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 27, 2023

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.)**
409 Illinois Street **San Francisco, California**		**94158**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 415 978-1200

(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(s)**	**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 27, 2023, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter and full year ended December 31, 2022. 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 2022 Financial Results," dated February 27, 2023
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 thereunto duly authorized.

FIBROGEN, INC.

Date: February 27, 2023

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

Exhibit 99.1

FibroGen Reports Fourth Quarter and Full Year 2022 Financial Results

- ***Topline Data from Five Pivotal Phase 3 Trials in 2023***
- ***Total Company Revenue $140.7 Million in 2022***
- ***Continued Strong Roxadustat Volume Growth in China***

SAN FRANCISCO, February 27, 2023 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year 2022 and provided an update on the company's recent developments.

"We are proud of the significant progress advancing our clinical pipeline in 2022 and excited and well-prepared to deliver results from five pivotal phase 3 trials in 2023," said Enrique Conterno, Chief Executive Officer, FibroGen. "FibroGen represents a catalyst-rich opportunity with each of these trials representing an opportunity to provide a novel treatment to address a significant unmet medical need."

Upcoming Milestones:

Pamrevlumab

- Topline data from the LELANTOS-1 Phase 3 study of pamrevlumab in non-ambulatory Duchenne muscular dystrophy (DMD) patients expected 2Q 2023.
- Topline data from the ZEPHYRUS-1 Phase 3 study of pamrevlumab in idiopathic pulmonary fibrosis (IPF) expected mid-2023.
- Topline data from the LELANTOS-2 Phase 3 study of pamrevlumab in ambulatory DMD patients expected 3Q 2023.
- Topline data from the LAPIS Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer (LAPC) expected 1H 2024.
- Topline data from the ZEPHYRUS-2 Phase 3 study of pamrevlumab in IPF expected mid-2024.

Roxadustat

- Topline data from the MATTERHORN Phase 3 study of roxadustat in anemia of myelodysplastic syndromes (MDS) expected 2Q 2023.
- Topline data from the China Phase 3 study of roxadustat for the treatment of chemotherapy-induced anemia (CIA) expected 2Q 2023.

Preclinical Pipeline

- Expect to file up to two INDs: FG-3165 (anti-Gal9 antibody) and FG-3163 (anti-CCR8 antibody) in 2H 2023.

Recent Developments and Key Events of 2022:

- Completed enrollment of the LELANTOS-1 Phase 3 clinical trial of pamrevlumab in non-ambulatory patients with DMD.
- Completed enrollment of the ZEPHYRUS-1 Phase 3 clinical trial of pamrevlumab in patients with IPF.
- Our partner Astellas received approval for roxadustat in Russia for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD), which triggered a $25 million milestone which FibroGen recorded in 1Q 2022.
- Completed enrollment of the LELANTOS-2 Phase 3 clinical trial of pamrevlumab in ambulatory patients with DMD.
- Completed non-dilutive revenue interest monetization transaction providing $50 million with NovaQuest Capital Management to support our strategic priorities.
- Completed enrollment of the MATTERHORN Phase 3 study of roxadustat in patients with anemia of MDS.

- In 1Q 2023, completed enrollment of the China Phase 3 study of roxadustat in patients with chemotherapy-induced anemia (CIA).
- In 1Q 2023, Partner Eluminex Biosciences implanted the first patient with a biosynthetic cornea in their pivotal clinical trial in China.
- Continuation in the Pancreatic Cancer Action Network's (PanCAN) Precision PromiseSM adaptive trial platform evaluating pamrevlumab [and standard of care] for patients with metastatic pancreatic cancer.

China:

- Fourth quarter FibroGen's net product revenue under U.S. GAAP from the sale of roxadustat in China was $23.4 million compared to $5.5 million in the fourth quarter of 2021, an increase of 328%.
- Full year 2022 FibroGen's net product revenue under U.S. GAAP from the sale of roxadustat in China was $82.9 million compared to $47.6 million in the full year 2021, an increase of 74%.
- Fourth quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca (JDE) was $53.1 million, compared to $32.0 million in the fourth quarter of 2021.
- Full year 2022 total roxadustat net sales in China1 by FibroGen and the JDE was $208.8 million, compared to $186.1 million in the full year 2021, 12% growth in net sales driven by over 80% growth in volume.
- Roxadustat continues to be the number one brand based on value share in the anemia of CKD market in China.

Financial:

- Total revenue for the fourth quarter of 2022 was $34.4 million, as compared to $16.5 million for the fourth quarter of 2021.
- Total revenue for 2022 was $140.7 million as compared to $235.3 million in 2021, which included $120 million of milestone payments from Astellas related to the EU approval of roxadustat.
- Net loss for the fourth quarter of 2022 was $66.2 million, or $0.70 net loss per basic and diluted share, compared to a net loss of $134.1 million, or $1.45 net loss per basic and diluted share one year ago.
- Net loss for the year was $293.7 million, or $3.14 net loss per basic and diluted share, compared to a net loss of $290.0 million, or $3.14 net loss per basic and diluted share one year ago.
- At December 31, 2022, FibroGen had $442.7 million in cash - defined as cash, cash equivalents, investments, and accounts receivable.
- Going forward, we believe we are funded through multiple key clinical milestones and we expect our cash, cash equivalents, investments, and accounts receivable to be sufficient to fund our operating plans into the second half of 2024 even without additional financing.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, February 27, 2023, at 5:00 PM Eastern Time to discuss financial results and provide a business update. Interested parties may access a live audio webcast of the conference call via the "Investor Relations" page of the Company's website at www.fibrogen.com. To access the call by phone, please go to this link (registration link), and you will be provided with dial in details. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time. A replay of the webcast will also be available for a limited time at the following link (webcast replay).

