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 4, 2022

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 Stock Market LLC (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 4, 2022, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2022 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 exhibits relate to Item 2.02, which shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 4, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 4, 2022

By: /s/ David L. Lucchino

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

Exhibit 99.1

Frequency Therapeutics Provides Business Updates and First Quarter 2022 Financial Results

FX-322-208 Phase 2b Study in Individuals with Acquired Sensorineural Hearing Loss Remains on Track for a Readout in Q4 2022 or Q1 2023

Reports Cash and Cash Equivalents of $124.8M, Providing Runway into 2024; Funds Enable Company to Meet Multiple Clinical Milestones for Programs Targeting Hearing Loss and Multiple Sclerosis

LEXINGTON, Mass., May 4, 2022 – Frequency Therapeutics, Inc. (Nasdaq: FREQ), a clinical-stage regenerative medicine company focused on developing therapeutics to activate a person's innate regenerative potential to restore function, today announced business updates and financial results for the first quarter ended March 31, 2022.

"Frequency continues to make important progress executing our pipeline of therapeutic programs for hearing loss and remyelination in multiple sclerosis (MS). We have taken steps to preserve capital, extending our cash runway into 2024 to ensure we have the resources to advance all of our programs through the next set of anticipated clinical milestones. These milestones include: FX-322 Phase 2b study results in hearing restoration, which are anticipated in Q4 2022 or Q1 2023; Phase 1 study results of FX-345, our second hearing restoration program that aims to distribute drug deeper into the cochlea and potentially treat additional individuals with hearing loss; and Phase 1 safety study results for our remyelination in MS program," said David L. Lucchino, Frequency's Chief Executive Officer.

"Enrollment for the FX-322-208 study in individuals with sudden and noise-induced sensorineural hearing loss is progressing well and we are seeing strong patient interest in this trial. We remain confident that the robust study protocol is driving recruitment of individuals with the severities and etiologies where we expect FX-322 to demonstrate the most profound clinical benefits," Lucchino added. "We are on track to submit an investigational new drug application (IND) for FX-345 in the second half of the year and continue to gain compelling pre-clinical insights as we prepare to commence our remyelination study in 2023. Overall, we are encouraged by the advances across our pipeline and in the potential for these therapeutic candidates to fundamentally transform the treatment of patients living with hearing loss and MS."

Recent Pipeline Progress and Corporate Highlights

FX-322-208 Phase 2b Study in Acquired 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 FX-322-208 Phase 2b study includes subjects with hearing loss associated with either noise-induced or sudden SNHL. The study's pre-specified primary endpoint is a measure of speech perception. Study enrollment is progressing with more than 25 clinical sites in operation across the US, including the first site at a Veteran's Administration hospital, which began recruiting subjects in April.

Based on learnings from five prior FX-322 studies, extensive design elements have been included in FX-322-208 to mitigate potential bias and to help ensure the consistency of baseline hearing assessments. Data from these studies have also enabled Frequency to design the FX-322-208 study inclusive of the hearing loss etiologies and severities where speech perception improvements were previously observed. To date, no drug-related serious adverse events have been reported by individuals who have been dosed in any FX-322 study.

FX-345, a Second Sensory Hair Cell Regeneration Program for SNHL: In November 2021, Frequency announced FX-345 as a new, highly potent, investigational therapeutic candidate for SNHL. Pharmacokinetic measures and human modeling data suggest that administration of FX-345 can result in therapeutically active drug levels in a larger portion of the cochlea, which could potentially address a broader set of hearing loss severities and etiologies. FX-345 is being evaluated in IND-enabling studies and Frequency anticipates filing an IND application for FX-345 in the second half of 2022.

Pre-clinical Program for Remyelination in MS: In November 2021, Frequency announced a discovery effort to remyelinate neurons in the central nervous system to treat MS. The Company has identified a new biological target relevant to myelination and demonstrated that modulation of this target drives robust oligodendrocyte differentiation and expression of myelin proteins *in vitro*. Multiple novel chemical entities have been identified that induce robust remyelination *in vivo*. The Company expects to finalize selection of a remyelination development candidate in 2022 with plans for an IND submission in 2023.

