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 28, 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 7.01. Regulation FD Disclosure.

On March 28, 2025, FibroGen, Inc. issued a press release in which it announced the peer-reviewed publication 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 Journal of Clinical Oncology. The manuscript includes the complete results from the Fortis Therapeutics-sponsored Phase 1 study of FOR46 (now known as FG-3246), a potential first-in-class anti-CD46 antibody drug conjugate with a monomethyl auristatin E-containing payload, in patients with metastatic castration-resistant prostate cancer.

A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in Exhibit 99.1 shall 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 Exhibit 99.1 shall 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 March 28, 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 28, 2025

By: /s/ John Alden
John Alden
General Counsel

Exhibit 99.1

FibroGen Announces Publication of Results from Phase 1 Monotherapy Study of FG-3246 in Patients with Metastatic Castration-Resistant Prostate Cancer in the Journal of Clinical Oncology

- *FG-3246 showed encouraging anti-cancer activity with an acceptable safety profile in patients with metastatic castration-resistant prostate cancer*

- *Initiation of Phase 2 monotherapy dose optimization study of FG-3246 in mCRPC expected by mid-2025*

SAN FRANCISCO, March 28, 2025 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today announced the peer-reviewed publication 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 Journal of Clinical Oncology. The manuscript includes the complete results from the Fortis Therapeutics-sponsored Phase 1 study of FOR46 (now known as FG-3246), a potential first-in-class anti-CD46 antibody drug conjugate (ADC) with an MMAE-containing payload, in patients with metastatic castration-resistant prostate cancer (mCRPC).

"I am excited to see the results from the Phase 1 monotherapy study of FOR46 (FG-3246) published in the Journal of Clinical Oncology. This is the first clinical trial targeting CD46 in patients with prostate cancer, and the totality of the data highlights the promising potential of FG-3246 anti-cancer activity, especially when considering the unselected, heavily pre-treated patient population in the trial. The trial results provide key insights into the potential clinical impact of targeting CD46 in the treatment of mCRPC and support its further development in this disease space with high unmet need," said Dr. Rahul Aggarwal, Professor of Medicine at the University of California San Francisco, and Principal Investigator of the study.

"We are looking forward to advancing FG-3246 in the clinic and remain on track for initiating the Phase 2 monotherapy study by mid-2025 as well as disclosing topline results from the combination trial of FG-3246 and enzalutamide in the second half of 2025," added Thane Wettig, Chief Executive Officer of FibroGen. "FG-3246 represents a potential first-in-class, non-PSMA approach to treating mCRPC and we, along with the medical community, are excited about the potential for CD46 to become a next generation target in the prostate cancer treatment paradigm."

This Phase 1 study was a multi-center, first-in-human, open label dose escalation and expansion study evaluating the safety, tolerability, and anti-tumor activity as measured by the decline of prostate-specific antigen (PSA) from baseline, objective tumor response rate in patients with measurable disease, and radiographic progression free survival (rPFS). The completed Phase 1 trial includes a total of 56 patients from the dose-escalation and dose-expansion cohorts. Notably, patients were biomarker unselected and heavily pre-treated, having received a median of 5 lines of therapy prior to receiving FG-3246.

Key highlights from the publication include:

- The maximally tolerated dose of FG-3246 was 2.7 mg/kg by adjusted body weight (AjBW) every 3 weeks
- The most frequent adverse events were consistent with other MMAE-based ADCs and included infusion related reactions (48.2%), neutropenia (41.1%), and peripheral neuropathy (32.1%).
    - Ocular adverse events were infrequent, which may be a distinguishing feature compared with other MMAE-based ADCs
- Efficacy observed in the RECIST-evaluable set of 25 patients:
    - Confirmed objective response rate was 20% with median duration of response of 7.5 months
        - All objective responses observed at a starting dose of 2.7 mg/kg or higher
    - Disease control rate was 80% with duration of treatment exceeding 24 weeks in 12 patients (48%)
- PSA50 response rate of 36% in 39 evaluable patients
    - Of eight evaluable patients who received docetaxel in the castration-sensitive setting, four (50%) achieved a confirmed PSA50 response
- Median radiographic progression-free survival of 8.7 months in all 40 subjects in the efficacy analysis set
- Of 15 evaluable baseline tumors, 12 (80%) were positive for CD46 expression by immunohistochemistry
- FG-3246 responders were found to have a significantly higher frequency of effector T cells and lower frequency of immunosuppressive myeloid cells

The Company anticipates initiating the Phase 2 monotherapy dose optimization study of FG-3246 in patients with mCRPC by mid-2025.

FG-3246 is also being evaluated in combination with enzalutamide in an investigator-sponsored study with topline results from the Phase 2 portion of the study anticipated in 2H 2025.

About the Phase 1 Study
FOR46-001 (NCT03575819) is a Phase 1, dose-escalation study sponsored by Fortis Therapeutics to evaluate multiple doses of IV-administered FG-3246 (also known as FOR46) in patients with mCRPC who have progressive disease on at least one ARSI, followed by a dose-expansion cohort, to evaluate the safety, tolerability, PK, biological activity, and preliminary evidence of anti-tumor activity of FG-3246 in this patient population.

Thirty-three (33) patients were enrolled in the dose-escalation phase of the study at doses between 0.1 mg/kg and 3.0 mg/kg every three weeks (Q3W), with adjusted body weight dosing (AjBW) used at most dose levels above 2.1 mg/kg. Safety and tolerability of FG-3246 were evaluated in the dose-escalation period of the study.

Twenty-three (23) patients were enrolled in the dose-expansion period of the study; 18 patients with adenocarcinoma mCRPC (Cohort 1) and five patients with neuroendocrine prostate cancer (Cohort 2). All patients in the expansion cohorts were treated at 2.7 mg/kg AjBW to a maximum of 270 mg every three weeks.

The safety profile of FG-3246 was characterized, and anti-tumor activity of FG-3246 in adenocarcinoma patients dosed at ≥ 1.2 mg/kg was evaluated.

About Metastatic Castration-Resistant Prostate Cancer
Prostate cancer is the second most common malignancy in men, contributing significantly to male mortality rates. Approximately 13% of men will be diagnosed with prostate cancer at some point during their lifetime. There are about 65,000 drug treatable mCRPC cases in the U.S. annually and 5-year survival in mCRPC is approximately 30%.[1]

About FG-3246
FG-3246 (also known as 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 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 1/2 study being conducted at UCSF to evaluate it in combination with enzalutamide with topline data from the Phase 2 portion of the study expected in the second half of 2025, and a biomarker trial using a PET biomarker for CD46 using the same antibody backbone. We anticipate the initiation of the Phase 2 monotherapy dose optimization trial in metastatic castration-resistant prostate cancer by mid-2025. FG-3246 is an investigational drug and not approved for marketing by any regulatory authority.

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, 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 most recent fiscal year, and any more recent Quarterly Reports 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.

References:
1. Seer.cancer.gov https://seer.cancer.gov/statfacts/html/prost.html

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