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): March 12, 2025

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		**94133**
(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 March 17, 2025, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter and year ended December 31, 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed, on September 12, 2024, FibroGen received a letter from the Nasdaq Listing Qualifications Staff of the Nasdaq Stock Market notifying FibroGen that for 30 consecutive business days the bid price of FibroGen's common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq listing rule 5450(a)(1) (the "Rule"). Therefore, in accordance with the Nasdaq listing rules, FibroGen was provided 180 calendar days, or until March 11, 2025 to regain compliance with the minimum bid price rule.

On March 12, 2025, FibroGen received written notice from Nasdaq notifying FibroGen that it did not regain compliance with the Rule and, unless the Company requested an appeal of this determination, is subject to delisting from the Nasdaq Global Select Market at the opening of business on March 21, 2025.

On March 14, 2025, FibroGen appealed this determination and therefore such delisting has been stayed. Our common stock will remain listed on the Nasdaq pending the ruling by the Nasdaq Hearings Panel.

We believe we will be successful in our appeal at the Nasdaq Hearings Panel and therefore be eligible for an additional 180-day period to regain compliance with the minimum bid price. We also believe we will be able to regain compliance with the Rule and cure the minimum bid price deficiency, including by effecting a reverse stock split, if necessary. However, there can be no assurance that our appeal to the Hearings Panel will be successful or that we will regain compliance with the minimum bid price rule or maintain compliance with the other listing requirements within the above timelines, or if it is necessary for us to effect a reverse stock split in order for us to regain compliance with the minimum bid price rule we may fail to do so, in which case our common stock may be delisted.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 17, 2025
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: March 17, 2025

By: /s/ David DeLucia
David DeLucia
Senior Vice President and Chief Financial Officer

Exhibit 99.1

FibroGen Reports Fourth Quarter and Full Year 2024 Financial Results

- ***Announced sale of FibroGen China to AstraZeneca for a total consideration of approximately $160 million***
  - ***Transaction expected to close by mid-2025***
- ***Upon close of sale of FibroGen China, cash runway extended into 2027***
- ***Initiation of the Phase 2 monotherapy trial of FG-3246, a potential first-in-class antibody-drug conjugate (ADC) targeting CD46 in metastatic castration-resistant prostate cancer (mCRPC), expected by mid-2025***
- ***Topline results from Phase 2 portion of the investigator-sponsored study of FG-3246 in combination with enzalutamide in patients with mCRPC expected in 2H 2025***
- ***FibroGen to host conference call and webcast presentation today at 5:00 PM ET***

SAN FRANCISCO, March 17, 2025 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the fourth quarter and full year 2024 and provided an update on the company's recent developments.

"We entered 2025 optimistic about our future, highlighted by the planned initiation of the Phase 2 monotherapy trial of FG-3246, our first-in-class ADC targeting CD46 for the treatment of mCRPC, by mid-2025," said Thane Wettig, Chief Executive Officer. "Through the successful implementation of our cost reduction plan, and upon the closing of our recently announced sale of FibroGen China, we will be a leaner and more focused organization, with a stronger financial position and a cash runway that takes us into 2027, with multiple potential value-creating milestones in sight."

Recent Developments and Key Highlights of 2024:

- Announced the sale of FibroGen China to AstraZeneca for a total consideration of approximately $160 million, representing an enterprise value of $85 million plus estimated net cash held in China at closing of approximately $75 million. The transaction is expected to close by mid-2025.
  - Upon closing, FibroGen will repay its term loan to Morgan Stanley Tactical Value, further simplifying the Company's capital structure.
  - FibroGen maintains its rights to roxadustat in the U.S. and in all markets outside of China, South Korea, and those licensed to Astellas.
- Appointed David DeLucia, CFA, as Senior Vice President and Chief Financial Officer.
- Completed previously announced cost reduction program.

Upcoming Milestones:

FG-3246 (CD46 Targeting ADC) and FG-3180 (CD46 Targeting PET Imaging Agent)

- Anticipate initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC by mid-2025.
  - Phase 2 trial will include a sub-study of FG-3180 to enable assessment of its diagnostic performance and the potential correlation between CD46 expression and response to FG-3246.
- 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 2H 2025.
  - Phase 2 portion of the study will include data on FG-3180.

Roxadustat

- Plan to meet with FDA in 2Q 2025 to determine the potential next steps for the development of roxadustat in anemia associated with lower-risk myelodysplastic syndrome (LR-MDS), an indication with significant unmet medical need, in the U.S.

Financial:

- Total revenue from continuing operations for the fourth quarter of 2024 was $3.1 million, as compared to $3.6 million for the fourth quarter of 2023.
- Total revenue from continuing operations for the full year 2024 was $29.6 million, as compared to $46.8 million for the full year 2023.
- Net loss from continuing operations for the fourth quarter of 2024 was $8.7 million, or $0.08 net loss per basic and diluted share, compared to a net loss of $62.5 million, or $0.63 net loss per basic and diluted share, one year ago.
- Net loss from continuing operations for the full year 2024 was $153.1 million, or $1.53 net loss per basic and diluted share, compared to a net loss of $323.0 million, or $3.32 net loss per basic and diluted share, for the full year 2023.
- At December 31, 2024, FibroGen reported $51.0 million in cash, cash equivalents and accounts receivable in the U.S. and $121.1 million in total consolidated cash, cash equivalents and accounts receivable.
- Upon closing of the announced sale of FibroGen China, the Company expects its cash, cash equivalents and accounts receivable to be sufficient to fund operations into 2027.

