to $730 million in cash, cash equivalents, restricted time deposits, investments, and receivables.
- 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.
- Appointed Thane Wettig to the newly-created position of Chief Commercial Officer.
- Appointed Aoife Brennan, M.B., B.Ch., President and CEO of Synlogic Inc. (NASDAQ:SYBX) to board of directors effective August 5, 2020.
- Appointed Ben Cravatt, Ph.D., Professor and the Norton B. Gilula Chair of Chemical Biology in the Department of Chemistry at The Scripps Research Institute to board of directors effective August 5, 2020.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Thursday, August 6, 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 second quarter 2020 financial results conference call, and use passcode 8363719. 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 8363719.

About Roxadustat

Roxadustat is a first-in-class, orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, and improved iron absorption, transport and mobilization. Roxadustat is approved in China for the treatment of anemia in adult patients with CKD, both on dialysis and not on dialysis. In Japan it is approved for the treatment of anemia in CKD patients on dialysis and a supplemental NDA for the treatment of anemia in CKD patients not on dialysis is under regulatory review. The roxadustat NDA for the treatment of anemia in CKD 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 in CKD 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 for 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 and Europe. 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.

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 to treat 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 June 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)

	June 30, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 429,269	$ 126,266
Short-term investments	256,317	407,491
Accounts receivable, net	26,519	28,455
Inventory	8,582	6,887
Prepaid expenses and other current assets	6,481	133,391
Total current assets	727,168	702,490
Restricted time deposits	2,072	2,072
Long-term investments	229	61,118
Property and equipment, net	36,984	42,743
Finance lease right-of-use assets	34,368	39,602
Other assets	6,862	9,372
Total assets	$ 807,683	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 5,015	$ 6,088
Accrued and other liabilities	50,464	83,816
Deferred revenue	9,813	490
Finance lease liabilities, current	12,279	12,351
Total current liabilities	77,571	102,745
Long-term portion of lease obligations	940	1,141
Product development obligations	16,959	16,780
Deferred revenue, net of current	138,242	99,449
Finance lease liabilities, non-current	31,586	37,610
Other long-term liabilities	127,242	64,266
Total liabilities	392,540	321,991
Total stockholders' equity	395,872	516,135
Non-controlling interests	19,271	19,271
Total equity	415,143	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 807,683	$ 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(Unaudited)			
Revenue:				
License revenue	$ —	$ 150,581	$ —	$ 150,581
Development and other revenue	18,957	40,985	38,402	64,848
Product revenue, net	15,693	—	20,648	—
Drug product revenue	8,238	—	8,238	—
Total revenue	42,888	191,566	67,288	215,429
Operating costs and expenses:				
Cost of goods sold	3,076	—	4,047	—
Research and development	61,414	52,008	116,315	102,505
Selling, general and administrative	63,535	26,739	113,138	48,948
Total operating costs and expenses	128,025	78,747	233,500	151,453
Income (loss) from operations	(85,137)	112,819	(166,212)	63,976
Interest and other, net:				
Interest expense	(651)	(736)	(1,284)	(1,507)
Interest income and other, net	644	4,125	3,810	8,303
Total interest and other, net	(7)	3,389	2,526	6,796
Income (loss) before income taxes	(85,144)	116,208	(163,686)	70,772
Provision for (benefit from) income taxes	169	205	(25)	180
Net income (loss)	$ (85,313)	$ 116,003	$ (163,661)	$ 70,592
Net income (loss) per share				
Basic	$ (0.95)	$ 1.34	$ (1.84)	$ 0.82
Diluted	$ (0.95)	$ 1.26	$ (1.84)	$ 0.77
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	89,451	86,445	88,835	86,077
Diluted	89,451	91,728	88,835	92,069

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