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 12, 2024

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.)**

350 Bay Street **Suite 100 #6009** **San Francisco, California** **(Address of Principal Executive Offices)**	**94133** **(Zip Code)**

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

FibroGen, Inc.
409 Illinois Street
San Francisco, California 94158
(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 12, 2024, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended September 30, 2024. 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 2024 Financial Results," dated November 12, 2024
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 hereunto duly authorized.

FIBROGEN, INC.

Date: November 12, 2024

By: /s/ Juan Graham

Juan Graham
Senior Vice President and Chief Financial Officer

Exhibit 99.1

FibroGen Reports Third Quarter 2024 Financial Results

- ***Topline results from Phase 2 portion of the investigator-sponsored study of FG-3246, a first-in-class antibody-drug conjugate (ADC) targeting CD46, in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) are expected in 1H 2025***
- ***Initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC anticipated in 1Q 2025***
- ***Third quarter net revenue growth of 15% year over year, driven by strong performance of roxadustat in China, with year over year volume growth of 34%***
  - ***Reiterate full year net product revenue guidance of $135 million to $150 million, representing full year total roxadustat net sales in China[1] between $330 million to $350 million***
- ***Meaningful progress on U.S. cost reduction plan***
  - ***Expected to be substantially complete by year-end 2024***
- ***Cash, cash equivalents and accounts receivable balance of $160.0 million***

SAN FRANCISCO, November 12, 2024 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the third quarter 2024 and provided an update on the company's recent developments.

"This past quarter we transformed into a lean and more focused organization, resulting in significant cost savings that will extend into the future. Moreover, roxadustat continued its impressive performance, generating $96.6 million in net sales in China during the quarter," said Thane Wettig, Chief Executive Officer, FibroGen. "Having implemented our cost reduction plan, we are well positioned to advance FG-3246, with topline results from the Phase 2 portion of the investigator-sponsored study of FG-3246 in combination with enzalutamide at the University of California San Francisco (UCSF) on track for the first half of 2025, and the anticipated start of our Phase 2 monotherapy trial in the first quarter of 2025. We continue to be optimistic about our future prospects."

Recent Developments and Key Events of Third Quarter 2024:

- Meaningful progress on U.S. cost reduction plan.
  - Expected to be substantially complete by year-end 2024
- Reported topline results from the pamrevlumab arm of PanCAN Precision Promise Phase 2/3 adaptive platform trial for the treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC), in which the trial did not meet the primary endpoint.
- Reported topline results from the LAPIS Phase 3 study of pamrevlumab in patients with locally advanced, unresectable pancreatic cancer (LAPC), in which the trial did not meet the primary endpoint.

Upcoming Milestones:

Roxadustat

- Expect approval decision for roxadustat in chemotherapy-induced anemia (CIA) in China in early 2025. If approved, FibroGen will receive a $10 million milestone payment from AstraZeneca.

FG-3246 and FG-3180 (PET Imaging Agent)

- Topline results from the Phase 2 portion of the investigator-sponsored Phase 1b/2 study conducted by UCSF of FG-3246 in combination with enzalutamide in patients with mCRPC expected in 1H 2025.
- Anticipate initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC in 1Q 2025. This trial will include a sub-study of FG-3180 to enable assessment of CD46 expression and response to FG-3246.

[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.

China:

- Third quarter FibroGen net product revenue under U.S. GAAP from the sale of roxadustat in China was $46.2 million compared to $29.4 million in the third quarter of 2023, an increase of 57% year over year.
- Third quarter total roxadustat net sales in China[1] by FibroGen and the distribution entity jointly owned by FibroGen and AstraZeneca (JDE) was $96.6 million, compared to $77.1 million in the third quarter of 2023, an increase of 25% year over year, driven by a 34% increase in volume.
- Roxadustat continues to be the number one brand based on value share in the anemia of CKD market in China.
- For 2024, FibroGen's expected full year net product revenue under U.S. GAAP reiterated to a range between $135 million to $150 million, representing expected full year roxadustat net sales in China1 by FibroGen and the JDE of $330 million to $350 million.

Financial:

- Total revenue for the third quarter of 2024 was $46.3 million, as compared to $40.1 million for the third quarter of 2023, an increase of 15% year over year.
- Net loss for the third quarter of 2024 was $17.1 million, or $0.17 net loss per basic and diluted share, compared to a net loss of $63.6 million, or $0.65 net loss per basic and diluted share one year ago.
- At September 30, 2024, FibroGen reported $160.0 million in cash, cash equivalents and accounts receivable.
- Assuming additional repatriation of cash from our China operations, we expect our cash, cash equivalents and accounts receivable to be sufficient to fund our operating plans into 2026.

