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): August 08, 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 August 8, 2022, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended June 30, 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 Second Quarter 2022 Financial Results," dated August 8, 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: August 8, 2022

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

Exhibit 99.1

FibroGen Reports Second Quarter 2022 Financial Results

- ***Completed enrollment of LELANTOS-2 Phase 3 study of pamrevlumab in ambulatory patients with Duchenne muscular dystrophy***
- ***2Q 2022 revenue of $29.8 million, growth of 22% vs. 2Q 2021***
- ***Continued significant roxadustat volume growth in China***

SAN FRANCISCO, August 8, 2022 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the second quarter 2022 and provided an update on the company's recent developments.

"We continue making excellent progress with pamrevlumab across all our high value indications and are pleased to have recently completed enrollment of the LELANTOS-2 Phase 3 study in ambulatory patients with Duchenne muscular dystrophy. We now expect topline data from three pivotal pamrevlumab Phase 3 trials in 2023: the ZEPHYRUS-1 trial in idiopathic pulmonary fibrosis, and the LELANTOS-1 and LELANTOS-2 trials in non-ambulatory and ambulatory Duchenne muscular dystrophy, respectively," said Enrique Conterno, Chief Executive Officer, FibroGen. "We are delighted with our roxadustat sales in China, showing significant year-over-year volume growth. In Europe, our partner Astellas continues with additional roxadustat launches."

Recent Developments:

- Completed enrollment of the LELANTOS-2 Phase 3 clinical trial of pamrevlumab in ambulatory patients with Duchenne muscular dystrophy (DMD).
- Completed interim analysis of event free survival in the LAPIS Phase 3 study of pamrevlumab in locally advanced pancreatic cancer (LAPC), and the study will continue to its primary endpoint of overall survival.
- Roxadustat continues to be approved in additional countries, most recently in Mexico and South Africa. It is now approved in China, Europe, Japan, and numerous other territories for the treatment of CKD patients on dialysis and patients not on dialysis.

China Performance:

- FibroGen's net product revenue under U.S. GAAP from sale of roxadustat in China was $23.3 million compared to $13.4 million in the second quarter of 2021.
- Second quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $53.1 million, compared to $52.8 million in the second quarter of 2021. This result was driven by an increase in volume of over 80% benefitting from the 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:

- Topline data from the LELANTOS-1 Phase 3 study of pamrevlumab in non-ambulatory DMD patients expected 1H 2023.
- Topline data from the MATTERHORN Phase 3 study of roxadustat in anemia of myelodysplastic syndromes (MDS) expected 1H 2023.
- Topline data from the ZEPHYRUS-1 Phase 3 study of pamrevlumab in IPF expected mid-2023.
- Topline data from the LELANTOS-2 Phase 3 study of pamrevlumab in ambulatory DMD patients expected 2H 2023.
- Topline data from the LAPIS Phase 3 study of pamrevlumab in LAPC expected 1H 2024.

Financial:

- Total revenue for the second quarter of 2022 was $29.8 million, as compared to $24.4 million for the second quarter of 2021.
- Net loss for the second quarter of 2022 was $72.6 million, or $0.78 net loss per basic and diluted share, compared to a net loss of $134.0 million, or $1.45 net loss per basic and diluted share one year ago.
- At June 30, 2022, FibroGen had $517.6 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 $330-$360 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, August 8, 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 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).

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, LAPC, and DMD. 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, LAPC, and 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 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, 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®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in CKD patients on dialysis and patients 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 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, and our clinical programs. 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 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, each as 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)

	June 30, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 167,758	$ 171,223
Short-term investments	270,375	233,967
Accounts receivable, net	33,573	17,401
Inventory	40,899	31,015
Prepaid expenses and other current assets	8,038	20,453
Total current assets	520,643	474,059
Restricted time deposits	2,072	2,072
Long-term investments	45,920	167,796
Property and equipment, net	24,505	28,277
Equity method investment in unconsolidated variable interest entity	4,494	3,825
Operating lease right-of-use assets	84,654	91,112
Other assets	4,501	6,680
Total assets	$ 686,789	$ 773,821
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 29,360	$ 26,097
Accrued and other liabilities	193,099	172,599
Deferred revenue	6,897	15,857
Operating lease liabilities, current	10,984	10,944
Total current liabilities	240,340	225,497
Product development obligations	16,439	17,613
Deferred revenue, net of current	205,351	186,801
Operating lease liabilities, non-current	83,080	88,776
Other long-term liabilities	17,832	26,021
Total liabilities	563,042	544,708
Total stockholders' equity	103,780	209,146
Non-controlling interests	19,967	19,967
Total equity	123,747	229,113
Total liabilities, stockholders' equity and non-controlling interests	$ 686,789	$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)			
Revenue:				
License revenue	$ —	$ —	$ 22,590	$ —
Development and other revenue	5,457	19,641	17,219	34,228
Product revenue, net	23,256	13,371	42,137	28,733
Drug product revenue	1,093	(8,648)	8,687	(168)
Total revenue	29,806	24,364	90,633	62,793
Operating costs and expenses:				
Cost of goods sold	6,809	3,078	11,048	6,479
Research and development	70,963	122,567	159,981	197,243
Selling, general and administrative	30,258	32,554	60,820	63,334
Total operating costs and expenses	108,030	158,199	231,849	267,056
Loss from operations	(78,224)	(133,835)	(141,216)	(204,263)
Interest and other, net:				
Interest expense	(141)	(355)	(238)	(856)
Interest income and other income (expenses), net	5,199	(363)	4,876	(817)
Total interest and other, net	5,058	(718)	4,638	(1,673)
Loss before income taxes	(73,166)	(134,553)	(136,578)	(205,936)
Provision for (benefit from) income taxes	23	(3)	136	130
Investment income in unconsolidated variable interest entity	565	562	885	323
Net loss	$ (72,624)	$ (133,988)	$ (135,829)	$ (205,743)
Net loss per share - basic and diluted	$ (0.78)	$ (1.45)	$ (1.46)	$ (2.24)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	93,475	92,276	93,260	91,983

# # #

Contacts:

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

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