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): March 2, 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 March 2, 2020, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended December 31, 2019. 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 Fourth Quarter and Full Year 2019 Financial Results," dated March 2, 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: March 2, 2020

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

Exhibit 99.1

FibroGen Reports Fourth Quarter and Full Year 2019 Financial Results

- *Roxadustat NDA submission accepted with PDUFA date of December 20, 2020*
- *Pamrevlumab pivotal trials for treatment of idiopathic pulmonary fibrosis (IPF) and locally advanced unresectable pancreatic cancer (LAPC) underway*
- *Enrique Conterno appointed Chief Executive Officer*

SAN FRANCISCO, March 2, 2020 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year of 2019 and provided an update on the company's recent developments.

"I am thrilled to be joining FibroGen at such an important inflection point for the company. In 2019 we submitted the roxadustat U.S. New Drug Application (NDA), launched roxadustat in China and Japan, and initiated pivotal programs for pamrevlumab in idiopathic pulmonary fibrosis (IPF) and locally advanced unresectable pancreatic cancer (LAPC)." said Enrique Conterno, Chief Executive Officer, FibroGen. "We begin 2020 with a strong foundation on which to build and with continued commitment to unlocking new treatment options that improve patients' lives.

FibroGen has a unique opportunity to leverage its world class science in three areas of focus: ensuring the regulatory and commercial success of roxadustat – a potentially transformational oral medicine in anemia therapy, first demonstrated in patients with chronic kidney disease; accelerating the development of pamrevlumab, in the three high-value indications of IPF, LAPC, and Duchenne muscular dystrophy (DMD); and advancing innovation of our hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) platforms."

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 non-dialysis-dependent and dialysis-dependent patients, accepted with a Prescription Drug User Fee Act (PDUFA) date of December 20, 2020.
- Received expanded approval of roxadustat (China tradename: □□□®) in China for the treatment of anemia in CKD patients who are not dialysis-dependent.
- Achieved roxadustat inclusion in the China National Reimbursement Drug List.
- In Japan, partner Astellas received approval of and launched roxadustat (Japan trade name Evrenzo®) in anemia in dialysis-dependent CKD patients, and submitted the supplemental NDA for the non-dialysis indication this past January.
- Results from the open-label portion of our Phase 3 study of roxadustat for treatment of anemia in patients with myelodysplastic syndromes (MDS) presented at the 2019 American Society of Hematology Annual Meeting. The randomized placebo-controlled, double-blind portion of this global Phase 3 study is ongoing.
- Initiated Phase 2 open-label study of roxadustat for chemotherapy-induced anemia (CIA).

Pamrevlumab

- Initiated the ZEPHYRUS Phase 3 clinical study of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF).
    - In 2020, we will initiate ZEPHYRUS 2, a second IPF Phase 3 study similar in design to ZEPHYRUS.
    - We plan to enroll approximately 340 patients in each study.
- Initiated the LAPIS Phase 3 clinical trial of pamrevlumab for the treatment of patients with locally advanced unresectable pancreatic cancer (LAPC).

Upcoming Events

- In Europe, partner Astellas expects to submit Marketing Authorization Application (MAA) for roxadustat for treatment of dialysis- and non-dialysis-dependent CKD anemia in the second quarter of 2020.
- Plan to initiate a pamrevlumab Phase 3 study in DMD in the second half 2020.

Corporate and Financial

- Net loss for the fourth quarter of 2019 was $98.1 million, or $1.12 net loss per basic and diluted share, compared to a net income of $21.0 million, or $0.25 net income per basic share and $0.23 net income per diluted share one year ago.
- Net loss for the year was $77.0 million, or $0.89 net loss per basic and diluted share, compared to a net loss of $86.4 million, or $1.03 net loss per basic and diluted share one year ago.
- At December 31, 2019, FibroGen had $627.1 million in cash, restricted time deposits, cash equivalents, investments, and receivables.
- Based on our latest forecast, we estimate our 2020 ending cash to be in the range of $720 million to $730 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, March 2, 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 fourth quarter 2019 financial results conference call, and use confirmation number **8058848**. 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 **8058848.**

About Roxadustat

Roxadustat is a first-in-class, orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin synthesis and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of chronic kidney disease (CKD) patients, including in the presence of inflammation and without a need for supplemental intravenous iron. Roxadustat is currently approved in China for the treatment of anemia in CKD patients on dialysis and patients not on dialysis and approved in Japan for the treatment of anemia in CKD patients on dialysis. The NDA filing for roxadustat for the treatment of CKD anemia was accepted by the U.S. Food and Drug Administration in February 2020. Astellas is in the process of preparing an MAA for submission to the European Medicines Agency in the second quarter of 2020. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia.

