
**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 13, 2021

GEMINI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39438
(Commission
File Number)

85-1612845
(I.R.S. Employer
Identification No.)

300 One Kendall Square, 3rd Floor
Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

(617) 401-4400
(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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication 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-commencements 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 Symbols	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	GMTX	The Nasdaq Global 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).
 - 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.
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Item 2.02. Results of Operations and Financial Condition.

On May 13, 2021, Gemini Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release by Gemini Therapeutics, Inc., dated May 13, 2021](#)

SIGNATURE

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.

Gemini Therapeutics, Inc.

By: /s/ Brian Piekos

Name: Brian Piekos

Title: Chief Financial Officer

Dated: May 13, 2021



Gemini Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

- *Fast Track Designation for GEM103 in dry AMD granted January 2021*
- *GEM103 Phase 2a study in geographic atrophy data on track for June 2021*
- *GEM103 Phase 2a as a possible add-on therapy for patients with wet AMD at risk for macular atrophy completed enrollment, with six-month data to be shared by year-end*
- *GEM103 preclinical data presentation demonstrating potential for differentiated safety profile*
- *Corporate leadership strengthened with key appointments to Board and leadership team*

CAMBRIDGE, Mass. – May 13, 2021 – Gemini Therapeutics, Inc. (Nasdaq: GMTX), a clinical stage precision medicine company developing innovative treatments for genetically-defined age-related macular degeneration (AMD), today reported its financial results for the first quarter ended March 31, 2021 and provided a business update.

“During the first quarter, we continued to make significant progress in the clinical development of GEM103 and look forward to releasing initial data from the ongoing Phase 2a ReGAtta study later this quarter,” said Jason Meyenburg, Chief Executive Officer of Gemini Therapeutics, Inc. “With Gemini’s transition to a public company complete, we have the financial resources and leadership team in place to rapidly advance GEM103 into its first pivotal trial and continuing to advance our pipeline. Today’s announcement that we completed enrollment in the Phase 2a study of GEM103 in wet AMD demonstrates our commitment to fully explore and harness the use of CFH’s role as primary endogenous complement regulator, which may represent a best-in-class approach in complement therapeutics.”

Recent Business and Clinical Highlights

- **Received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for GEM103 for the treatment of dry AMD in patients with complement factor H (CFH) loss of function gene variants.** In January 2021, the Company announced that GEM103 had been granted Fast Track Designation by the FDA, a designation intended to facilitate development and expedite review of investigational therapies to address unmet medical needs.
- **Completed enrollment in Phase 2a trial of GEM103 in dry AMD in patients with high-risk genetic variants.** In February 2021, the Company announced the completion of enrollment of approximately 60 patients in its Phase 2a “ReGAtta” study, a dose escalation trial of GEM103, a recombinant human CFH, in dry AMD patients with loss of function CFH variants. The Company expects to share initial data from the trial, designed to evaluate safety and tolerability, as well as measures of intraocular pharmacokinetics and exploratory, disease-relevant biomarkers, in the second quarter of 2021. The Company believes the learnings from the Phase 2a trial will inform the design of the Phase 2b/3 sham-controlled study which will be powered for efficacy.
- **Commenced and completed enrollment of a Phase 2a study of GEM103 as a potential add-on to anti-vascular endothelial growth factor (anti-VEGF) therapy for patients suffering from wet AMD.** In February 2021, The Company initiated a Phase 2a study investigating GEM103 as a potential add-on therapy for patients suffering from wet AMD who have, or may be at risk for, macular atrophy (MA) but require ongoing anti-VEGF treatment. Enrollment of this trial completed in May 2021 and the Company expects to release six-month dosing data related to safety, tolerability, effect on intraocular CFH levels and disease-related biomarkers in the fourth quarter of 2021.

