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): August 12, 2021

GEMINI THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39438**	**85-1612845**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

300 One Kendall Square, 3rd Floor
Cambridge, MA **02139**
(Address of principal executive offices) **(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.

Item 2.02. Results of Operations and Financial Condition.

On August 12, 2021, Gemini Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 Item 2.02, including Exhibit 99.1 to this Current Report on Form 8-K, is "furnished" and 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release by Gemini Therapeutics, Inc., dated August 12, 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: August 12, 2021

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

- *Initial data from ongoing Phase 2a study in geographic atrophy demonstrated ability of GEM103 to durably regulate complement and showed a differentiated safety profile with no increased risk of CNV*
- *Completed enrollment in Phase 2a study of GEM103 in wet AMD with six-month data to be shared by year-end*
- *A randomized, sham-controlled clinical trial to evaluate GEM103's ability to limit geographic atrophy is planned to initiate in 1H 2022*

CAMBRIDGE, Mass. – August 12, 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 second quarter ended June 30, 2021 and provided a business update.

"The initial results shared in June from the ongoing Phase 2a ReGAtta study in patients with geographic atrophy showed biomarker results that support the biological activity of GEM103 and its ability to regulate complement in a dose-dependent and durable manner as early as after just three months of GEM103 administration," said Jason Meyenburg, Chief Executive Officer of Gemini Therapeutics, Inc. "These compelling results, in an open-label, single arm study designed primarily to demonstrate the safety and tolerability of GEM103, met its key endpoint and provides us the confidence to advance to a sham-controlled study designed to assess the efficacy of GEM103 as a potential treatment for geographic atrophy."

Recent Business and Clinical Highlights

- **Announced initial data from ongoing Phase 2a study of GEM103 in patients with geographic atrophy (GA) secondary to dry AMD.** In June 2021, Gemini shared initial data from its ongoing ReGAtta study, an open-label Phase 2a trial of its lead product candidate, GEM103, in patients with GA secondary to dry AMD. The single-arm, multiple-dose escalation study design is the first repeat dose experience with GEM103. Initial study data highlighted GEM103's generally favorable safety and tolerability profile, the primary goal of the study, while also providing evidence of the candidate's biological activity in patients with dry AMD, achieving another key study goal. Key initial findings include the following:

- Results indicated GEM103's ability to regulate complement in a dose-dependent and durable manner by reducing complement biomarkers Ba and C3a by ~40% and ~20%, respectively. Reductions in the biomarker C3a is indicative of a potential reduction in the proinflammatory state of the retina in patients with GA.
- GEM103 continues to be generally well-tolerated and initial data supports a differentiated safety profile with minimal drug-related inflammation. Observed inflammation was attributed either to injection procedures or was seen in patients with autoimmune co-morbidities. Additionally, no increased risk of choroidal neovascularization (CNV) was observed to date.

- **Completed enrollment in Phase 2a study of GEM103 as potential add-on to anti-vascular endothelial growth factor (anti-VEGF) therapy for patients suffering from wet AMD**. In May 2021, the Company completed enrollment in the Phase 2a safety and tolerability study. The Company expects to release six-month dosing data related to safety, tolerability, effect on intraocular complement factor H (CFH) levels and disease-related biomarkers, in late 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 CNV following intravitreal administration in a laser induced mouse model of disease.

Financial Results

Research and development expenses totaled $10.8 million for the three months ended June 30, 2021, compared to $5.5 million for the same period in 2020. The increase was primarily due to increased expenses related to clinical studies and headcount costs.

General and administrative expenses were $5.5 million for the three months ended June 30, 2021, compared to $1.1 million for the same period in 2020. The increase was primarily due to increased expenses related to professional fees associated with being a public company, as well as headcount costs.

For the three months ended June 30, 2021, Gemini reported a net loss of $16.4 million, or $0.38 per share, compared to a net loss of $6.8 million, or $0.44 per share, in the corresponding period in 2020. The increase in net loss for the three months ended June 30, 2021 was primarily due to an increase in operating expenses.

