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): November 07, 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**	**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 November 7, 2022, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 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 Third Quarter 2022 Financial Results," dated November 7, 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: November 7, 2022

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

Exhibit 99.1

FibroGen Reports Third Quarter 2022 Financial Results

- ***Continued advancement of pamrevlumab clinical trials – topline data from five pivotal Phase 3 trials beginning in 1H 2023 through mid-2024***
- ***Completed enrollment of MATTERHORN Phase 3 study of roxadustat in patients with anemia of myelodysplastic syndromes with topline data expected 1H 2023***
- ***Strong roxadustat volume growth in China of over 80% vs 3Q 2021***
- ***Announced non-dilutive royalty monetization transaction with NovaQuest for $50 million of capital secured by 22.5% of roxadustat royalty revenue in the Astellas territories***

SAN FRANCISCO, November 7, 2022 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the third quarter 2022 and provided an update on the company's recent developments.

"I am very pleased with our progress across our clinical development programs with 3 pivotal trials expected to read out for pamrevlumab in 2023 and two more in 2024. Notably, our Phase 3 trials of roxadustat in the U.S. and Europe for anemia of myelodysplastic syndromes, and chemotherapy-induced anemia in China add two more pivotal readouts next year," said Enrique Conterno, Chief Executive Officer, FibroGen. "The strategic financing transaction with NovaQuest provides additional non-dilutive capital which strengthens our balance sheet to support the development and commercialization of pamrevlumab while continuing to advance and expand our pipeline."

Recent Developments:

- Announced non-dilutive royalty monetization transaction with NovaQuest Capital Management secured by 22.5% of roxadustat royalty revenue in the territories licensed to Astellas Pharma Inc., providing $50 million to support our strategic priorities.
- Completed enrollment of the MATTERHORN Phase 3 study of roxadustat in patients with anemia of myelodysplastic syndromes (MDS).
- Roxadustat continues to gain approvals in additional countries around the world. It is now approved in China, Europe, Japan, and numerous other territories for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis.

China Performance:

- FibroGen's net product revenue under U.S. GAAP from the sale of roxadustat in China was $17.4 million compared to $13.4 million in the third quarter of 2021, an increase of 29%.
- Third quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity (JDE) jointly owned by FibroGen and AstraZeneca was $59.0 million, compared to $57.8 million in the third quarter of 2021.
- 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:

Pamrevlumab

- Topline data from the LELANTOS-1 Phase 3 study of pamrevlumab in non-ambulatory DMD patients 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.
- 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 MDS expected 1H 2023.
- Topline data from the China Phase 3 study of roxadustat for the treatment of chemotherapy-induced anemia (CIA) expected mid-2023.

Financial:

- Total revenue for the third quarter of 2022 was $15.7 million, as compared to $156.0 million for the third quarter of 2021, which included $120 million of milestone payments from Astellas related to the EU approval of roxadustat.
- Net loss for the third quarter of 2022 was $91.7 million, or $0.98 net loss per basic and diluted share, compared to a net income of $49.8 million, or $0.54 net income per basic and diluted share one year ago.
- At September 30, 2022, FibroGen had $441.6 million in cash - defined as cash, cash equivalents, investments, and accounts receivable.
- Today we announced a non-dilutive royalty monetization transaction with NovaQuest Capital Management, providing $50 million to support our strategic priorities.
- After this transaction and based on our latest forecast, we anticipate our 2022 ending cash balance to be $380-$410 million.

Conference Call and Webcast Details

FibroGen will host a conference call and webcast today, Monday, November 7, 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, 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®, EVRENZO™) 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 the 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 September 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.

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Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 155,960	$ 171,223
Short-term investments	252,560	233,967
Accounts receivable, net	15,328	17,401
Inventory	39,950	31,015
Prepaid expenses and other current assets	10,426	20,453
Total current assets	474,224	474,059
Restricted time deposits	2,072	2,072
Long-term investments	17,780	167,796
Property and equipment, net	22,287	28,277
Equity method investment in unconsolidated variable interest entity	4,631	3,825
Operating lease right-of-use assets	82,903	91,112
Other assets	4,940	6,680
Total assets	$ 608,837	$ 773,821
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 19,323	$ 26,097
Accrued and other liabilities	213,806	172,599
Deferred revenue	7,361	15,857
Operating lease liabilities, current	11,504	10,944
Total current liabilities	251,994	225,497
Product development obligations	15,422	17,613
Deferred revenue, net of current	199,758	186,801
Operating lease liabilities, non-current	81,091	88,776
Other long-term liabilities	14,299	26,021
Total liabilities	562,564	544,708
Total stockholders' equity	26,306	209,146
Non-controlling interests	19,967	19,967
Total equity	46,273	229,113
Total liabilities, stockholders' equity and non-controlling interests	$ 608,837	$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)			
Revenue:				
License revenue	$ —	$ 116,434	$ 22,590	$ 116,434
Development and other revenue	2,453	26,097	19,672	60,325
Product revenue, net	17,359	13,442	59,495	42,175
Drug product revenue	(4,077)	—	4,610	(168)
Total revenue	15,735	155,973	106,367	218,766
Operating costs and expenses:				
Cost of goods sold	4,308	3,266	15,355	9,746
Research and development	75,182	75,880	235,163	273,123
Selling, general and administrative	29,902	25,853	90,722	89,186
Total operating costs and expenses	109,392	104,999	341,240	372,055
Income (loss) from operations	(93,657)	50,974	(234,873)	(153,289)
Interest and other, net:				
Interest expense	(84)	(109)	(321)	(965)
Interest income and other income (expenses), net	1,798	(1,303)	6,672	(2,120)
Total interest and other, net	1,714	(1,412)	6,351	(3,085)
Income (loss) before income taxes	(91,943)	49,562	(228,522)	(156,374)
Provision for income taxes	114	106	250	235
Investment income in unconsolidated variable interest entity	407	342	1,293	664
Net income (loss)	$ (91,650)	$ 49,798	$ (227,479)	$ (155,945)
Net income (loss) per share - basic and diluted	$ (0.98)	$ 0.54	$ (2.43)	$ (1.69)
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	93,767	92,644	93,431	92,206
Diluted	93,767	92,808	93,431	92,206

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