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): May 13, 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.)**

19 Presidential Way, 2nd Floor
Woburn, MA 01801
(Address of principal executive offices) (Zip Code)

(866) 389-1970
(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 2.02. Results of Operations and Financial Condition.

On May 13, 2021 Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2021 and provided operational updates. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Form 8-K (including Exhibit 99.1) 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 provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relates to Item 2.02, which shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 13, 2021

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: May 13, 2021

By: /s/ David L. Lucchino

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

Exhibit 99.1

Frequency Therapeutics Provides Business Updates and Reports First Quarter 2021 Financial Results

Data From Recent FX-322 Clinical Readouts, Including New Data from Phase 1b Study in Presbycusis (Age-Related Hearing Loss), Further Clarify Acquired Sensorineural Hearing Loss Target Patient Populations and Future Study Design

Company Anticipates Initiation of New FX-322 Phase 2 Study in H2 2021

LEXINGTON, Mass., May 13, 2021 – Frequency Therapeutics, Inc. (Nasdaq: FREQ), a clinical-stage biotechnology company focused on harnessing the body's innate biology to repair or reverse damage caused by a broad range of degenerative diseases, today announced business updates and financial results for the first quarter ended March 31, 2021.

"As we work to develop a novel medicine for the treatment of the most common form of hearing loss, our initial focus has been to investigate the broadest set of potential conditions and severities through a comprehensive series of probing studies. With data from all of our single administration studies, we have been able to better define the groups of patients that we believe are responding to FX-322, while also informing the optimal study design for new placebo-controlled Phase 2 trials," said David L. Lucchino, Frequency's Chief Executive Officer.

Most recently, Frequency completed a Phase 1b study (FX-322-112) in subjects with presbycusis (age-related hearing loss). No subjects enrolled in the 112 study had either noise-induced or sudden sensorineural hearing loss (SSNHL), conditions where FX-322 associated hearing benefits were observed in prior studies. In the 112 study, the Company observed no significant treatment effect with FX-322 administration compared to placebo. Results showed a favorable safety and tolerability profile and, importantly, that the inclusion of multiple baseline hearing tests prior to treatment mitigated the impact of potential study bias (e.g. placebo response) previously observed in Frequency's Phase 2a study (FX-322-202). This lead-in approach was also used in the Company's recently reported open-label study of subjects with mild-to-severe SNHL (FX-322-111). The Company expects to utilize study lead-in measures, and other approaches, to minimize potential bias in future clinical studies.

"To date, Frequency has shown statistically significant hearing benefits in multiple, independent FX-322 studies and these hearing benefits have been observed in subjects diagnosed with sudden sensorineural or noise-induced hearing loss. Based on the available clinical data, we are able to continue to refine the targeted patient populations we expect to include in our next set of clinical studies, populations that include millions of individuals," Mr. Lucchino concluded.

Clinical Study Overview and Recent Corporate Highlights

Sensorineural hearing loss is the most common form of hearing loss, typically resulting from damage to auditory sensory hair cells in the inner ear. These cells convert sound waves to a signal sent to the brain. Sensory hair cells may be lost due to chronic noise exposure, aging, certain viral infections or exposure to drugs that are toxic to the ear.

In February, findings from Frequency's Phase 1/2 study of FX-322 were published in the journal *Otology & Neurotology*, which showed statistically significant increases in word recognition (WR) and words-in-noise (WIN) scores. Individuals with stable SNHL that received a single dose of FX-322 showed improvements in the number of words recognized in quiet from baseline to day 90 in the WR test and the level of background noise in which words could be identified in the WIN test.

These effects also were observed to be durable in four out of the five responders in the study 13 – 21 months following initial administration. In the study, there were no meaningful changes in the WR and WIN scores of the placebo group and FX-322 was also shown to be well tolerated. The publication also includes data demonstrating consistent cochlear drug delivery in both preclinical and human studies.

The Company's clinical development strategy has been to build off these data and subsequent findings regarding delivery and durability, conducting exploratory studies in subjects with different etiologies and severities of SNHL in order to best understand the population that may be best treated by FX-322.

