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 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 **(Address of Principal Executive Offices)**		**94133** **(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 12, 2025, FibroGen, Inc. ("FibroGen") issued a press release announcing financial results for the quarter ended March 31, 2025. 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 dated May 12, 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: May 12, 2025

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

Exhibit 99.1

FibroGen Reports First Quarter 2025 Financial Results and Provides Business Update

- *Total consideration for the sale of FibroGen China to AstraZeneca now expected to be approximately $185 million, a $25 million increase from initial guidance*
  - *Net cash held in China at closing now estimated to be approximately $100 million*
  - *Transaction expected to close in 3Q-2025*
- *Upon close of sale of FibroGen China, cash runway extended into 2H 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 in 3Q-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 4Q 2025*
- *Filed Type-C meeting request with FDA for roxadustat in anemia associated with lower-risk myelodysplastic syndromes (LR-MDS)*
  - *Expect feedback on potential path forward in 3Q-2025*

SAN FRANCISCO, May 12, 2025 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today reported financial results for the first quarter 2025 and provided an update on the company's recent developments.

"We continue to focus on our most important strategic priority of advancing our lead asset, FG-3246, with the initiation of the Phase 2 monotherapy dose optimization study in mCRPC, expected to start in the third quarter of 2025," said Thane Wettig, Chief Executive Officer, FibroGen. "In addition, we have filed a Type C meeting request with the FDA to discuss the potential Phase 3 development program for roxadustat in the treatment of anemia associated with LR-MDS, an indication with significant unmet medical need. As we look to finalize the sale of FibroGen China in the third quarter of 2025, we remain highly focused on driving significant shareholder value by supporting our US development initiatives with our strong balance sheet and extended cash runway into the second half of 2027."

Recent Developments and Key Highlights of First Quarter 2025:

- Sale of FibroGen China to AstraZeneca now expected to be for a total consideration of approximately $185 million, representing an enterprise value of $85 million plus estimated net cash held in China at closing of approximately $100 million. The transaction is expected to close in the third quarter of 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.
- Publication of results from Phase 1 Monotherapy Study of FG-3246 titled, *"A Phase 1, First-in-Human Study of FOR46 (FG-3246), an Immune-Modulating Antibody-Drug Conjugate Targeting CD46, in Patients with Metastatic Castration Resistant Prostate Cancer",* in the peer-reviewed Journal of Clinical Oncology (JCO). The trial results provide key insights into the clinical impact of targeting CD46 and its potential to become the next generation target in the prostate cancer treatment paradigm.

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 in the third quarter of 2025.
  - Phase 2 trial will include 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 the fourth quarter of 2025.
  - Phase 2 portion of the study will include data on FG-3180.

Roxadustat

- Filed a Type-C meeting request with the FDA for roxadustat in anemia associated with LR-MDS. The Company expects feedback on a potential path forward in the third quarter of 2025.

Financial:

- Total revenue from continuing operations for the first quarter of 2025 was $2.7 million, as compared to $25.4 million for the first quarter of 2024.
- Net loss from continuing operations for the first quarter of 2025 was $16.8 million, or $0.16 net loss per basic and diluted share, compared to a net loss of $49.0 million, or $0.49 net loss per basic and diluted share, one year ago.
- At March 31, 2025, FibroGen reported $33.8 million in cash, cash equivalents and accounts receivable in the U.S. and $128.4 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 our operating plans into the second half of 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 in the third quarter of 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", statements about regulatory interactions, 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 the second half of 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)

	March 31, 2025 (Unaudited)	December 31, 2024 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 33,609	$ 50,482
Accounts receivable, net	147	481
Inventory	3,155	3,155
Prepaid expenses and other current assets	3,326	31,542
Current assets held for sale	108,292	110,849
Total current assets	148,529	196,509
Other assets	1,121	1,405
Long-term assets held for sale	15,563	16,611
Total assets	$ 165,213	$ 214,525
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 7,282	$ 5,064
Accrued and other liabilities	35,324	62,035
Deferred revenue	22,509	27,290
Current liabilities held for sale	8,275	38,917
Total current liabilities	73,390	133,306
Product development obligations	17,799	17,012
Deferred revenue, net of current	115,347	114,708
Senior secured term loan facilities, non-current	73,419	73,092
Liability related to sale of future revenues, non-current	59,168	58,864
Other long-term liabilities	830	822
Long-term liabilities held for sale	189	356
Total liabilities	340,142	398,160
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to FibroGen	(216,896)	(225,602)
Nonredeemable non-controlling interests	20,487	20,487
Total deficit	(196,409)	(205,115)
Total liabilities, redeemable non-controlling interests and deficit	$ 165,213	$ 214,525

(1) The condensed consolidated balance sheet amounts at December 31, 2024 are derived from audited financial statements.

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

	Three Months Ended March 31,	
	2025	2024
	(Unaudited)	
Revenue:		
Development and other revenue	$ 144	$ 878
Drug product revenue, net	2,595	24,486
Total revenue	2,739	25,364
Operating costs and expenses:		
Cost of goods sold	252	21,343
Research and development	9,175	36,489
Selling, general and administrative	8,106	16,714
Restructuring charge	126	—
Total operating costs and expenses	17,659	74,546
Loss from operations	(14,920)	(49,182)
Interest and other, net:		
Interest expense	(2,257)	(2,092)
Interest income and other income (expenses), net	413	2,235
Total interest and other, net	(1,844)	143
Loss from continuing operations before income taxes	(16,764)	(49,039)
Provision for income taxes	2	7
Loss from continuing operations	(16,766)	(49,046)
Income from discontinued operations, net of tax	21,405	16,113
Net income (loss)	$ 4,639	$ (32,933)
Loss from continuing operations per share - basic and diluted	$ (0.16)	$ (0.49)
Income from discontinued operations per share - basic and diluted	0.21	0.16
Net income (loss) per share - basic and diluted	$ 0.05	$ (0.33)
Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted	100,954	98,982

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For Investor Inquiries:
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