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 09, 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.)**
409 Illinois Street **San Francisco, California** **(Address of Principal Executive Offices)**		**94158** **(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 9, 2022, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 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 First Quarter 2022 Financial Results," dated May 9, 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 thereunto duly authorized.

FIBROGEN, INC.

Date: May 9, 2022

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

Exhibit 99.1

FibroGen Reports First Quarter 2022 Financial Results

• Completed enrollment in ZEPHYRUS-1 Phase 3 study of pamrevlumab in idiopathic pulmonary fibrosis
• 1Q 2022 revenue of $60.8M, growth of 58% vs. 1Q 2021
• Significant roxadustat volume growth in China in first quarter 2022 offsetting NRDL price reduction

SAN FRANCISCO, May 9, 2022 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter 2022 and provided an update on the company's recent developments.

"We continue our progress in advancing pamrevlumab in three high value indications and are delighted to have completed enrollment of the ZEPHYRUS-1 Phase 3 study in idiopathic pulmonary fibrosis," said Enrique Conterno, Chief Executive Officer, FibroGen. "In addition, roxadustat is off to a strong start in 2022 in China with significant year over year volume growth."

Recent Developments:

- Completed enrollment of the ZEPHYRUS-1 Phase 3 clinical trial of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF).
- Completed enrollment of the LELANTOS-1 Phase 3 clinical trial of pamrevlumab in non-ambulatory patients with Duchenne muscular dystrophy (DMD).
- 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 payable to FibroGen.

China Performance:

- FibroGen's net product revenue under U.S. GAAP from sale of roxadustat in China was $18.9 million compared to $15.4 million in the first quarter of 2021. Increase driven mainly due to release of deferred revenue.
- First quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $43.5 million, flat as compared to the first quarter of 2021. This result was driven by an increase in volume of over 70% offset by the recent National Reimbursement Drug List (NRDL) price reduction.
- 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.

Upcoming Milestones:

- Interim analysis of event free survival of the LAPIS Phase 3 study of pamrevlumab in locally advanced pancreatic cancer (LAPC) to be conducted in 2Q 2022.
- Topline data from the LELANTOS-1 Phase 3 study of pamrevlumab in DMD expected 1H 2023.
- Expect to complete enrollment in the LELANTOS-2 Phase 3 study of pamrevlumab in ambulatory patients with DMD in 2Q 2022.
- 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 1H 2023.

Financial:

- Total revenue for the first quarter of 2022 was $60.8 million, as compared to $38.4 million for the first quarter of 2021.
- Net loss for the first quarter of 2022 was $63.2 million, or $0.68 net loss per basic and diluted share, compared to a net loss of $71.8 million, or $0.78 net loss per basic and diluted share one year ago.
- At March 31, 2022, FibroGen had $565.4 million in cash - defined as cash, cash equivalents, investments, and accounts receivable.
- Based on our latest forecast, we estimate a 2022 ending cash balance of $310-340 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, May 9, 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 first quarter 2022 financial results conference call, and use confirmation number 2487763. 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 2487763.

About Pamrevlumab

Pamrevlumab is a potential first-in-class antibody being 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). 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 European Union (EU) member states, including the European Economic Area (EEA) countries, as well as in Japan, China, Chile, South Korea, Russia, and the UK 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 potential 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.

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Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 185,896	$ 171,223
Short-term investments	242,179	233,967
Accounts receivable, net	43,883	17,401
Inventory	43,067	31,015
Prepaid expenses and other current assets	9,390	20,453
Total current assets	524,415	474,059
Restricted time deposits	2,072	2,072
Long-term investments	93,488	167,796
Property and equipment, net	26,881	28,277
Equity method investment in unconsolidated variable interest entity	4,155	3,825
Operating lease right-of-use assets	87,990	91,112
Other assets	6,933	6,680
Total assets	$ 745,934	$ 773,821
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 36,353	$ 26,097
Accrued and other liabilities	203,299	172,599
Deferred revenue	4,744	15,857
Operating lease liabilities, current	10,978	10,944
Total current liabilities	255,374	225,497
Product development obligations	17,374	17,613
Deferred revenue, net of current	184,893	186,801
Operating lease liabilities, non-current	85,948	88,776
Other long-term liabilities	24,330	26,021
Total liabilities	567,919	544,708
Total stockholders' equity	158,048	209,146
Non-controlling interests	19,967	19,967
Total equity	178,015	229,113
Total liabilities, stockholders' equity and non-controlling interests	$ 745,934	$ 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 March 31,	
	2022	2021
	(Unaudited)	
Revenue:		
License revenue	$ 22,590	$ —
Development and other revenue	11,762	14,587
Product revenue, net	18,881	15,362
Drug product revenue	7,594	8,480
Total revenue	60,827	38,429
Operating costs and expenses:		
Cost of goods sold	4,238	3,401
Research and development	89,018	74,676
Selling, general and administrative	30,564	30,779
Total operating costs and expenses	123,820	108,856
Loss from operations	(62,993)	(70,427)
Interest and other, net:		
Interest expense	(97)	(501)
Interest income and other income (expenses), net	(322)	(453)
Total interest and other, net	(419)	(954)
Loss before income taxes	(63,412)	(71,381)
Provision for income taxes	113	134
Investment income (loss) in unconsolidated variable interest entity	320	(240)
Net loss	$ (63,205)	$ (71,755)
Net loss per share - basic and diluted	$ (0.68)	$ (0.78)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	93,043	91,688

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