FX-322-112 Phase 1b Study in Presbycusis (Age-Related Hearing Loss or ARHL): The recently completed study was a double-blind, placebo-controlled, randomized, multicenter safety study of 30 individuals aged 66-85 with age-related hearing loss. The primary objectives of the study were to assess the local and systemic safety of a single dose of FX-322 and evaluate hearing responses in an older adult cohort. Study participants were randomized 4:1 to receive either FX-322 or placebo in one ear. Validated hearing measures, as well as safety, otologic and audiologic assessments were also evaluated in the study. By design, the study recruited subjects with no medical history of noise-induced or sudden sensorineural hearing loss (SSNHL), etiologies where FX-322 associated hearing benefits were observed in prior studies. This was done as the Company continues to separately evaluate subjects with specific forms of hearing loss to better refine cohorts for future studies. While the treatment effect was not significant compared to placebo, results from the FX-322-112 study showed a favorable safety and tolerability profile, no treatment-related serious adverse events were reported and no meaningful improvements in the placebo group were observed.

FX-322-111 Phase 1b Study (Open-Label Administration Study): In March 2021, Frequency announced data from a multi-center, randomized open-label study of subjects with mild to severe SNHL (n=33) designed to evaluate the impact of injection conditions on tolerability. Subjects were injected in one ear with FX-322, with the untreated ear as the control. Hearing function was tested over the course of 90 days following dosing. At day 90, thirty-four percent (34%) of the 32 subjects that completed the study achieved a ten percent (10%) or greater absolute improvement in WR scores in the treated ear, which was statistically significant compared to the untreated ear. This included a subset of subjects that more than doubled their WR scores. The single dose had a favorable safety profile and was well tolerated.

FX-322-202 Phase 2a Study in Mild to Moderately Severe SNHL: In March 2021, the Company announced interim day-90 topline study results. No treatment-related serious adverse events were observed in the study. While WR scores increased across all groups, repeated weekly injections appeared to dampen the hearing benefit observed compared to other single-injection studies and there was no discernible hearing benefit of FX-322 over placebo. The Phase 2a interim results also showed an unexpected apparent level of hearing benefit in the placebo group that did not occur in previous trials and exceeded well-established published standards, potentially suggesting bias due to trial design. The Company expects to utilize lead-in hearing measures, and other study design approaches, in future

studies to minimize the risk of study bias. The Company expects to report complete results of the study in late Q2 2021.

FX-322-113 Phase 1b Study in Severe SNHL: In November 2020, Frequency commenced a Phase 1b study in patients aged 18-65 with severe SNHL. Enrollment remains ongoing. The primary objectives of the study are to assess the local and systemic safety of a single dose of FX-322 and evaluate hearing responses in a more severe adult cohort. Study participants are randomized 4:1 to receive either FX-322 or placebo in one ear. Validated measures of hearing including WR, the Bamford-Kowal-Bench Speech-in-Noise (BKB-SIN) test and pure tone audiometry are utilized in the study. Safety, otologic and audiologic assessments are being conducted at days 30 and 90 following administration of FX-322 or placebo. Frequency expects to obtain topline results from this study in the second half of 2021.

Expanded Clinical Development Team: In April 2021, the Company announced the expansion of its clinical development team with the addition of Jeffery T. Lichtenhan, Ph.D., a leading expert in hearing diagnostics and measurement. He joins Frequency from the Washington University School of Medicine in St. Louis, where he was Assistant Professor of Otolaryngology and Audiology and Communication Sciences. In February 2021, Frequency previously announced the appointment of Kevin Franck, Ph.D., who joined the Company as Senior Vice President of Strategic Marketing and New Product Planning from Massachusetts Eye and Ear, where he served as Director of Audiology and was on the Harvard Medical School Faculty of the Department of Otolaryngology-Head and Neck Surgery.

Multiple Sclerosis Preclinical Program: Frequency continues to advance preclinical research efforts designed to repair neurological damage in patients with multiple sclerosis. Research efforts remain underway to confirm the optimal candidate for a future clinical program.

First Quarter 2021 Financial Results

Cash Position: Cash, cash equivalents and short-term investments on March 31, 2021 were $194.9 million, as compared to $220.3 million on December 31, 2020. Excluding cash payments of approximately $2.0 million made during the first quarter ended March 31, 2021 related to fixed assets and the buildout of the Company’s new Lexington facility, cash, cash equivalents, and short-term investments at March 31, 2021 would have been $196.9 million. Based on current plans and assumptions, the Company expects its existing cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2023. This guidance does not include potential future milestones which could be received from Astellas for continued FX-322 development.