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 to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and for the treatment of locally advanced unresectable pancreatic cancer (LAPC), and in Phase 2 clinical development for the treatment of Duchenne muscular dystrophy (DMD). The U.S. Food and Drug Administration has granted Orphan Drug Designation to pamrevlumab for the treatment of patients with IPF, LAPC, and DMD. Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and LAPC. Across all clinical studies, pamrevlumab has consistently demonstrated a good safety and tolerability profile to date. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About FibroGen
FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading biopharmaceutical company 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, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, is approved by the National Medical Products Administration in China for CKD patients on dialysis and not on dialysis and by the Ministry of Health, Labour and Welfare in Japan for CKD patients on dialysis. The NDA filing for roxadustat for the treatment of CKD anemia was accepted by the U.S. Food and Drug Administration in February 2020. Astellas is in the process of preparing an MAA for submission to the European Medicines Agency in the second quarter of 2020. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). 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 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)

	December 31, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 126,266	$ 89,258
Short-term investments	407,491	532,144
Accounts receivable, net	28,455	63,684
Inventory	6,887	—
Prepaid expenses and other current assets	133,391	4,929
Total current assets	702,490	690,015
Restricted time deposits	2,072	4,145
Long-term investments	61,118	55,820
Property and equipment, net	42,743	127,198
Finance lease right-of-use assets	39,602	—
Other assets	9,372	3,420
Total assets	$ 857,397	$ 880,598
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 6,088	$ 9,139
Accrued and other liabilities	83,816	66,123
Deferred revenue	490	13,771
Finance lease liabilities, current	12,351	—
Total current liabilities	102,745	89,033
Long-term portion of lease obligations	1,141	97,157
Product development obligations	16,780	16,798
Deferred rent	—	3,038
Deferred revenue, net of current	99,449	136,109
Finance lease liabilities, non-current	37,610	—
Other long-term liabilities	64,266	9,993
Total liabilities	321,991	352,128
Total stockholders' equity	516,135	509,199
Non-controlling interests	19,271	19,271
Total equity	535,406	528,470
Total liabilities, stockholders' equity and non-controlling interests	$ 857,397	$ 880,598

(1) The condensed consolidated balance sheet amounts at December 31, 2018 are derived from audited financial statements.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	(1)
Revenue:				
License revenue	$ 14,569	$ 7,947	$ 177,086	$ 22,269
Development and other revenue	28,607	35,331	114,115	125,913
Product revenue, net	(35,202)	64,776	(34,624)	64,776
Total revenue	7,974	108,054	256,577	212,958
Operating costs and expenses:				
Cost of goods sold	905	—	1,147	—
Research and development	56,797	70,284	209,265	235,839
Selling, general and administrative	50,708	17,851	135,479	63,812
Total operating costs and expenses	108,410	88,135	345,891	299,651
Income (loss) from operations	(100,436)	19,919	(89,314)	(86,693)
Interest and other, net:				
Interest expense	(668)	(2,734)	(2,876)	(10,991)
Interest income and other, net	3,053	3,772	15,548	11,568
Total interest and other, net	2,385	1,038	12,672	577
Income (loss) before income taxes	(98,051)	20,957	(76,642)	(86,116)
Provision for income taxes	72	5	328	304
Net income (loss)	$ (98,123)	$ 20,952	$ (76,970)	$ (86,420)
Net income (loss) per share				
Basic	$ (1.12)	$ 0.25	$ (0.89)	$ (1.03)
Diluted	$ (1.12)	$ 0.23	$ (0.89)	$ (1.03)
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	87,352	85,096	86,633	84,062
Diluted	87,352	91,260	86,633	84,062

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2018 are derived from audited financial statements.

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