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 8, 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 November 8, 2022, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 8, 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: November 8, 2022

By: /s/ David L. Lucchino

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

EX 99.1

Frequency Therapeutics Provides Business Updates and Third Quarter 2022 Financial Results

Enrollment Completed for Phase 2b Study of FX-322 for the Treatment of Sensorineural Hearing Loss; Readout Expected in Q1 2023

Company on Track for Q4 Clinical Trial Start of its Second Hearing Restoration Program, FX-345

Multiple Sclerosis Remyelination Program Candidate Advanced to IND-Enabling Studies, with Anticipated 2H 2023 IND Filing

LEXINGTON, Mass., Nov. 8, 2022 – Frequency Therapeutics, Inc. (Nasdaq: FREQ), a clinical-stage regenerative medicine company focused on developing therapeutics to activate a person's innate potential to restore function, today announced business updates and financial results for the third quarter ended September 30, 2022.

"This past quarter has been one of momentum and execution. With the completion of enrollment for the Phase 2b study of our lead therapeutic candidate, FX-322, we are now preparing for a data readout next quarter for what may be the first medicine to treat hearing loss. The FX-322-208 study is designed to show a statistically significant improvement in speech perception, and its pre-specified endpoint would also demonstrate a clinically meaningful outcome for patients. We believe the pending FX-322 data have the potential to support a future marketing application and the design of a subsequent Phase 3 study," said David L. Lucchino, Frequency's chief executive officer.

Mr. Lucchino continued: "We continue to progress with our second hearing restoration candidate, FX-345, and anticipate initiating a Phase 1b trial in the coming weeks. With a readout planned for the second half of next year, we look forward to exploring the impact of greater cochlear drug exposure and whether that will enable us to expand the SNHL populations we may treat. Finally, our remyelination in multiple sclerosis program is also progressing in IND-enabling studies and we remain on track to move this high potential program toward an IND filing in the second half of 2023. We expect our current cash position will enable us to reach our next set of clinical milestones as we work to continue to advance our pipeline and expand our research focus."

The Company will review its FX-322 clinical program and other pipeline activity on a webcast with management and key opinion leaders on Dec. 13, 2022, at 8am ET.

Recent Pipeline Progress and Corporate Highlights

FX-322-208 Phase 2b Study in Acquired Sensorineural Hearing Loss (SNHL): In October, Frequency announced enrollment completion for its FX-322-208 study. FX-322-208 is a randomized, placebo-controlled, multi-center study designed to evaluate the efficacy of a single administration of FX-322 on speech perception. The study enrolled 142 participants, exceeding the original enrollment target of 124. The FX-322-208 Phase 2b study enrolled subjects with hearing loss associated with either noise-induced

or sudden SNHL, indications where the Company observed the greatest concentration of speech perception improvements in prior studies. The study's pre-specified primary efficacy endpoint is the improvement in a measure of speech perception, the ability to hear more words correctly. The Company has aligned with the US Food and Drug Administration (FDA) on this endpoint. FX-322-208 study results are expected in Q1 2023.

The FX-322-208 study is powered at 80% (significance level of 0.05) to observe a statistically significant and clinically meaningful improvement in speech perception at Day 90 following dosing, with study responders defined as individuals exceeding the upper 95% confidence interval in the speech perception test. The Company has not publicly disclosed the specific test used for the primary endpoint to maximize the rigor of the study and mitigate potential bias.

During the study, subjects participate in a range of audiologic exams, including pure-tone audiometry, word recognition in quiet, word recognition in noise, the Tinnitus Functional Index (TFI), as well as multiple patient-reported outcome measures. The study's rigorous design includes a lead-in phase with multiple baseline measures and subjects with instability of baseline tests were disqualified from participation in the study. More than 200 individuals have been dosed with a single injection of FX-322 in prior or ongoing studies, and the drug candidate has continued to exhibit a favorable safety profile with no drug-related serious adverse events.

FX-345, a Second Program for SNHL: In the coming weeks, the Company plans to initiate a Phase 1b study in subjects with SNHL to assess safety, tolerability and preliminary impact on a number of audiometric measures. The Company anticipates study results in H2 2023. FX-345 is the Company's second 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 patients with SNHL.