- **Presented preclinical data on GEM103 at the 2021 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting.** In May 2021, the Company presented a poster at ARVO that demonstrated GEM103 does not pose an increased risk of choroidal neovascularization (CNV) following intravitreal administration in a laser induced mouse model of disease. In addition, GEM103 demonstrated an anti-angiogenic effect in this model.
- **Closed business combination with FS Development Corp (FSDC) transitioning to a public company with funding into 2023.** Business combination with FSDC, a special purpose acquisition company (SPAC) sponsored by Foresite Capital, and the PIPE financing closed in February 2021, resulting in net proceeds to Gemini of \$195.9 million.
- **Continued expansion of leadership team.** In May 2021, Gemini appointed Samuel Barone, M.D., as Chief Medical Officer. Dr. Barone brings to Gemini extensive expertise as a board-certified ophthalmologist specializing in the treatment of retinal and macular diseases. Additionally, the Company appointed Georges Gemayel, Ph.D., as the Chair of the Company's Board of Directors. Dr. Gemayel brings to Gemini 30 years of experience in the pharmaceutical industry developing and commercializing drugs.

Financial Results

Research and development expenses totaled \$11.8 million for the three months ended March 31, 2021, compared to \$8.2 million for the same period in 2020. The increase was primarily due to increased expenses related to clinical studies, salaries and benefits and stock-based compensation.

General and administrative expenses were \$4.7 million for the three months ended March 31, 2021, compared to \$1.4 million for the same period in 2020. The increase was primarily due to increased expenses related to professional fees related to being a public company, salaries and benefits and stock-based compensation.

For the three months ended March 31, 2021, Gemini reported a net loss of \$19.0 million, or \$0.59 per share, compared to a net loss of \$9.7 million, or \$0.67 per share, in the corresponding period in 2020. The increase in net loss and net loss per share for the three months ended March 31, 2021 was primarily due to an increase in operating expenses and interest expense related to the beneficial conversion feature of the convertible notes extinguished during the business combination.

At March 31, 2021, Gemini held \$185.0 million in cash, \$9.2 million of principal outstanding debt and 43.0 million shares outstanding.

About the Phase 2a ReGAtta Study

The ongoing Phase 2a, multi-center, open-label, multiple ascending dose study of GEM103 in genetically defined patients with GA secondary to dry AMD is designed to investigate safety and tolerability, PK, exploratory ocular biomarkers, and measures of retinal anatomy and function. In the study, GEM103 is delivered monthly by an intravitreal injection and PK and biomarkers of complement regulation are determined from aqueous humor sampling. The study was designed to enroll approximately 60 patients. The study population was enriched for patients with genetic variants in CFH that have been linked to the progression of dry AMD from early to late-stage.

About the Phase 2a Study of Repeat Intravitreal Injections of GEM103 in Neovascular Age-related Macular Degeneration

The ongoing Phase 2a, multicenter, multiple-dose study in subjects with Neovascular Age-related Macular Degeneration (nAMD) with or at risk for macular atrophy, is designed to investigate the safety and tolerability of GEM103 as an adjunct to standard of care aflibercept therapy. The study is designed to enroll approximately 45 patients randomized 2:1 between GEM103 plus aflibercept and sham plus aflibercept arms, with treatment administered via intravitreal injection every other month for twelve months. CFH levels and disease relevant biomarkers of complement regulation are determined from aqueous humor sampling throughout the study with visual acuity and macular atrophy size measured at defined dosing dates.

About GEM103

Gemini's lead program, GEM103, a full-length recombinant complement factor H (rCFH) protein, is believed to be the first ever recombinant native complement regulator. GEM103 delivered by intravitreal injection is designed to address both complement hyperactivity and restore retinal health in patients with AMD. In a genetically-defined subset of AMD patients GEM103 may circumvent dysfunctional CFH loss-of-function variants and slow the progression of their retinal disease. In patients undergoing anti-VEGF treatment GEM103 may help regulate the hyperactive amplification of the alternative pathway believed to lead to cell loss and macular atrophy. The U.S. Food and Drug Administration (FDA) granted Fast Track Designation for GEM103 for the treatment of dry AMD in patients with CFH loss of function gene variants.

