

**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): November 15, 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 August 15, 2021, Gemini Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release by Gemini Therapeutics, Inc., dated November 15, 2021</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: November 15, 2021



**Gemini Therapeutics Reports Third Quarter 2021 Financial Results  
and Provides Business Update**

*GEM103 updated safety information presented during AAO including no increased risk  
for CNV observed to date in ongoing ReGAtta Phase 2a study*

*Expect to provide six-month update from GEM103 ReGAtta study by year-end*

*Scheduled to meet with the FDA in 4Q'21 and expect to initiate late-stage trial for GEM103 in patients with GA in 1Q'22*

**CAMBRIDGE, Mass. – November 15, 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 third quarter ended September 30, 2021 and provided a business update.

“This weekend at the American Academy of Ophthalmology (AAO) annual meeting, Dr. Maturi provided a safety update on our ongoing Phase 2a ReGAtta study of GEM103 which shows GEM103 is generally well-tolerated with no increased risk of CNV in over 500 intravitreal injections of GEM103. We look forward to presenting a six-month update for the study before year end. We are meeting with the FDA this quarter and anticipate initiating our late-stage study of GEM103 for geographic atrophy (GA) secondary to dry AMD in the first quarter of 2022,” said Jason Meyenburg, Chief Executive Officer of Gemini Therapeutics, Inc.

**Recent Business and Clinical Highlights**

- **Presented newly available safety data from ongoing ReGAtta Phase 2a study of GEM103 at AAO 2021.** During the AAO Meeting in November Dr. Raj Maturi, M.D., Adjunct Clinical Assistant Professor of Ophthalmology, at Indiana University School of Medicine and an investigator in the ReGAtta study, presented an e-poster with newly available safety data that updated the May 2021 initial data from the ongoing ReGAtta Phase 2a study of GEM103 in GA. The most recent safety update from the ReGAtta study showed that across 510 intravitreal injections, GEM103 was generally well-tolerated with no ocular serious adverse events and no interruption in GEM103 therapy. 17 patients (27.4%) experienced mild to moderate ocular adverse events in the study eye and there continued to be no increased risk of CNV in the study eyes treated with GEM103.
- **Presented GEM103 biology and development at 2nd Annual Dry AMD Therapeutic Development Summit.** In October 2021 the Company further discussed the previously released initial data from its ongoing Phase 2a ReGAtta study in a presentation titled “Spotlight on GEM103 – Restoring Physiologic Complement Activity with Complement Factor H (CFH) for GA” at the 2nd Annual Dry AMD Therapeutic Development Summit: Uncovering the Largest Untapped Eyecare Market.

- **Announced corporate restructuring to prioritize late-stage clinical development of GEM103 for GA.** In October 2021, Gemini announced a corporate restructuring including several executive officer transitions to prioritize assets and focus on initiating and executing GEM103's resource-intensive pivotal trial in GA.
- **Presented preclinical data on GEM103 at the 13th International Conference on Complement Therapeutics.** In September 2021 at the 13th International Conference on Complement Therapeutics, an oral presentation and three poster presentations highlighted the potential of GEM103 as the next class of complement therapeutics for the treatment of AMD by regulating complement. GEM103 rapidly biodistributed to key tissues of interest including the retina, choroid and retinal pigment epithelium (RPE), and was retained on the RPE cell surface for an extended duration and remains functionally active in the eye following intravitreal administration.
- **Presented data from its ongoing Phase 2a study of GEM103 at EURETINA 2021 Virtual.** In September 2021, Dr. Maturi presented Gemini's previously released initial results from its ongoing Phase 2a ReGAtta study that GEM103 demonstrated the ability to regulate complement in GA patients with treatment resulting in a reduction of elevated complement biomarkers and a dose dependent reduction in the overall inflammatory state.
- **Presented data from its ongoing Phase 2a study of GEM103 at Clinical Trials at the Summit.** In August 2021, Gemini participated in panel discussions at Clinical Trials at the Summit and presented an analysis of the baseline GA lesion sizes for patients enrolled in the ongoing Phase 2a ReGAtta study that showed imbalances in GA baseline characteristics prevent efficacy assessment in a non-controlled open-label study.

## Financial Results

Research and development expenses totaled \$13.5 million for the three months ended September 30, 2021 compared to \$6.7 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 \$5.0 million for the three months ended September 30, 2021 compared to \$1.2 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 September 30, 2021 Gemini reported a net loss of \$18.6 million, or \$0.43 per share compared to a net loss of \$10.0 million, or \$0.65 per share, in the corresponding period in 2020. The increase in net loss for the three months ended September 30, 2021 was primarily due to an increase in operating expenses.

At September 30, 2021, Gemini held \$150.1 million in cash, \$6.7 million of principal outstanding debt and 43.1 million shares outstanding.

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## **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 Geographic Atrophy 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 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 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 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, Gemini believes 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 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)**

AMD is a progressive retinal disease affecting millions of older adults, and is 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 million with wet AMD. The genetic risk of developing dry AMD is significant, with approximately 70% of the risk of advanced disease being attributable 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 the CFH gene 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 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 those relating to the timing of and costs associated with our restructuring, and the benefits we expect to receive from the restructuring, 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 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](mailto:gemini@argotpartners.com)

**Media Contact:**

Argot Partners  
David Rosen  
212-600-1902  
[gemini@argotpartners.com](mailto:gemini@argotpartners.com)



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 13,455	\$ 6,727	\$ 36,083	\$ 20,472
General and administrative	4,995	1,222	15,177	3,774
Total operating expenses	<u>18,450</u>	<u>7,949</u>	<u>51,260</u>	<u>24,246</u>
Loss from operations	(18,450)	(7,949)	(51,260)	(24,246)
Other income (expense):				
Interest expense	(104)	(2,047)	(2,073)	(2,307)
Interest income	5	1	11	37
Loss on conversion of convertible notes	—	—	(711)	—
Change in fair value of warrant liability	—	(8)	—	(6)
Other expense	(2)	—	(13)	—
Net loss and comprehensive loss	<u>\$ (18,551)</u>	<u>\$ (10,003)</u>	<u>\$ (54,046)</u>	<u>\$ (26,522)</u>
Net loss per share, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.65)</u>	<u>\$ (1.37)</u>	<u>\$ (1.77)</u>
Weighted average common shares outstanding, basic and diluted	43,091,822	15,282,987	39,427,476	15,016,038

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

	<u>September 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
<b>Assets</b>		
Cash and cash equivalents	\$ 150,069	\$ 4,503
Other current assets	4,731	562
Total current assets	154,800	5,065
Other assets	735	3,254
Total assets	<u>\$ 155,535</u>	<u>\$ 8,319</u>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities	\$ 12,661	\$ 24,876
Long-term liabilities	2,013	5,304
Total liabilities	14,674	30,180
Total stockholders' equity (deficit)	140,861	(21,861)
Total liabilities and stockholders' equity (deficit)	<u>\$ 155,535</u>	<u>\$ 8,319</u>