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): May 08, 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 May 8, 2023, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 31, 2023. 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 First Quarter 2023 Financial Results," dated May 8, 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: May 8, 2023

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

Exhibit 99.1

FibroGen Reports First Quarter 2023 Financial Results

- ***Topline Data From Four Phase 3 Trials Expected Through 3Q 2023***
- ***Completed Non-Dilutive Term Loan Financing for up to $150 Million with Morgan Stanley Tactical Value***
- ***Entered Into Exclusive License for FOR46 with Fortis Therapeutics***

SAN FRANCISCO, May 8, 2023 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter 2023 and provided an update on the company's recent developments.

"We look forward to reporting topline data from four pivotal phase 3 trials through the third quarter of this year," said Enrique Conterno, Chief Executive Officer, FibroGen. "We are excited about expanding our clinical pipeline with FOR46 and strengthening our balance sheet with the recent corporate financing activities."

Recent Developments and Key Events of First Quarter 2023:

- Completed enrollment of the ZEPHYRUS-2 Phase 3 clinical trial of pamrevlumab in patients with idiopathic pulmonary fibrosis.
- Completed enrollment of the China Phase 3 study of roxadustat in patients with chemotherapy-induced anemia.
- Completed non-dilutive term loan facility with Morgan Stanley Tactical Value of up to $150 million.
- Entered into exclusive license for FOR46 with Fortis Therapeutics.
- Partner Eluminex Biosciences implanted the first patient with a biosynthetic cornea in their pivotal clinical trial in China.
- Reported topline results from the MATTERHORN Phase 3 study of roxadustat in anemia of myelodysplastic syndromes.

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 China Phase 3 study of roxadustat for the treatment of chemotherapy-induced anemia expected 2Q 2023.

Preclinical Pipeline

- Expect to file up to two INDs: FG-3165 (anti-Gal9 antibody) and FG-3163 (anti-CCR8 antibody) near year-end 2023.

China Performance:

- First quarter FibroGen's net product revenue under U.S. GAAP from the sale of roxadustat in China was $24.2 million compared to $18.9 million in the first quarter of 2022, an increase of 28%.
- First quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $64.1 million, compared to $43.5 million in the first quarter of 2022, an increase of 47%.
- 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 first quarter of 2023 was $36.2 million, as compared to $60.8 million for the first quarter of 2022, which included a $25 million milestone payment.
- Net loss for the first quarter of 2023 was $76.7 million, or $0.81 net loss per basic and diluted share, compared to a net loss of $63.2 million, or $0.68 net loss per basic and diluted share one year ago.
- At March 31, 2023, cash – defined as cash, cash equivalents, investments, and accounts receivable – was $373.6 million, including proceeds received during the quarter from recent use of the Company's at-the-market equity facility.
- We expect our cash, cash equivalents, investments, and accounts receivable to be sufficient to fund our operating plans through 2024.

Conference Call and Webcast Details
FibroGen will host a conference call and webcast today, Monday, May 8, 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 in to 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).

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.

[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 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 clinical development for anemia of chronic kidney disease (CKD) and 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 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 through 2024, 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 May 8, 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)

	March 31, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 188,550	$ 155,700
Short-term investments	167,399	266,308
Accounts receivable, net	17,654	16,299
Inventory	42,456	40,436
Prepaid expenses and other current assets	14,490	14,083
Total current assets	430,549	492,826
Restricted time deposits	2,072	2,072
Long-term investments	—	4,348
Property and equipment, net	18,693	20,605
Equity method investment in unconsolidated variable interest entity	5,884	5,061
Operating lease right-of-use assets	76,674	79,893
Other assets	4,672	5,282
Total assets	$ 538,544	$ 610,087
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 71,282	$ 30,758
Accrued and other liabilities	157,042	219,773
Deferred revenue	16,495	12,739
Operating lease liabilities, current	9,927	10,292
Total current liabilities	254,746	273,562
Product development obligations	17,276	16,917
Deferred revenue, net of current	163,089	185,722
Operating lease liabilities, non-current	76,885	79,593
Liability related to sale of future revenues, non-current	48,370	49,333
Other long-term liabilities	7,063	6,440
Total liabilities	567,429	611,567
Total stockholders' equity (deficit)	(48,852)	(21,447)
Non-controlling interests	19,967	19,967
Total equity (deficit)	(28,885)	(1,480)
Total liabilities, stockholders' equity and non-controlling interests	$ 538,544	$ 610,087

(1) The condensed consolidated balance sheet amounts at December 31, 2022 are derived from audited financial statements.

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

	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
Revenue:		
License revenue	$ 6,000	$ 22,590
Development and other revenue	3,891	11,762
Product revenue, net	24,161	18,881
Drug product revenue	2,109	7,594
Total revenue	36,161	60,827
Operating costs and expenses:		
Cost of goods sold	3,491	4,238
Research and development	74,486	89,018
Selling, general and administrative	34,275	30,564
Total operating costs and expenses	112,252	123,820
Loss from operations	(76,091)	(62,993)
Interest and other, net:		
Interest expense	(2,372)	(97)
Interest income and other income (expenses), net	1,036	(322)
Total interest and other, net	(1,336)	(419)
Loss before income taxes	(77,427)	(63,412)
Provision for income taxes	74	113
Investment income in unconsolidated variable interest entity	796	320
Net loss	$ (76,705)	$ (63,205)
Net loss per share - basic and diluted	$ (0.81)	$ (0.68)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	94,691	93,043

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Contacts:
FibroGen, Inc.

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

Media:
Meichiel Jennifer Keenan
Investor Relations and Corporate Communications
mkeenan@fibrogen.com