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 22, 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 7.01 Regulation FD Disclosure

On June 22, 2021, Gemini Therapeutics, Inc. (the "Company") issued a press release entitled "Gemini Therapeutics Announces Initial Data from its Ongoing Phase 2a Study of GEM103 in Patients with Geographic Atrophy Secondary to Dry Age-related Macular Degeneration."

The information in this Item 7.01, including Exhibit 99.1 to this Current Report on Form 8-K, 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 8.01 Other Events.

On June 22, 2021, the Company announced initial data from its Phase 2a ReGAtta study of GEM103 as of May 2021 in patients with geographic atrophy ("GA") secondary to dry age-related macular degeneration ("AMD"). ReGAtta is a dose escalation trial of GEM103, which is intravitreally administered recombinant human complement factor H ("CFH"), in dry AMD patients. The trial, which remains ongoing, is designed to evaluate safety and tolerability, as well as measures of intraocular pharmacokinetics ("PK") and disease-relevant biomarkers, to inform the late-stage development program.

ReGAtta was designed to evaluate repeat dosing of GEM103 and assess its safety in an open-label study that enrolled 62 patients with GA secondary to dry AMD. The first 36 patients enrolled received monthly 250µg intravitreally administered doses of GEM103. After evaluating the safety profile of repeated dosing over three months, patients were dose escalated to 500µg and an additional 26 patients enrolled and received monthly 500µg doses. After completing the first six months of dosing, each patient will have the option to continue receiving GEM103 for up to an additional 12 months.

Patients enrolled in ReGAtta had a mean age of 78 and GA secondary to dry AMD in the study eye with 63% of patients also having GA in the fellow eye. Choroidal neovascularization ("CNV") in the study eye was an exclusion criterion, however 30% of patients had a history of CNV in the fellow eye at baseline. Among the baseline characteristics in the study eye, mean best corrected visual acuity (BCVA) score, as measured by Early Treatment Diabetic Retinopathy Study (ETDRS) letters, at enrollment was 61.5 (with a range of 14-86). Average GA size was 8.1 mm^2. The GA was foveal in 68% of patients and multifocal in 63% of patients. Loss of function variants in the CFH gene were confirmed in 55 of the 62 patients enrolled. A total of 43 patients carry a homozygous AMD risk variation at the 402 locus of the CFH gene and six patients carry a rare heterozygous variant in CFH.

Summarized results observed to date in the ongoing Phase 2a ReGAtta study include the following:

Demonstration of Biological Activity, Complement Regulation and Dosing Frequency

Intraocular measures of CFH and biomarkers demonstrated GEM103's biological activity to regulate complement and support every other month dosing.

- Both 250µg and 500µg doses of GEM103 resulted in sustained, elevated CFH levels from the first evaluated time point of one month (at least 6-fold and 12-fold above baseline, respectively) that continued to increase dose dependently.
- Changes in biomarkers of complement activation indicated that GEM103 has the ability to regulate the complement system and overall disease-related inflammation, with an ~40% reduction in Ba, ~20% reduction in C3a and an increase in CFB, consistent across all genotypes.

GEM103 Continued to be Well-tolerated with a Differentiated Safety Profile with No Increased Risk of CNV and Minimal Inflammation

- GEM103 was well-tolerated with no serious adverse events related to study drug and no serious ocular adverse events as of May. There were no early discontinuations due to the study drug.
- Over 390 injections of GEM103 were administered, which equates to a total of 28 patient-years of exposure. Treatment was well-tolerated with only 16 patients (26%) experiencing adverse events in the study eye. Among these events, 12 patients' adverse events were related to the intravitreal administration procedure with conjunctival hemorrhage as the most common reported adverse event.
- Active monitoring was conducted for retina-specific safety including inflammation and CNV. Dilated retina exams were conducted at every study visit and retinal imaging was performed every three months. An independent reading center reviewed such data.
    - There were no endophthalmitis and no vitritis, retinal vasculitis or vascular occlusive events. Mild iritis ($\leq$ 1+ cell) was observed in the study eye in three patients (4.8%); all cases resolved with either observation only or topical therapy. One case was reported as related to GEM103, and all patients continued on study without disruption of GEM103 dosing schedule.
    - One case of CNV in a study eye presented as a macular hemorrhage at month 1 in the 500µg cohort was determined by the investigator not to be related to GEM103 or the intravitreal administration procedure. The patient is receiving anti-VEGF treatment and has continued on study.
    - There were no cases of CNV confirmed in the study eye by the independent reading center's analysis of the retinal imaging.
- Visual acuity remained stable (±5 EDTRS letters) throughout the study.
- GA progression at three months and six months in the study eye compared to fellow eyes that also meet the inclusion criteria was statistically indistinguishable.

The Company continues to evaluate the data coming out of the ReGAtta study while seeking alignment with regulators on GEM103's late stage trial designs.