Conference Call and Webcast Details
FibroGen management will host a conference call and webcast today, Tuesday, November 12, 2024, at 5:00 PM Eastern Time to discuss financial results and provide a business update. Interested parties may access the conference call by dialing 1-877-300-8521 (in the U.S.) or 1-412-317-6026 (outside the U.S.). The call will be available via webcast by clicking here or on the "Events and Presentation" page on the FibroGen website.

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 chemotherapy-induced anemia (CIA) and a Supplemental New Drug Application (sNDA) has been accepted by the China Health Authority.

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). 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. AstraZeneca and FibroGen continue to collaborate on the development and commercialization of roxadustat in China.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company focused on accelerating the development of novel therapies at the frontiers of cancer biology. Roxadustat (爱瑞卓®, EVRENZO™) is currently approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia (CIA) and a Supplemental New Drug Application (sNDA) has been accepted for review by the China Health Authority. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46 is in development for the treatment of metastatic castration-resistant prostate cancer. This program also includes the development of an associated CD46-targeted PET imaging agent, FG-3180. In addition, FibroGen's research and development portfolio includes two immuno-oncology product candidates for the treatment of solid tumors. For more information, please visit www.fibrogen.com.

[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.

Forward-Looking Statements

This release contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs and those of its collaboration partners Fortis and UCSF. These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential clinical or commercial success of FibroGen products and product candidates, statements under the caption "Upcoming Milestones", statements regarding the potential for cash, cash equivalents and accounts receivable to fund FibroGen's operating plans into 2026, and statements about FibroGen's plans and objectives. These forward-looking statements are typically 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, 2023, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, 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 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)

	September 30, 2024 (Unaudited)	December 31, 2023 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 131,003	$ 113,688
Short-term investments	—	121,898
Accounts receivable, net	29,030	12,553
Inventory	23,937	41,565
Prepaid expenses and other current assets	60,559	41,855
Total current assets	244,529	331,559
Restricted time deposits	1,658	1,658
Property and equipment, net	7,603	13,126
Equity method investment in unconsolidated variable interest entity	5,806	5,290
Operating lease right-of-use assets	2,093	68,093
Other assets	2,732	3,803
Total assets	$ 264,421	$ 423,529
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 9,238	$ 17,960
Accrued and other liabilities	151,141	172,891
Deferred revenue	28,858	12,740
Operating lease liabilities, current	1,293	14,077
Total current liabilities	190,530	217,668
Product development obligations	18,199	17,763
Deferred revenue, net of current	126,219	157,555
Operating lease liabilities, non-current	707	66,537
Senior secured term loan facilities, non-current	72,779	71,934
Liability related to sale of future revenues, non-current	56,850	51,413
Other long-term liabilities	837	2,858
Total liabilities	466,121	585,728
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to FibroGen	(243,667)	(204,166)
Nonredeemable non-controlling interests	20,487	20,487
Total deficit	(223,180)	(183,679)
Total liabilities, redeemable non-controlling interests and deficit	$ 264,421	$ 423,529

(1) The condensed consolidated balance sheet amounts at December 31, 2023 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,	
	2024	2023	2024	2023
	(Unaudited)			
Revenue:				
License revenue	$ —	$ 2,649	$ —	$ 9,649
Development and other revenue	385	6,775	1,532	15,825
Product revenue, net	46,210	29,390	126,391	77,439
Drug product revenue, net	(262)	1,320	24,954	17,701
Total revenue	46,333	40,134	152,877	120,614
Operating costs and expenses:				
Cost of goods sold	5,295	4,243	36,227	13,441
Research and development	21,708	61,194	94,206	231,158
Selling, general and administrative	17,554	25,573	62,650	91,029
Restructuring charge	18,554	12,606	18,554	12,606
Total operating costs and expenses	63,111	103,616	211,637	348,234
Loss from operations	(16,778)	(63,482)	(58,760)	(227,620)
Interest and other, net:				
Interest expense	(4,994)	(5,022)	(14,774)	(10,464)
Interest income and other income (expenses), net	3,802	4,296	5,092	7,984
Total interest and other, net	(1,192)	(726)	(9,682)	(2,480)
Loss before income taxes	(17,970)	(64,208)	(68,442)	(230,100)
Benefit from income taxes	12	84	(217)	(77)
Investment income in unconsolidated variable interest entity	898	677	2,664	2,023
Net loss	$ (17,084)	$ (63,615)	$ (65,561)	$ (228,000)
Net loss per share - basic and diluted	$ (0.17)	$ (0.65)	$ (0.66)	$ (2.35)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	100,515	98,245	99,780	96,901

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For Investor Inquiries:
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