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): February 28, 2022

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 February 28, 2022, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter and full year ended December 31, 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 Fourth Quarter and Full Year 2021 Financial Results," dated February 28, 2022
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: February 28, 2022

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

Exhibit 99.1

FibroGen Reports Fourth Quarter and Full Year 2021 Financial Results

• Completed enrollment in LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer
• Completed enrollment in LELANTOS-1 Phase 3 study of pamrevlumab in Duchenne muscular dystrophy
• Total company revenue increased from $176.3 million in 2020 to $235.3 million in 2021

SAN FRANCISCO, February 28, 2022 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year 2021 and provided an update on the company's recent developments.

"We are excited to advance pamrevlumab in three high value indications - completing enrollment in our LAPIS and LELANTOS-1 Phase 3 studies, and expecting to complete enrollment of the ZEPHYRUS-1 Phase 3 study in idiopathic pulmonary fibrosis in the next few weeks," said Enrique Conterno, Chief Executive Officer, FibroGen. "In China, roxadustat had a strong 2021 performance and after inclusion in the updated NRDL, we are off to a good start in 2022."

Recent Developments and Key Events:

- Following the European Commission approval of EVRENZOTM (roxadustat) for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD), Astellas has launched EVRENZOTM in Germany, the United Kingdom, Netherlands, Austria, and the Nordic countries.
- Completed enrollment of the LAPIS Phase 3 clinical trial of pamrevlumab in patients with locally advanced unresectable pancreatic cancer (LAPC).
- Completed enrollment of the LELANTOS-1 Phase 3 clinical trial of pamrevlumab in patients with Duchenne muscular dystrophy (DMD).
- Exercised option to exclusively license HiFiBiO's CCR8 drug program to advance next-generation therapies for patients with solid tumors.

China:

- Roxadustat net transfer price from sales to the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $12.2 million for the fourth quarter. From the net transfer price, FibroGen defers a certain portion for revenue recognition purposes under U.S. GAAP. FibroGen reported $5.5 million in roxadustat net product revenue for the quarter.
  - In the fourth quarter of 2021, China's National Healthcare Security Administration renewed the listing of roxadustat on the National Reimbursement Drug List (NRDL).
  - Due to the price reduction associated with the NRDL listing renewal, we have updated our estimates and reflected a cumulative adjustment in our revenue in the fourth quarter.
- Fourth quarter total roxadustat net sales in China[1] of $32.0 million[2] by FibroGen and the JDE compared to $29.2 million in the fourth quarter of 2020.
- Full year 2021 total roxadustat net sales in China[1] of $186.1 million by FibroGen and the JDE compared to $72.5 million in the full year 2020.
- Roxadustat continues to be the number one brand based on value share in the anemia of CKD market in China.

---

[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.

[2] As a result of the price reduction associated with the NRDL listing renewal, the roxadustat net sales for the fourth quarter of 2021 reflected a one-time adjustment driven by a revaluation of channel inventory.

Upcoming Milestones:

- Expect to complete enrollment in the ZEPHYRUS-1 Phase 3 study of pamrevlumab in idiopathic pulmonary fibrosis (IPF) in the next few weeks.
- Interim analysis of event free survival of the LAPIS Phase 3 study of pamrevlumab in LAPC expected to be conducted in 2Q 2022.
- Topline data from the LELANTOS-1 Phase 3 study of pamrevlumab in DMD expected 1H 2023.
- Topline data from the ZEPHYRUS-1 Phase 3 study of pamrevlumab in IPF expected mid-2023.
- Topline data from the MATTERHORN Phase 3 study of roxadustat in anemia of myelodysplastic syndromes (MDS) expected 2H 2022 / 1H 2023.

Corporate:

- Implemented a plan to reduce our projected expenses by approximately $100 million per year, for each of the next 3 years, compared to our previous internal plans.

