

**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): January 10, 2022

**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.)

**Address Not Applicable<sup>1</sup>**  
(Address of principal executive offices)

**Address Not Applicable<sup>1</sup>**  
(Zip Code)

**(617) 401-4400**  
(Registrant's telephone number, including area code)

**300 One Kendall Square, 3rd Floor**  
**Cambridge, MA 02139**  
(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
<b>Common stock, par value \$0.0001 per share</b>	<b>GMTX</b>	<b>The Nasdaq Global Market</b>

- 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.

<sup>1</sup> In January 2022, the Company became a remote-first company. Accordingly, the Company does not currently maintain a headquarters.

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**Item 7.01 Regulation FD Disclosure**

On January 10, 2022, the Company issued a press release entitled “Gemini Therapeutics Provides GEM103 Program Update.”

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 January 10, 2022, Gemini Therapeutics, Inc. (the “Company”) announced that the Company will discontinue both of its ongoing Phase 2a clinical trials, the ReGAtta study and the GEM103 as an Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study, as both studies have achieved their intended purpose of evaluating GEM103’s safety and tolerability, and have also provided data indicating that GEM103 had biological activity and sustained supraphysiologic pharmacokinetics levels at both monthly and every-other-month doses. The Company is actively evaluating next steps with GEM103’s continued clinical development.

**GEM103 Phase 2a ReGAtta Study Update**

Ongoing analysis of the 62 patients enrolled in the ReGAtta study continues to show that more than nine months of GEM103 exposure has been generally well-tolerated, able to durably reduce biomarkers of complement activation, and able to maintain supraphysiological levels of Complement Factor H (CFH). ReGAtta, an open-label, non-controlled study, was designed to evaluate GEM103’s safety and pharmacokinetics over multiple intravitreal injections.

## **GEM103 Phase 2a as an Add-On to Anti-VEGF Therapy for the Treatment of Wet AMD Study Update**

In December 2021, the Company received six-month data for the 50 patients enrolled in the wet AMD study. This study was designed to investigate the safety and tolerability of GEM103 as an adjunct to standard of care aflibercept therapy, with patients randomized 2:1 between a GEM103 plus aflibercept arm and a sham comparator plus aflibercept arm. Interim analysis showed that intravitreal GEM103 plus aflibercept was generally well-tolerated, and the safety profile was generally consistent with the sham plus aflibercept arm. Patients in this study were dosed every other month concurrently with aflibercept. CFH levels remained supraphysiologic and greater than five times above baseline at the trough timepoints throughout the six months.

### **GEM103 Study Plans**

Having achieved the ReGAtta study's primary goal of assessing GEM103's safety and tolerability, as well as the primary goal of assessing GEM103's safety and tolerability as an add-on to aflibercept for the treatment of wet AMD, the Company will end both of these ongoing Phase 2a studies with patients returning for a final safety visit.

### **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 the success, cost, timing and status of our product development activities and clinical trials, the timing of anticipated announcements of updates with respect to our product candidates and the timing to commence any potential 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, including serious adverse events, resulting from the administration of our product candidates, our ability to obtain and maintain regulatory approval for our product candidates. 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 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release by Gemini Therapeutics, Inc., dated January 10, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**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: January 10, 2022



## **Gemini Therapeutics Provides GEM103 Program Update**

**CAMBRIDGE, Mass. – January 10, 2022** – Gemini Therapeutics, Inc. (Nasdaq: GMTX), a clinical stage precision medicine company developing innovative treatments for genetically-defined age-related macular degeneration (AMD), today announced updates from its ongoing phase 2a clinical studies of GEM103 and strategic evaluation of GEM103's clinical development program.

### **GEM103 Phase 2a ReGAtta Study Update**

Ongoing analysis of the 62 patients enrolled in the ReGAtta study continues to show that more than nine months of GEM103 exposure has been generally well-tolerated, able to durably reduce biomarkers of complement activation, and able to maintain supraphysiological levels of Complement Factor H (CFH). ReGAtta, an open-label, non-controlled study, was designed to evaluate GEM103's safety and pharmacokinetics (PK) over multiple intravitreal injections.

### **GEM103 Phase 2a as an Add-On to Anti-VEGF Therapy for the Treatment of Wet AMD Study Update**

In December 2021, the Company received six-month data for the 50 patients enrolled in the wet AMD study. This study was designed to investigate the safety and tolerability of GEM103 as an adjunct to standard of care aflibercept therapy, with patients randomized 2:1 between a GEM103 plus aflibercept arm and a sham comparator plus aflibercept arm. Interim analysis showed that intravitreal GEM103 plus aflibercept was generally well-tolerated, and the safety profile was generally consistent with the sham plus aflibercept arm. Patients in this study were dosed every other month concurrently with aflibercept. CFH levels remained supraphysiologic and greater than five times above baseline at the trough timepoints throughout the six months.

### **GEM103 Study Plans**

Having achieved the ReGAtta study's primary goal of assessing GEM103's safety and tolerability, as well as the primary goal of assessing GEM103's safety and tolerability as an add-on to aflibercept for the treatment of wet AMD, the Company will end both of these ongoing Phase 2a studies with patients returning for a final safety visit.

“The ReGAtta and wet AMD clinical studies have achieved their intended purpose of evaluating GEM103's safety and tolerability, and have also provided data indicating that GEM103 had biological activity and sustained supraphysiologic PK levels at both monthly and every-other-month doses,” stated Jason Meyenburg, Gemini's Chief Executive Officer. “We want to express our gratitude to the patients who participated in these studies as well as the investigators and site staff conducting the studies. We are actively evaluating next steps with GEM103's continued clinical development and intend to provide an update by the end of the first quarter 2022.”



## 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 has been evaluated 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 is also working to advance a potentiating antibody for CFH, GEM307, towards clinical development for treatment of systemic diseases. For more information, visit [www.geminitherapeutics.com](http://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](http://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 the success, cost, timing and status of our product development activities and clinical trials, the timing of anticipated announcements of updates with respect to our product candidates and the timing to commence any potential 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, including serious adverse events, resulting from the administration of our product candidates, our ability to obtain and maintain regulatory approval for our product candidates. 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 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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