About Dry Age-Related Macular Degeneration (AMD)

Age-related macular degeneration (AMD) is a progressive retinal disease affecting millions of older adults, and the leading cause of irreversible blindness in the western world. Symptoms, which include blurry vision, loss of night vision and loss of central vision, make activities of daily living such as reading, driving and even recognizing faces progressively more difficult. Third-party reports indicate there are approximately 16 million patients with AMD in the United States alone. Dry AMD, which results from an interaction of environmental and genetic risk factors, represents about 90% of that population (or about 15 million) in the US compared to about 1.4 million with wet AMD. Genetic risk of developing dry AMD is significant, with approximately 70% attributable risk of advanced disease to heritability, while aging and smoking confer the strongest non-genetic risk. CFH risk variants occur in approximately 40% of patients with dry AMD and these patients have a significantly increased risk of developing the disease as well as progression from intermediate AMD to GA. The complement system, of which CFH is a modulator, is dysregulated in patients with these risk variants, and results in amplification of aberrant inflammatory responses in the eye. Over time, this dysregulation leads to damage to the macular region of the retina.

About Gemini Therapeutics

Gemini Therapeutics is a clinical stage precision medicine company developing novel therapeutic compounds to treat genetically defined age-related macular degeneration (AMD). Gemini's lead candidate, GEM103, is a recombinant form of human complement factor H protein (CFH) and is designed to address both complement hyperactivity and restore retinal health in patients with AMD. GEM103 is currently in a Phase 2a trial in dry AMD patients with a CFH risk variant and a Phase 1/2a study in patients with neovascular age-related macular degeneration with or at risk for macular atrophy. The company has generated a rich pipeline including recombinant proteins, gene therapies, and monoclonal antibodies and is advancing a potentiating antibody for CFH, GEM307, into clinical development for treatment of systemic diseases.

For more information, visit www.gemini therapeutics.com.

Gemini's Forward-Looking Statements

Certain statements in this press release and the information incorporated herein by reference may constitute "forward-looking statements" for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, including those relating to the success, cost and timing of our product development activities and clinical trials, including our estimates regarding when data will be reported from ongoing clinical trials and the timing to commence future clinical trials, the potential attributes and benefits of our product candidates, including our lead product candidate GEM103, our ability to obtain and maintain regulatory approval for our product candidates, our projected cash runway and our ability to obtain funding for our operations when needed. Forward-looking statements include statements relating to our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking

statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading “Risk Factors” in the final proxy/prospectus for our recently completed business combination, and those that are included in any of our future filings with the SEC, including our periodic reports under the Exchange Act. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Our forward-looking statements only speak as of the date they are made, and we do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

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Gemini Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 11,786	\$ 8,217
General and administrative	4,704	1,414
Total operating expenses	<u>16,490</u>	<u>9,631</u>
Loss from operations	(16,490)	(9,631)
Other income (expense):		
Interest expense	(1,848)	(153)
Interest income	1	36
Loss on conversion of convertible notes	(711)	—
Change in fair value of warrant liability	—	2
Net loss and comprehensive loss	<u>\$ (19,048)</u>	<u>\$ (9,746)</u>
Net loss attributable to common stockholders	\$ (19,048)	\$ (9,746)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.59)	\$ (0.67)
Weighted average common shares outstanding, basic and diluted	32,027,161	14,495,972

Gemini Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	\$184,986	\$ 4,503
Other current assets	3,619	562
Total current assets	188,605	5,065
Other assets	777	3,254
Total assets	<u>\$189,382</u>	<u>\$ 8,319</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities	\$ 13,776	\$ 24,876
Long-term liabilities	4,445	5,304
Total liabilities	18,221	30,180
Total stockholders' equity (deficit)	171,161	(21,861)
Total liabilities and stockholders' equity (deficit)	<u>\$189,382</u>	<u>\$ 8,319</u>