First Quarter 2022 Financial Results

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2022, were $124.8 million (excluding restricted cash). These resources are sufficient to fund the ongoing Phase 2b clinical program for the Company's lead candidate for hearing restoration (FX-322); a second pre-clinical program for hearing restoration (FX-345); and a pre-clinical program for remyelination in MS. The Company is appropriately resourced to advance its pipeline of potential first-in-class treatments through key development milestones, including completion of the Phase 2b study of FX-322, a Phase 1 study of FX-345 and a Phase 1 study in the MS program.

Based on current plans and assumptions, the Company believes its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into 2024, representing an extension to its previously announced guidance. This guidance does not include potential future milestones which could be received from Astellas Pharma Inc. (Astellas) for continued FX-322 development.

Revenue: The $80.0 million upfront payment from Astellas, initially recorded as deferred revenue, was fully recognized as of June 30, 2021. As such, no revenue was recorded for the three months ending March 31, 2022, compared to $4.7 million in the comparable period of 2021.

Research & Development Expenses: Research and development expenses were $13.8 million for the three months ending March 31, 2022, as compared to $15.1 million for the comparable period of 2021. The decrease was due to reduced costs for the direct research and development of MS as the Company progressed in its research such that it could narrow the scope of efforts leading up to the selection of a lead remyelination development candidate for advancement into clinical development. Excluding stock-based compensation expense of $2.3 million for the three months ending March 31, 2022, research and development expenses for the three months ending March 31, 2022, were $11.5 million.

General and Administrative Expenses: General and administrative expenses were $9.5 million for the three months ending March 31, 2022, as compared to $9.7 million for the comparable period of 2021. The decrease was primarily due to a decrease in professional services fees as the Company leveraged internal resources. Excluding stock-based compensation expense of $3.0 million for the three months ending March 31, 2022, general and administrative expenses for the three months ending March 31, 2022, were $6.5 million.

Net Loss: Net loss was $23.4 million for the three months ending March 31, 2022, as compared to $20.4 million for the comparable period of 2021. The period over period increase in net loss was primarily due to a decrease in revenue for the three months ended March 31, 2022.

About Frequency Therapeutics

Frequency Therapeutics is leading a new category in regenerative medicine that aims to restore human function – first in hearing loss and then in Multiple Sclerosis – by developing therapeutics that activate a person's innate regenerative potential within the body through the activation of progenitor cells. Frequency's hearing research focuses on cochlear restoration and auditory repair, and its lead asset, FX-322, is a small-molecule product candidate that is the first to show statistically significant and clinically meaningful hearing improvements in clinical trials for sensorineural hearing loss. Frequency is also following early restorative signals in MS to develop medicines with the same underlying regenerative science being brought to hearing loss.

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, the 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 timing and design of the Phase 2b study (FX-322-208), including the timing of topline results and the ability of design features to reduce bias, the interpretation and implications of the results and learnings of other FX-322 clinical studies, the timing and progress of the FX-345 and remyelination programs, including the timing of INDs, clinical trials and candidate selection, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in MS, the sufficiency of the Company's capital resources, the license and collaboration with Astellas Pharma Inc., and the potential application of the progenitor cell activation (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 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 and the inability to identify additional potential product candidates; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; the Company's 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; ability to seek and receive Breakthrough Therapy designation for FX-322; the Company's ability to enroll and retain patients in clinical trials; 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 changing laws and regulations, including healthcare and environmental, health, data privacy and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property rights covering product candidates; security breaches or failure to protect private personal information; attracting and retaining key personnel; and the Company's 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 4, 2022 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.

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

	Three Months Ended March 31,	
	2022	2021
Revenue	$ —	$ 4,651
Operating expenses:		
Research and development	13,781	15,106
General and administrative	9,477	9,744
Total operating expenses	23,258	24,850
Loss from operations	(23,258)	(20,199)
Interest income	95	25
Interest expense	(178)	(218)
Realized loss on investments	-	(4)
Foreign exchange gain	1	21
Other expense, net	(34)	—
Loss before income taxes	(23,374)	(20,375)
Income taxes	(12)	—
Net loss	$ (23,386)	$ (20,375)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.67)	$ (0.60)
Weighted-average shares of common stock outstanding-basic and diluted	34,810,676	34,115,682

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	124,771	142,426
Working capital	107,766	123,319
Total assets	164,939	185,358
Total liabilities	52,269	54,534
Accumulated deficit	(203,471)	(180,085)
Total stockholders' equity	112,670	130,824

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