Revenue: Revenue was $4.7 million for the first quarter of 2021. The Company had revenue of $7.3 million in the comparable period of 2020.

Research & Development Expenses: Research and development expenses were $15.1 million for the first quarter of 2021, as compared to $6.7 million for the first quarter of 2020. The increase was due to increased costs related to the Company’s lead product candidate, FX-322, including external development costs related to the Company’s ongoing trials for FX-322, as well as increased personnel-related costs due to additional headcount to support the growth of Frequency’s research and development organization. Excluding stock-based compensation expense of $1.5 million, research and development expenses for the three months ended March 31, 2021 were $13.6 million.

General and Administrative Expenses: General and administrative expenses were $9.7 million for the first quarter of 2021, as compared to $6.2 million for the first quarter of 2020. The increase was

primarily due to an increase in personnel-related costs, including stock-based compensation, for additional headcount required to support the growth of the Company as well as costs associated with being a public company, primarily comprised of professional fees. Excluding stock-based compensation expense of $3.1 million, general and administrative expenses for the three months ended March 31, 2021 were $6.6 million.

Net Loss: Net loss was $20.4 million for the first quarter of 2021, as compared to $4.9 million for the first quarter of 2020. The increase in net loss reflects the increase in research and development costs associated with the growth of Frequency's research and development organization as well as the increase in general and administrative expenses required to support the growth of Frequency as a public company.

About Frequency Therapeutics

Frequency Therapeutics is a leader in the development of medicines designed to activate progenitor cells within the body to treat degenerative diseases. The Company's progenitor cell activation (PCA) approach stimulates progenitor cells to create functional tissue with the aim of developing disease modifying therapies. The Company's lead product candidate, FX-322, is designed to regenerate auditory hair cells to restore hearing function. FX-322 is being evaluated in multiple ongoing clinical studies in patients with sensorineural hearing loss. The Company also is evaluating additional diseases where its PCA approach could create functional tissue, including in a pre-clinical program in multiple sclerosis.

Headquartered in Lexington, Mass., Frequency has an ex-U.S. license and collaboration agreement with Astellas Pharma Inc. for FX-322, as well as additional collaboration and licensing agreements with academic and nonprofit research organizations including Massachusetts Eye and Ear, Mass General Brigham, Massachusetts Institute of Technology, The Scripps Research Institute and Cambridge Enterprises Limited. For more information, visit www.frequencytx.com and follow Frequency on Twitter @Frequencytx.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the interpretation and implications of the results of the interim day-90 Phase 2a data, the FX-322-112 data and the FX-322-111 data, including advancing FX-322 as a single-dose regimen and re-treatment at longer intervals, the impact of the trial design of the Phase 2a study on clinical data, the timing of results of the Company's clinical studies, including timing of initiation of additional planned studies in FX-322, the treatment potential of FX-322, the ability of our technology platform to provide patient benefit, estimates of the size of the hearing loss population and population at risk for hearing loss, the Company's ability to advance its hearing program and further diversify its portfolio, the timing of the Company's remyelination program, the sufficiency of the the Company's capital resources, the license and collaboration with Astellas Pharma Inc., and the potential application of the PCA platform to other diseases.

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 relocation of the Company's offices and laboratory facilities, 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 May 13, 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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 press release.

###

Frequency Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2021	2020
Revenue	$ 4,651	$ 7,264
Operating expenses:		
Research and development	15,106	6,670
General and administrative	9,744	6,249
Total operating expenses	24,850	12,919
Loss from operations	(20,199)	(5,655)
Interest income	25	710
Interest (expense)	(218)	—
Realized (loss) gain on investments	(4)	69
Foreign exchange gain	21	1
Loss before income taxes	$ (20,375)	$ (4,875)
Income taxes	—	(38)
Net loss	$ (20,375)	$ (4,913)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.60)	$ (0.16)
Weighted-average shares of common stock outstanding-basic and diluted	34,115,682	30,868,220

Frequency Therapeutics, Inc.
Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 194,909	$ 220,341
Working capital	181,159	198,430
Total assets	241,511	264,722
Total liabilities	64,104	72,231
Accumulated deficit	(115,774)	(95,399)
Total stockholders' equity	177,407	192,491

Contacts:

Investor Contact:
Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com
617-914-0008

Media Contact:
Suzanne Day
Frequency Therapeutics
Tel: 781-496-2211
Email: sday@frequencytx.com