[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.

About Pamrevlumab

Pamrevlumab is a potential first-in-class antibody being 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), locally advanced unresectable pancreatic cancer (LAPC), and Duchenne muscular dystrophy (DMD), and in Phase 2/3 for the treatment of metastatic pancreatic cancer. The U.S. Food and Drug Administration has granted Orphan Drug Designation (ODD), and Fast Track designation to pamrevlumab for the treatment of patients with IPF, DMD, and LAPC. The U.S. Food and Drug Administration has also granted Rare Pediatric Disease Designation to pamrevlumab for the treatment of patients with DMD. Pamrevlumab has demonstrated a safety and tolerability profile that has supported ongoing clinical investigation in IPF, DMD, and LAPC. Pamrevlumab is an investigational drug and not approved for marketing by any regulatory authority. 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 China, Europe, Japan, and numerous other countries 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, and 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), metastatic pancreatic cancer, and Duchenne muscular dystrophy (DMD). Roxadustat (爱瑞卓®, EVRENZOTM) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in CKD patients on dialysis and not on dialysis. Roxadustat is in Phase 3 clinical development in the U.S. and Europe for anemia associated with myelodysplastic syndromes (MDS), and in Phase 3 clinical development in China for treatment of 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 FibroGen's 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 its product candidates, and its clinical programs. These forward-looking statements include, but are not limited to, statements under the caption "Upcoming Milestones", the statement that FibroGen expects its cash, cash equivalents, investments, and accounts receivable to be sufficient to fund its operating plans into the second half of 2024 even without additional financing, and statements about FibroGen's plans and objectives 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. FibroGen's 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 its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in FibroGen's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission (SEC) on February 27, 2023, 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 FibroGen undertakes 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, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 155,700	$ 171,223
Short-term investments	266,308	233,967
Accounts receivable, net	16,299	17,401
Inventory	40,436	31,015
Prepaid expenses and other current assets	14,083	20,453
Total current assets	492,826	474,059
Restricted time deposits	2,072	2,072
Long-term investments	4,348	167,796
Property and equipment, net	20,605	28,277
Equity method investment in unconsolidated variable interest entity	5,061	3,825
Operating lease right-of-use assets	79,893	91,112
Other assets	5,282	6,680
Total assets	$ 610,087	$ 773,821
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 30,758	$ 26,097
Accrued and other liabilities	219,773	172,599
Deferred revenue	12,739	15,857
Operating lease liabilities, current	10,292	10,944
Total current liabilities	273,562	225,497
Product development obligations	16,917	17,613
Deferred revenue, net of current	185,722	186,801
Operating lease liabilities, non-current	79,593	88,776
Liability related to sale of future revenues, non-current	49,333	—
Other long-term liabilities	6,440	26,021
Total liabilities	611,567	544,708
Total stockholders' equity (deficit)	(21,447)	209,146
Non-controlling interests	19,967	19,967
Total equity (deficit)	(1,480)	229,113
Total liabilities, stockholders' equity and non-controlling interests	$ 610,087	$ 773,821

(1) The condensed consolidated balance sheet amounts at December 31, 2021 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,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	(1)
Revenue:				
License revenue	$ —	$ —	$ 22,590	$ 116,434
Development and other revenue	4,517	9,951	24,189	70,275
Product revenue, net	23,374	5,463	82,869	47,638
Drug product revenue	6,476	1,129	11,086	962
Total revenue	34,367	16,543	140,734	235,309
Operating costs and expenses:				
Cost of goods sold	4,924	3,125	20,280	12,871
Research and development	61,628	113,920	296,791	387,043
Selling, general and administrative	33,966	34,739	124,688	123,925
Total operating costs and expenses	100,518	151,784	441,759	523,839
Loss from operations	(66,151)	(135,241)	(301,025)	(288,530)
Interest and other, net:				
Interest expense	(1,119)	(110)	(1,440)	(1,075)
Interest income and other income (expenses), net	923	1,042	7,596	(1,078)
Total interest and other, net	(196)	932	6,156	(2,153)
Loss before income taxes	(66,347)	(134,309)	(294,869)	(290,683)
Provision for income taxes	108	112	358	347
Investment income in unconsolidated variable interest entity	280	342	1,573	1,007
Net loss	$ (66,175)	$ (134,079)	$ (293,654)	$ (290,023)
Net loss per share - basic and diluted	$ (0.70)	$ (1.45)	$ (3.14)	$ (3.14)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	94,032	92,774	93,582	92,349

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2021 are derived from audited financial statements.

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