At June 30, 2021, Gemini held $167.5 million in cash, $7.9 million of principal outstanding debt and 43.1 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, pharmacokinetics (PK), exploratory ocular biomarkers, and measures of retinal anatomy and function. This study is not designed to assess the efficacy of GEM103. GEM103 is delivered monthly by an intravitreal injection, and PK and biomarkers of complement regulation are determined from aqueous humor sampling. The study enrolled 62 patients with gene variants 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 (nAMD)

The ongoing Phase 2a, multicenter, multiple-dose study in subjects with nAMD, with or at risk for MA, is designed to investigate the safety and tolerability of GEM103 as an adjunct to standard of care aflibercept therapy. The study enrolled 50 patients that are randomized 2:1 between GEM103 plus aflibercept and sham plus aflibercept arms, with treatment administered via intravitreal injection every other month for twelve months. This study is not designed to assess the efficacy of GEM103. 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 candidate, GEM103, is a pioneering precision medicine approach, targeting trial enrichment with genetically defined patients. GEM103 targets a genetically defined subset of age-related macular degeneration (AMD) patients with complement dysregulation. Of the 15 million dry AMD patients in the United States, approximately 40% (or six million) have variants in the complement factor H (CFH) gene. Such loss of function variants are associated with increased dry AMD disease risk. GEM103 is believed to be the first ever recombinant complement regulator and is a full-length and human, recombinant complement factor H (rCFH) protein. When delivered by intravitreal injection, we believe GEM103 has the potential to address unmet medical need in genetically defined AMD patients by circumventing the complement dysfunction resulting from CFH loss of function variants and slowing the progression of their retina disease. 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 regulator, 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 2a study in patients with neovascular age-related macular degeneration with or at risk for macular atrophy. Gemini has generated a rich pipeline including recombinant proteins, gene therapies, and monoclonal antibodies and is working to advance a potentiating antibody for CFH, GEM307, into clinical development for treatment of systemic diseases.

For more information, visit www.geminitherapeutics.com.

Availability of Other Information About Gemini Therapeutics

Investors and others should note that we communicate with our investors and the public using our website (www.geminitherapeutics.com), the investor relations website (https://investors.geminitherapeutics.com/), and on social media (Twitter and LinkedIn), including but not limited to investor presentations and investor fact sheets, U.S. Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Gemini posts on these channels and websites could be deemed to be material information. As a result, Gemini encourages investors, the media, and others interested in Gemini to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Gemini's investor relations website and may include additional social media channels. The contents of Gemini's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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, whether such data, when final, will be consistent with interim reported data, the timing to commence future clinical trials, the potential attributes and benefits of our product candidates, including GEM103, the reliability of the interim or final results of studies relating to safety and possible adverse effects resulting from the administration of our product candidates, 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 Gemini's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors included in any of our subsequent or future filings with the SEC. 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 ongoing 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 10,842	$ 5,528	$ 22,628	$ 13,745
General and administrative	5,478	1,138	10,182	2,552
Total operating expenses	16,320	6,666	32,810	16,297
Loss from operations	(16,320)	(6,666)	(32,810)	(16,297)
Other income (expense):				
Interest expense	(121)	(107)	(1,969)	(260)
Interest income	5	—	6	36
Loss on conversion of convertible notes	—	—	(711)	—
Change in fair value of warrant liability	—	—	—	2
Other expense	(11)	—	(11)	—
Net loss and comprehensive loss	$ (16,447)	$ (6,773)	$ (35,495)	$ (16,519)
Net loss attributable to common stockholders	$ (16,447)	$ (6,773)	$ (35,495)	$ (16,519)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.44)	$ (0.94)	$ (1.11)
Weighted average common shares outstanding, basic and diluted	43,041,856	15,266,222	37,564,936	14,881,097

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

	June 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$167,477	$ 4,503
Other current assets	3,834	562
Total current assets	171,311	5,065
Other assets	1,111	3,254
Total assets	$172,422	$ 8,319
Liabilities and stockholders' equity (deficit)		
Current liabilities	$ 11,505	$ 24,876
Long-term liabilities	3,235	5,304
Total liabilities	14,740	30,180
Total stockholders' equity (deficit)	157,682	(21,861)
Total liabilities and stockholders' equity (deficit)	$172,422	$ 8,319