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): March 29, 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 March 29, 2021, Gemini Therapeutics, Inc. (the "Company") announced its financial results for the year ended December 31, 2020. 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 March 29, 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: March 29, 2021

Exhibit 99.1

Gemini Therapeutics Reports Full Year 2020 Financial Results and Provides Business Update

- *Business combination with FS Development Corp. resulted in new public listing, strengthened management team, and cash position of approximately $200 million*
- *Significantly advanced GEM103 clinical development; completed Phase 2a "ReGAtta" study enrollment; initiated Phase 2a study of GEM103 as a possible add-on for patients with wet AMD at risk for macular atrophy*

CAMBRIDGE, Mass. – March 29, 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 year ended December 31, 2020 and provided a business update.

"The past 12 months have been truly transformative for Gemini as we successfully transitioned to a publicly traded precision medicine company with a strong balance sheet and resources to advance to important clinical milestones," said Jason Meyenburg, Chief Executive Officer of Gemini Therapeutics, Inc. "The successful completion of the Phase 1 study provided encouraging safety results and biomarker evidence GEM103 has biological activity consistent with functioning CFH. These results provided us the confidence to advance into two Phase 2a trials from which we expect to see initial data later this year. Our open-label Phase 2a ReGAtta study in patients with genetically-defined dry AMD completed enrollment in February. Also in February, we initiated a Phase 2a study of GEM103 as a potential add-on therapy for patients treated with anti-VEGF for wet AMD who are at risk for macular atrophy. We are committed to the further development of these innovative potential new treatments for patients and look forward to sharing our progress throughout the year."

Recent Business Highlights

- **Debuted as a publicly traded precision medicine company focused on genetically defined age-related macular degeneration (AMD) following the closing of a business combination with FS Development Corp (FSDC).** In February 2021, Gemini Therapeutics closed the business combination with FSDC, a special purpose acquisition company (SPAC) sponsored by Foresite Capital. Also in February 2021, the Company expanded its leadership team with the appointment of Brian Piekos as Chief Financial Officer and the promotion of Walter R. Strapps, Ph.D., to Chief Scientific Officer. Mr. Piekos joined from AMAG Pharmaceuticals where he most recently served as Executive Vice President, Chief Financial Officer and Treasurer. Dr. Strapps joined Gemini in 2018 from Intellia Therapeutics where he led CRISPR/Cas9 therapeutic programs through discovery into IND-enabling studies across a range of tissues and indications.

- **Made significant progress in the clinical development of GEM103, the Company's lead precision medicine program, targeting trial enrichment with genetically defined patients.**

    - 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 complement factor H (CFH) in dry AMD patients with loss of function CFH variants. The Company expects to share data from the trial, designed to evaluate safety and tolerability, as well as measures of intraocular pharmacokinetics and exploratory, disease-relevant biomarkers, in the first half of 2021. The Company believes the learnings from the Phase 2a trial will inform the design of the Phase 2b sham-controlled study which will be powered for efficacy.

    - In February 2021, Gemini Therapeutics commenced a Phase 2a study of 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. Six-month dosing data related to safety, tolerability, effect on intraocular CFH levels and disease-related biomarkers is expected around year-end 2021.

    - Positive Phase 1 data for GEM103 were presented at the 2020 Virtual Annual Meeting of the American Academy of Ophthalmology (AAO). In November 2020, Gemini Therapeutics announced that GEM103 met all endpoints in a Phase 1 clinical study. Data presented by Arshad M. Khanani, M.D., M.A., Director of Clinical Research at Sierra Eye Associates and Clinical Associate Professor of Ophthalmology, University of Nevada, demonstrated that there were no dose-limiting toxicities or treatment-related adverse events in 12 patients receiving a single intravitreal (IVT) injection of GEM103. Pharmacokinetic and exploratory biomarkers of complement activity as measured in the aqueous humor (AH) from patients enrolled in the Phase 1 single ascending dose (SAD) study support the mechanism of action of GEM103 and continued clinical development. Additionally, in GEM103 demonstrated a promising safety profile, with no observed dose-limiting toxicities or treatment-related adverse events.

Full Year 2020 Financial Results

Gemini reported a net loss of $40.8 million for the full year 2020 compared to $41.4 million for the same period in 2019. Research and development expenses were $28.2 million and $34.5 million for the twelve months ended December 31, 2020 and 2019, respectively. The full year decrease was primarily due to reduced spend in our product development activities as we focused our effort on the GEM103 product candidate.

General and administrative expenses were $5.9 million and $6.8 million for the twelve months ended December 31, 2020 and 2019, respectively. The full year decrease was primarily due to reduced employee headcount and related expenses.

Following the close of the business combination with FSDC and PIPE financing in February 2021, the Company expects its cash will fund operations into 2023.

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 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, 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, 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 modulator and is a full-length and human, recombinant complement factor H (rCFH) protein. When delivered by intravitreal injection, 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 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.geminitherapeutics.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 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. 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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