

**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): July 19, 2021

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36740
(Commission
File Number)

77-0357827
(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 July 19, 2021, FibroGen, Inc. (“FibroGen”) and Eluminex Biosciences (Suzhou) Limited (“Eluminex”) announced that Eluminex has exclusively licensed from FibroGen global rights for the development and commercialization of an investigational biosynthetic cornea derived from recombinant human collagen type III.

Under the terms of the Exclusive License Agreement (the “Agreement”), Eluminex will make an \$8 million upfront payment to FibroGen. In addition, FibroGen may receive up to a total of \$64 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as \$36 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid single-digit royalties based upon worldwide net sales of other recombinant human collagen type III products that are not cornea products.

The Agreement contains other industry standard license terms including related to exclusivity, sublicensing, manufacturing, 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 September 30, 2021.

A copy of such 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled “Eluminex Biosciences Exclusively Licenses FibroGen’s Biosynthetic Cornea Technology and Recombinant Collagen III Platform” dated July 19, 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.

Dated: July 20, 2021

FIBROGEN, INC.

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

Eluminex Biosciences Exclusively Licenses FibroGen's Biosynthetic Cornea Technology and Recombinant Collagen III Platform

- *Exclusive Global Development and Commercialization Rights for Recombinant Human Collagen-Based Biosynthetic Cornea*
- *Clinical Stage Asset Has Potential for First Approved Biosynthetic Human Cornea*
- *Biosynthetic Cornea Designed to Address Significant Unmet Need in Global Demand for Corneal Grafts for the Treatment of Corneal Blindness*
- *Edward Holland, MD, Joins Eluminex's Scientific Advisory Board*

SUZHOU, China and SAN FRANCISCO, CA, July 19, 2021 (GLOBE NEWSWIRE) -- Eluminex Biosciences (Suzhou) Limited (Eluminex), an ophthalmology-focused biotechnology company headquartered in Suzhou, China with a US-subsiary office in San Francisco Bay Area, California, announced today that it has exclusively licensed global rights for the development and commercialization of an investigational biosynthetic cornea derived from recombinant human collagen Type III intended to treat patients with corneal blindness, from FibroGen, Inc. (FibroGen; NASDAQ: FGEN).

"We are extremely excited to bring this novel technology initially to the China market to help meet a large unmet medical need for an alternative to human donor cornea tissue," commented Dr. Jinzhong ("JZ") Zhang, Chairman and CEO of Eluminex. "Over 100,000 cases of corneal blindness occur each year in China due to scarring from traumatic injury or infection that could be treated with a surgically implanted bioengineered cornea. Typical treatments in China include human donor corneal transplantation or use of corneal tissue harvested from genetically modified pigs. There is a significant shortage of human donor tissue and porcine corneas have issues with a lack of optical clarity and durability, however, and both methods require the need for additional immunosuppressive medications to prevent graft rejection. The biosynthetic cornea, that is optically clear, offers an alternative using human Type III collagen, a key structural protein that is found in normal human corneas and therefore does not require immunosuppressive medications."

Under the terms of the agreement, Eluminex will make an \$8 million upfront payment to FibroGen. In addition, FibroGen may receive up to a total of \$64 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as \$36 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will also be eligible to receive royalties based upon worldwide net sales.

Eluminex also announced that Edward Holland, M.D., has joined the company's Scientific Advisory Board (SAB). Charles Semba, M.D. and Chief Medical Officer of Eluminex commented, "We are excited to introduce Dr. Edward Holland, Professor of Ophthalmology at the University of Cincinnati and Director of the Cornea Service at the Cincinnati Eye Institute and past Chairman of the Eye Bank Association of America, as the newest member of our SAB."

He is an internationally recognized expert in corneal allograft surgery and ocular surface disease. Additionally, over the past three decades, he has taught and lectured in China regarding corneal transplant techniques and will provide us critical insights into our biosynthetic cornea program.”

“The possibility for an abundant global supply of a biosynthetic human corneal tissue substitute has real potential to transform the lives of the hundreds of thousands of patients around the world in regions where corneal donations are scarce and who otherwise are unlikely to receive a sight-saving corneal transplant,” said Dr. Holland.

“We are pleased to enter into this agreement with Eluminex and license this technology to a seasoned ophthalmology team,” said Enrique Conterno, CEO of FibroGen. “This transaction enables FibroGen to focus on development of next generation biopharmaceutical therapies in our core areas of cancer, autoimmune and fibrotic diseases, and anemia.”

About the Eluminex Biosynthetic Cornea Program

The Eluminex biosynthetic cornea (EB-301) is a clinical stage corneal stromal substitute that will be initially developed for the China market. EB-301 is regulated as a Class III medical device and is anticipated to enter a clinical market authorization registration study in China in 2H 2022 to confirm its safety and effectiveness. The corneal device has been implanted in 10 patients in Europe with 4 years of follow-up and has demonstrated excellent biocompatibility, maintenance of optical clarity, and significantly improved visual acuity without immunosuppression. (Fagerholm et al, *Biomaterials*, 35 (2014): 2420-2427).

About Corneal Blindness in China

According to the World Health Organization, corneal diseases are one of the leading causes of blindness globally. Approximately 180,000 sight-restoring corneal transplantations are performed worldwide in which nearly a quarter are conducted in the United States. China is the largest most populous developing country in the world and corneal diseases are the second leading cause of blindness with an estimated 2-3 million patients with corneal blindness in at least one eye. However, due to the scarcity of donor corneas, only approximately 5000 to 9000 corneal transplants are conducted in China each year. Corneal porcine xenografts have been available in China since 2015 but technical issues remain with the lack of optical clarity and secondary immunologic complications (eg, graft dissolution and graft rejection). An unmet need exists for a suitable corneal stromal tissue replacement as an alternative to the shortage of donated human cornea and an alternative to porcine xenografts.

About Eluminex Biosciences

Eluminex Biosciences is a privately-held clinical-stage biotechnology company focused on both global and regional development and commercialization of innovative therapeutics to fulfill unmet medical needs in the treatment and management of ophthalmic diseases. Eluminex is devoted towards innovating the next generation of first-in-class or best-in-class ocular therapeutics for vision-threatening or lifestyle-limiting ocular diseases. In addition to the biosynthetic cornea (EB-301), Eluminex has developed a pipeline of next generation protein therapeutics for retinal diseases (EB-101, EB-102, EB-105, and EB-107) including age-related macular degeneration, macular edema, and diabetic retinopathy; these assets are wholly owned and developed by Eluminex. The Eluminex global headquarters and research and development center are located in Suzhou BioBay Industrial Park, China with a US-subsiidiary located in the San Francisco Bay Area. Eluminex is supported by three premiere global life science venture

funds: Lilly Asia Ventures, Hill House Capital, and Quan Capital. For more information, please visit www.eluminexbio.com.

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.

Forward-Looking Statements of FibroGen

This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the company's product candidates subject to the transaction described above, the potential safety and efficacy profile of the product candidates, their commercial prospects and the incidence and prevalence of possible indications of use for such products and existing treatments. 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, 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.

Contacts:**FibroGen, Inc.****Investors:**

Michael Tung, M.D.

Corporate Strategy / Investor Relations

415.978.1434

mtung@fibrogen.com

Media:

GCI Health

FibroGenMedia@gcihealth.com

Eluminex Biosciences

Investors/Media:

Zhenze John Hu, Ph.D., MPD

Business Development

John.hu@eluminexbio.com