Conference Call and Webcast Presentation
The FibroGen management team will host a conference call and webcast presentation to discuss the financial results and provide a business update. A live Q&A session will follow the brief presentation. Interested parties may access a live audio webcast of the conference call here. To access the call by phone, please register here, and you will be provided with dial in details. A replay of the webcast will also be available for a limited time on the Events & Presentations page on FibroGen's website.

About FG-3246
FG-3246 (FOR46) is a potential first-in-class fully human antibody-drug conjugate (ADC), exclusively in-licensed from Fortis Therapeutics, and is being developed by FibroGen for metastatic castration-resistant prostate cancer and potentially other tumor types. FG-3246 binds to an epitope of CD46, a cell receptor target, that induces internalization upon antibody binding, is present at high levels in prostate cancer and other tumor types and demonstrates very limited expression in most normal tissues. FG-3246 is comprised of an anti-CD46 antibody, YS5, linked to the anti-mitotic agent, MMAE, which is a clinically and commercially validated ADC payload. FG-3246 has demonstrated anti-tumor activity in both preclinical and clinical studies.

FG-3246 is currently in an ongoing Phase 1b/2 study being conducted at UCSF as an investigator-sponsored trial to evaluate FG-3246 in combination with enzalutamide. An additional investigator-sponsored radiopharmaceutical marker trial using a zirconium-89 positron emission tomography (PET) tracer for CD46 that utilizes the YS5 antibody is also underway at UCSF. The initiation of the Phase 2 monotherapy dose optimization trial for FG-3246 in metastatic castration-resistant prostate cancer is anticipated by mid-2025. FG-3246 is an investigational drug and not approved for marketing by any regulatory authority.

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). FibroGen has the sole rights to roxadustat in the United States, Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas. Astellas and FibroGen are collaborating on the commercialization of roxadustat for the treatment of anemia in territories including Japan, Europe, Turkey, Russia, and the Commonwealth of Independent States, the Middle East, and South Africa.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company focused on development of novel therapies at the frontiers of cancer biology and anemia. 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. The Company continues to evaluate a development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndrome (LR-MDS) in the U.S. 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 FG-3180, an associated CD46-targeted PET biomarker. 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 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", the net cash portion of the purchase price and closing of the sale of FibroGen China as well as the payoff of the Morgan Stanley Tactical Value term loan, statements regarding cash, such as the expectation that cash, cash equivalents and accounts receivable will be sufficient to fund FibroGen's operating plans into 2027, 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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, 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)

	December 31, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 50,482	$ 81,553
Short-term investments	—	121,898
Accounts receivable, net	481	5,121
Inventory	3,155	17,173
Prepaid expenses and other current assets	31,542	40,038
Current assets held for sale	110,849	65,776
Total current assets	196,509	331,559
Restricted time deposits	—	1,658
Property and equipment, net	—	4,785
Operating lease right-of-use assets	—	64,939
Other assets	1,405	2,538
Long-term assets held for sale	16,611	18,050
Total assets	$ 214,525	$ 423,529
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 5,064	$ 15,778
Accrued and other liabilities	62,035	132,987
Deferred revenue	27,290	12,740
Operating lease liabilities, current	—	12,647
Current liabilities held for sale	38,917	43,516
Total current liabilities	133,306	217,668
Product development obligations	17,012	17,763
Deferred revenue, net of current	114,708	157,555
Operating lease liabilities, non-current	—	65,033
Senior secured term loan facilities, non-current	73,092	71,934
Liability related to sale of future revenues, non-current	58,864	51,413
Other long-term liabilities	822	2,858
Long-term liabilities held for sale	356	1,504
Total liabilities	398,160	585,728
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to FibroGen	(225,602)	(204,166)
Nonredeemable non-controlling interests	20,487	20,487
Total deficit	(205,115)	(183,679)
Total liabilities, redeemable non-controlling interests and deficit	$ 214,525	$ 423,529

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

	Three Months Ended December 31,		Years Ended December 31,	
	2024	2023	2024	2023
	(Unaudited)			
Revenue:				
License revenue	$ —	$ —	$ —	$ 9,649
Development and other revenue	416	2,575	1,948	18,401
Drug product revenue, net	2,720	1,052	27,673	18,753
Total revenue	3,136	3,627	29,621	46,803
Operating costs and expenses:				
Cost of goods sold	(5,845)	1,201	15,561	3,962
Research and development	6,870	48,710	95,692	266,473
Selling, general and administrative	8,345	16,378	49,330	86,483
Restructuring charge	900	—	19,454	12,606
Total operating costs and expenses	10,270	66,289	180,037	369,524
Loss from operations	(7,134)	(62,662)	(150,416)	(322,721)
Interest and other, net:				
Interest expense	(2,217)	(2,175)	(8,247)	(8,095)
Interest income and other income (expenses), net	688	2,314	5,296	7,594
Total interest and other, net	(1,529)	139	(2,951)	(501)
Loss from continuing operations before income taxes	(8,663)	(62,523)	(153,367)	(323,222)
Benefit from income taxes	2	10	(269)	(252)
Loss from continuing operations	(8,665)	(62,533)	(153,098)	(322,970)
Income from discontinued operations, net of tax	26,647	6,301	105,519	38,738
Net income (loss)	$ 17,982	$ (56,232)	$ (47,579)	$ (284,232)
Loss from continuing operations per share - basic and diluted	$ (0.08)	$ (0.63)	$ (1.53)	$ (3.32)
Income from discontinued operations per share - basic and diluted	0.26	0.06	1.05	0.40
Net income (loss) per share - basic and diluted	$ 0.18	$ (0.57)	$ (0.48)	$ (2.92)
Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted	100,830	98,496	100,044	97,303

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