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): June 17, 2021

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.)**

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(Address of principal executive offices, including zip code)

(415) 978-1200
(Registrant's telephone number, including area code)

Not Applicable
(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	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 1.01 Entry into a Material Definitive Agreement

On June 17, 2021, FibroGen, Inc. ("FibroGen") and HiFiBiO Therapeutics ("HiFiBiO"), a private, multinational clinical-stage biotherapeutics company with expertise in immune modulation and single cell science announced a partnership covering three HiFiBiO programs.

Under the terms of the Exclusive License and Option Agreement, dated June 16, 2021 (the "Agreement"), FibroGen will make a $25 million upfront payment to HiFiBiO, as well as payments upon option exercise. In addition, HiFiBiO may receive up to a total of an additional $1.1B in future option, clinical, regulatory, and commercial milestone payments across all three programs. HiFiBiO will also be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales.

FibroGen exclusively licensed all products in the Galectin-9 program and will have sole right to develop them worldwide. The lead product candidate in the Galectin-9 program is expected to enter clinical development in the first quarter of 2023. FibroGen has also obtained exclusive options to license all product candidates in HiFiBiO's CXCR5 and CCR8 programs. Each option may be independently exercised following delivery of program-specific data to be generated by HiFiBiO. If an option is exercised, FibroGen will have the sole right to develop products from that program worldwide. The lead product candidates from the CXCR5 and CCR8 programs are expected to enter clinical development by the middle of 2023.

The Agreement contains other industry standard license and collaboration terms including related to exclusivity, sublicensing, development, regulatory, manufacturing, commercialization, milestones, royalties, intellectual property, and termination. The Agreement will expire on a product-by-product and country-by-country basis at the end of the applicable royalty term.

The foregoing description of the Agreement is not a complete description thereof, and is qualified in its entirety by reference to the actual Agreement that will be filed with the Securities and Exchange Commission as an exhibit to FibroGen's Quarterly Report on Form 10-Q for the quarter ending June 30, 2021.

A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen and HiFiBiO Announce Transformative Partnership to Advance Next-Generation Therapies for Patients with Cancer and Autoimmune Disease" dated June 17, 2021
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.

Dated: June 17, 2021

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Officer

FibroGen and HiFiBiO Announce Transformative Partnership to Advance Next-Generation Therapies for Patients with Cancer and Autoimmune Disease

- *FibroGen Exclusively Licenses HiFiBiO's Galectin-9 Program, and Obtains an Exclusive Option to their CXCR5 and CCR8 Programs*
- *Transformative Transaction for FibroGen's Early-stage Pipeline*
- *HiFiBiO to Receive $25 Million Upfront, and Up to a Total of $1.1B in Additional Milestone Payments Across All Three Programs, Plus Royalties*

SAN FRANCISCO, CA and CAMBRIDGE, MA, June 17, 2021 (GLOBE NEWSWIRE) – FibroGen, Inc. (Nasdaq: FGEN) and HiFiBiO Therapeutics, a private, multinational clinical-stage biotherapeutics company with expertise in immune modulation and single cell science announced a partnership covering three HiFiBiO programs.

"We are very pleased to add the HiFiBiO drug candidates to our pre-clinical development pipeline," said Enrique Conterno, Chief Executive Officer, FibroGen. "With the addition of up to three programs in the immuno-oncology and autoimmune space, we have the potential to transform our early development pipeline."

"The FibroGen partnership represents significant validation of our Drug Intelligent Science (DIS™) approach and deep expertise in disease biology and translation science," said Liang Schweizer, Ph.D., Chief Executive Officer, HiFiBiO. "As another successful showcase of our open innovation approach, we look forward to working closely with FibroGen, an exciting, growing biopharmaceutical company."

Under the terms of the agreement, FibroGen will make a $25 million upfront payment to HiFiBiO, as well as payments upon option exercise. In addition, HiFiBiO may receive up to a total of an additional $1.1B in future option, clinical, regulatory, and commercial milestone payments across all three programs. HiFiBiO will also be eligible to receive royalties based upon worldwide net sales.

FibroGen exclusively licensed all products in the Galectin-9 program and will have sole right to develop them worldwide. The lead product candidate in the Galectin-9 program is expected to enter clinical development in the first quarter of 2023. FibroGen has also obtained exclusive options to license all product candidates in HiFiBiO's CXCR5 and CCR8 programs. Each option may be independently exercised following delivery of program-specific data to be generated by HiFiBiO. If an option is exercised, FibroGen will have the sole right to develop products from that program worldwide. The lead product candidates from the CXCR5 and CCR8 programs are expected to enter clinical development by the middle of 2023.

“We look forward to a productive partnership with HiFiBiO, a leader in the field of single-cell science for antibody discovery and translational medicine,” said Mark Eisner, M.D, M.P.H, Chief Medical Officer, FibroGen. “We are excited to bring the Galectin-9 antibody program into the FibroGen portfolio. As Galectin 9 plays a role in suppressing the anti-tumor immune response in both myeloid malignancies and solid tumors, we believe this antibody candidate from HiFiBiO can advance the treatment of cancer in combination with chemotherapy or other immuno-oncology agents. The exclusive option to access projects directed to CXCR5 and CCR8 provides additional opportunities to expand our therapeutic area focus on oncology and immunology. These are both important biological targets playing clear roles in autoimmune disease and cancer.”

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 hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For more information, please visit www.fibrogen.com.

About HiFiBiO Therapeutics

HiFiBiO Therapeutics is transforming the field of immunotherapy by combining proprietary single-cell profiling technologies with advanced data intelligence and deep knowledge of immune system biology. This approach enables the development of novel antibody therapies that are paired with biomarkers to predict patient response. HiFiBiO Therapeutics is working actively to address unmet medical needs around the world through its own innovative pipeline programs and open-innovation partnerships with world-renowned industry and academic researchers. The company’s strong global footprint features cutting-edge laboratories on three continents, in Cambridge, Mass., Paris, Shanghai, and Hong Kong. To learn more, please visit www.hifibio.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, our clinical programs and regulatory events, and those of our partners. 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, 2020 and our Quarterly Report on Form 10-Q for quarter ended March 31, 2021 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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