Financial:

- Total revenue for the fourth quarter of 2021 was $16.5 million, as compared to $65.0 million for the fourth quarter of 2020.
- Total revenue for 2021 was $235.3 million as compared to $176.3 million in 2020.
- Net loss for the fourth quarter of 2021 was $134.1 million, or $1.45 net loss per basic and diluted share, compared to a net loss of $58.6 million, or $0.64 net loss per basic and diluted share one year ago.
- Net loss for the year was $290.0 million, or $3.14 net loss per basic and diluted share, compared to a net loss of $189.3 million, or $2.11 net loss per basic and diluted share one year ago.
- At December 31, 2021, FibroGen had $590.4 million in cash - defined as cash, cash equivalents, investments, and accounts receivable.
- Based on our latest forecast, we estimate our 2022 ending cash to be in the range of $270 to $300 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, February 28, 2022, 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 2021 financial results conference call, and use confirmation number 1795663. 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 1795663.

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 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 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 not licensed to Astellas.

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 connective tissue growth factor (CTGF) biology and hypoxia-inducible factor (HIF) to advance innovative medicines for the treatment of unmet needs. 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). 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). 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, 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)

	December 31, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 171,223	$ 678,393
Short-term investments	233,967	8,144
Accounts receivable, net	17,401	41,883
Inventory	31,015	16,530
Prepaid expenses and other current assets	20,453	10,160
Total current assets	474,059	755,110
Restricted time deposits	2,072	2,072
Long-term investments	167,796	244
Property and equipment, net	28,277	33,647
Finance lease right-of-use assets	761	29,606
Equity method investment in unconsolidated variable interest entity	3,825	2,728
Operating lease right-of-use assets	91,112	2,043
Other assets	5,919	1,390
Total assets	$ 773,821	$ 826,840
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 26,097	$ 24,789
Accrued and other liabilities	172,588	118,333
Deferred revenue	15,857	6,547
Finance lease liabilities, current	11	12,330
Operating lease liabilities, current	10,944	1,188
Total current liabilities	225,497	163,187
Product development obligations	17,613	18,697
Deferred revenue, net of current	186,801	138,474
Finance lease liabilities, non-current	3	25,391
Operating lease liabilities, non-current	88,776	853
Other long-term liabilities	26,018	38,789
Total liabilities	544,708	385,391
Total stockholders' equity	209,146	422,178
Non-controlling interests	19,967	19,271
Total equity	229,113	441,449
Total liabilities, stockholders' equity and non-controlling interests	$ 773,821	$ 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 December 31,		Years Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	(1)
Revenue:				
License revenue	$ —	$ 14,323	$ 116,434	$ 14,323
Development and other revenue	9,951	21,527	70,275	80,592
Product revenue, net	5,463	29,167	47,638	72,498
Drug product revenue	1,129	(17)	962	8,906
Total revenue	16,543	65,000	235,309	176,319
Operating costs and expenses:				
Cost of goods sold	3,125	2,615	12,871	8,869
Research and development	113,920	78,132	387,043	252,924
Selling, general and administrative	34,739	42,249	123,925	106,406
Total operating costs and expenses	151,784	122,996	523,839	368,199
Loss from operations	(135,241)	(57,996)	(288,530)	(191,880)
Interest and other, net:				
Interest expense	(110)	(538)	(1,075)	(2,402)
Interest income and other income (expenses), net	1,042	261	(1,078)	5,553
Total interest and other, net	932	(277)	(2,153)	3,151
Loss before income taxes	(134,309)	(58,273)	(290,683)	(188,729)
Provision for income taxes	112	171	347	360
Investment income (loss) in unconsolidated variable interest entity	342	(190)	1,007	(202)
Net loss	$ (134,079)	$ (58,634)	$ (290,023)	$ (189,291)
Net loss per share - basic and diluted	$ (1.45)	$ (0.64)	$ (3.14)	$ (2.11)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	92,774	91,166	92,349	89,854

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2020 are derived from audited financial statements.

# # #

Contacts:
FibroGen, Inc.

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

Media:
Meichiel Keenan
Public Affairs
mkeenan@fibrogen.com