Pre-clinical Program for Remyelination in Multiple Sclerosis (MS): Frequency is advancing to IND-enabling studies its program for remyelination in MS. The Company previously reported that it had 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*. The Company has identified multiple novel chemical entities that induce robust remyelination in an *in vivo* animal model and plans to file an IND for the program in H2 2023.

Sublease Agreement: On July 8, 2022, the Company entered into a two-year agreement to sublease excess laboratory and office space, significantly reducing expenses. The Company has sufficient laboratory and other workspace for its teams and to support upcoming milestones and future plans.

Third Quarter 2022 Financial Results

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2022, were $99.3 million (excluding restricted cash). The Company is believed to be 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 1b study of FX-345 and a Phase 1 study for 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. 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 and nine months ended September 30, 2022, compared to $0 and $14.1 million in the comparable periods of 2021.

Research and Development Expenses: Research and development expenses were $11.7 million for the three months ended September 30, 2022, as compared to $15.7 million for the comparable period of 2021. Research and development expenses were $38.8 million for the nine months ended September 30, 2022, as compared to $48.2 million for the comparable period of 2021. Excluding stock-based compensation expense of $2.1 million for the three months ended September 30, 2022, and $6.0 million for the nine months ended September 30, 2022, research and development expenses for the three and nine months ended September 30, 2022, were $9.6 million and $32.8 million, respectively.

General and Administrative Expenses: General and administrative expenses were $8.6 million for the three months ended September 30, 2022, as compared to $9.3 million for the comparable period of 2021. General and administrative expenses were $26.0 million for the nine months ended September 30, 2022, as compared to $28.6 million for the comparable period of 2021. Excluding stock-based compensation expense of $3.5 million for the three months ended September 30, 2022, and $9.4 million for the nine months ended September 30, 2022, general and administrative expenses for the three and nine months ended September 30, 2022, were $5.1 million and $16.6 million, respectively.

Net Loss: Net loss was $19.5 million for the three months ended September 30, 2022, as compared to $25.2 million for the comparable period of 2021. Net loss was $64.2 million for the nine months ended September 30, 2022, as compared to $63.2 million for the comparable period of 2021.

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 combination 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 similar 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, and the Scripps Research Institute.

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 results, the ability of design features to reduce bias, and the indications of the enrolled subjects, the commencement of any future FX-322 trials, the interpretation and implications of the results and

learnings of other FX-322 clinical studies, the timing of future trials of FX-345, including the timing of results, the timing of IND submission in the MS remyelination program, the treatment potential of FX-322, FX-345, and the MS remyelination program, estimates of the size of the hearing loss population, the acceptance by the FDA of particular endpoints in the Company's trials, the sufficiency of the Company's laboratory and workspaces, the potential application of the progenitor cell activation (PCA) platform to other diseases, and the sufficiency of the Company's capital resources.

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 November 8, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ —	$ —	$ —	$ 14,068
Operating expenses:				
Research and development	11,715	15,662	38,769	48,169
General and administrative	8,560	9,328	26,037	28,571
Total operating expenses	20,275	24,990	64,806	76,740
Loss from operations	(20,275)	(24,990)	(64,806)	(62,672)
Interest income	351	172	871	315
Interest expense	(263)	(182)	(649)	(582)
Realized gain (loss) on investments	1	(9)	3	(23)
Foreign exchange (loss) gain	(5)	(4)	(7)	16
Other income (expense), net	621	(139)	361	(227)
Loss before income taxes	(19,570)	(25,152)	(64,227)	(63,173)
Income tax benefit (provision)	23	(3)	9	(13)
Net loss	$ (19,547)	$ (25,155)	$ (64,218)	$ (63,186)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.55)	$ (0.73)	$ (1.83)	$ (1.84)
Weighted-average shares of common stock outstanding-basic and diluted	35,247,680	34,448,746	35,013,189	34,268,736

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	99,347	142,426
Working capital	80,987	123,319
Total assets	136,013	185,358
Total liabilities	54,040	54,534
Accumulated deficit	(244,303)	(180,085)
Total stockholders' equity	81,973	130,824

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