Forward-Looking Statements

Certain statements in this Current Report on Form 8-K 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 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release by Gemini Therapeutics, Inc., dated June 22, 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: June 23, 2021

Exhibit 99.1

Gemini Therapeutics Announces Initial Data from its Ongoing Phase 2a Study of GEM103 in Patients with Geographic Atrophy Secondary to Dry Age-related Macular Degeneration

- Biomarker results indicate GEM103's ability to regulate complement and complement factor H therapeutic approach in geographic atrophy –

- GEM103 continues to be well-tolerated and demonstrates a differentiated safety profile with no increased risk of CNV and minimal inflammation –

- GEM103 program for GA advancing in discussions with regulators to seek alignment on late-stage trial design including every other month dosing –

CAMBRIDGE, Mass. – June 22, 2021 – Gemini Therapeutics, Inc. (Nasdaq: GMTX), a clinical stage precision medicine company developing innovative treatments for genetically defined age-related macular degeneration (AMD), today announced initial data from its Phase 2a ReGAtta study of GEM103 as of May 2021 in patients with geographic atrophy (GA) secondary to dry AMD. ReGAtta is a dose escalation trial of GEM103, which is intravitreally administered recombinant human complement factor H (CFH), in dry AMD patients. The trial, which remains ongoing, is designed to evaluate safety and tolerability, as well as measures of intraocular pharmacokinetics (PK) and disease-relevant biomarkers, to inform the late-stage development program.

"We are very excited these results demonstrate that GEM103 has biological activity and support CFH's mechanism of action to regulate complement activity in patients with dry AMD. Critically, GEM103 also continues to show a positive safety profile in the setting of repeat dosing for up to six months," said Samuel Barone, M.D., Chief Medical Officer of Gemini Therapeutics. "The ReGAtta study includes novel analysis of the biological pathways involved in GA and we are encouraged by GEM103's activity seen at this early point and look forward to the additional analyses expected later this year."

ReGAtta was designed to evaluate repeat dosing of GEM103 and assess its safety in an open-label study that enrolled 62 patients with GA secondary to dry AMD. The first 36 patients enrolled received monthly 250µg intravitreally administered doses of GEM103. After evaluating the safety profile of repeated dosing over three months, patients were dose escalated to 500µg and an additional 26 patients enrolled and received monthly 500µg doses. After completing the first six months of dosing, each patient will have the option to continue receiving GEM103 for up to an additional 12 months.

Patients enrolled in ReGAtta had a mean age of 78 and GA secondary to dry AMD in the study eye with 63% of patients also having GA in the fellow eye. Choroidal neovascularization (CNV) in the study eye was an exclusion criterion, however 30% of patients had a history of CNV in the fellow eye at baseline. Among the baseline characteristics in the study eye, mean best corrected visual acuity (BCVA) score, as measured by Early Treatment Diabetic Retinopathy Study (ETDRS) letters, at enrollment was 61.5 (with a range of 14-86). Average GA size was 8.1 mm^2. The GA was foveal in 68% of patients and multifocal in 63% of patients. Loss of function variants in the CFH gene were confirmed in 55 of the 62 patients enrolled. A total of 43 patients carry a homozygous AMD risk variation at the 402 locus of the CFH gene and six patients carry a rare heterozygous variant in CFH.

Summarized results observed to date in the ongoing Phase 2a ReGAtta study include the following:

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GEM103 Continued to be Well-tolerated with a Differentiated Safety Profile

- GEM103 was well-tolerated with no serious adverse events related to study drug and no serious ocular adverse events as of May. There were no early discontinuations due to the study drug.
- Over 390 injections of GEM103 were administered, which equates to a total of 28 patient-years of exposure. Treatment was well-tolerated with only 16 patients (26%) experiencing adverse events in the study eye. Among these events, 12 patients' adverse events were related to the intravitreal administration procedure with conjunctival hemorrhage as the most common reported adverse event.
- Active monitoring was conducted for retina-specific safety including inflammation and CNV. Dilated retina exams were conducted at every study visit and retinal imaging was performed every three months. An independent reading center reviewed such data.
    - There were no endophthalmitis and no vitritis, retinal vasculitis or vascular occlusive events. Mild iritis ($\leq$ 1+ cell) was observed in the study eye in three patients (4.8%); all cases resolved with either observation only or topical therapy. One case was reported as related to GEM103, and all patients continued on study without disruption of GEM103 dosing schedule.

    - One case of CNV in a study eye presented as a macular hemorrhage at month 1 in the 500µg cohort was determined by the investigator not to be related to GEM103 or the intravitreal administration procedure. The patient is receiving anti-VEGF treatment and has continued on study.
    - There were no cases of CNV confirmed in the study eye by the independent reading center's analysis of the retinal imaging.
- Visual acuity remained stable (±5 EDTRS letters) throughout the study.
- GA progression at three months and six months in the study eye compared to fellow eyes that also meet the inclusion criteria was statistically indistinguishable.

"This is an important milestone for the GEM103 program that supports the potential advantages of a well-tolerated safety profile without an increased risk for CNV and every other month dosing," said Jason Meyenburg, Chief Executive Officer of Gemini Therapeutics. "We continue to evaluate the data coming out of ReGAtta while seeking alignment with regulators on GEM103's late-stage trial designs."

Information on Gemini Therapeutics, including GEM103 and ReGAtta initial data, are included in its corporate presentation which is available on Gemini Therapeutics' website under the Investors & Media section: Events and Presentations.

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. GEM103 is delivered monthly by an intravitreal injection and PK and biomarkers of complement regulation are determined from aqueous humor sampling. To date, the study has enrolled 62 patients with gene variants that have been linked to the progression of dry AMD from early to late-stage.

About GEM103

Gemini's lead program, 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 1/2a 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 advancing 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 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 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.

Investor Contact:

Argot Partners
Sherri Spear
212-600-1902
gemini@argotpartners.com

Media Contact:

Argot Partners
Joshua R. Mansbach
212-600-1902
gemini@argotpartners.com