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): October 21, 2021

FREQUENCY THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39062**	**47-2324450**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

75 Hayden Avenue, Suite 300
Lexington, MA 02421
(Address of principal executive offices) (Zip Code)

(781) 315-4600
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2 below):

☐ Written communications 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-commencement 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 Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**FREQ**	**The Nasdaq Global Select 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).

Emerging growth company ☒

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 8.01. Other Events.

On October 21, 2021, Frequency Therapeutics, Inc. (the "Company") announced that the first subject has been dosed in a new FX-322 Phase 2b study (FX-322-208) being conducted in a refined population of individuals with sensorineural hearing loss ("SNHL").

FX-322-208 is a randomized, placebo-controlled, multi-center study designed to evaluate the impact of a single administration of FX-322 on speech perception in approximately 124 subjects with SNHL. The study's primary endpoint is speech perception, a measure of sound clarity and understanding speech. The Phase 2b study's inclusion criteria are designed to enroll subjects with the same hearing loss severities and etiologies as those subjects in which statistically significant improvements in speech perception were observed in prior FX-322 clinical studies. FX-322-208 will include subjects with hearing loss associated with either noise-induced or sudden SNHL.

The U.S. Food and Drug Administration (FDA), in a recent Type-C meeting with the Company, agreed that speech perception is an acceptable primary efficacy endpoint. A variety of other listening tests, including multiple measures of speech perception and pure tone thresholds, will also be assessed.

In two previous clinical studies, the Company observed statistically significant improvements in speech perception scores in individuals with acquired sensorineural hearing loss. These studies are FX-322-201, a randomized placebo-controlled study of subjects with mild to moderately severe SNHL, and FX-322-111, an open-label study evaluating different FX-322 administration conditions, where nine of 32 subjects that completed the study showed speech perception improvements between 90 days and one year following administration. To date, more than 175 individuals have been dosed with FX-322 across previous studies and no drug-related serious adverse events have been reported.

The Company will maintain flexibility in the overall FX-322-208 design in order to be able to include additional etiologies and severities based on pending results from its ongoing FX-322 study in severe subjects (FX-322-113).

FX-322-208 is expected to be conducted at approximately 25 U.S.-based study sites consisting of both private ENT clinics and academic medical centers.

Forward-Looking Statements

This Current Report of Form 8-K (the "Current Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the design of the new Phase 2b trial of FX-322, including the number of patients that will be enrolled, the type of SNHL that these patients will have, the number of study sites, and the measurements used in the study, the interpretation and implications of the results and learnings of other FX-322 clinical studies, including the FX-322-111, FX-322-201, and FX-322-113 studies, the acceptance by the FDA of particular endpoints in the Company's trials, and the treatment potential of FX-322.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the impact of COVID-19 on the Company's ongoing and planned clinical trials, research and development and manufacturing activities; the Company's business and financial markets; the Company has incurred and will continue to incur significant losses and is not and may never be profitable; the Company's need for additional funding to complete development and commercialization of any product candidate; the Company's dependence on the development of FX-322; the unproven approach of the PCA platform; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; limited experience successfully obtaining marketing approval for and commercializing product candidates; the results of earlier clinical trials not being indicative of the results from later clinical trials; differences between preliminary or interim data and final data; adverse events or undesirable side effects; disruptions at the FDA and other regulatory agencies; failure to identify additional product candidates; new or changed legislation; failure to maintain Fast Track designation for FX-322 and such designation failing to result in faster development or regulatory review or approval; costly and damaging litigation, including related to product liability or intellectual property or brought by stockholders; dependence on Astellas Pharma Inc. for the development and commercialization of FX-322 outside of the United States; misconduct by employees or independent contractors; reliance on third parties, including to conduct clinical trials and manufacture product candidates; compliance with laws and regulations, including healthcare and environmental, health, and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property; security breaches or failure to protect private personal information; attracting and retaining key personnel; and ability to manage growth.

These and other important factors discussed under the caption "Risk factors" in the Company's Form 10-Q filed with the Securities and Exchange Commission ("SEC") on August 12, 2021 and its other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

SIGNATURES

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.

FREQUENCY THERAPEUTICS, INC.

Date: October 21, 2021

By: /s/ David L. Lucchino
Name: David L. Lucchino
Title: President and Chief Executive Officer