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): August 9, 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 August 9, 2022, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 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 August 9, 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: August 9, 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 Second Quarter 2022 Financial Results

Q1 2023 Readout Planned for FX-322-208 Phase 2b Sensorineural Hearing Loss Study, with Enrollment Completion Anticipated in Q3

Q4 Enrollment Start Planned for Phase 1b Study of Second Hearing Restoration Program, FX-345

Company Advances Remyelination in Multiple Sclerosis Program, Remains on Pace for 2023 Clinical Start

LEXINGTON, Mass., August 9, 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 second quarter ended June 30, 2022.

"I am very pleased with our team's pipeline execution and the clear progress across all of our clinical and pre-clinical programs. We have reached a predictable cadence in our FX-322-208 enrollment, giving us confidence in our timelines for a Phase 2b study readout in Q1 2023. The rigorous FX-322-208 study design includes an extended lead-in period to ensure the stability of an individual's hearing prior to entering the trial, and we have narrowed participation to individuals with the etiologies and severities where we have observed the strongest hearing signal in prior FX-322 studies," said David L. Lucchino, Frequency's chief executive officer.

"Our second hearing restoration candidate, FX-345, which is designed to gain better distribution in the cochlea to potentially address sensorineural hearing loss in a broader set of individuals, remains on track to commence enrollment later this year. Our remyelination in multiple sclerosis program also is progressing very well as we advance a candidate toward IND-enabling studies, and I am very pleased with the pace and productivity of our research group as we work to move that program into the clinic in 2023. Across the enterprise, we continue to carefully manage expenses and have cash sufficient to move our programs through important data events and milestones."

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 efficacy 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 efficacy endpoint is the improvement in a measure of speech perception, the ability to hear more words correctly, and the Company has aligned with the US Food and Drug Administration (FDA) on this endpoint. Study enrollment is progressing with approximately 30 clinical sites in operation across the US.

FX-345, a Second Program for SNHL: 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. The Company intends to conduct a Phase 1b study in subjects with SNHL to assess safety, exposure and preliminary impact on a number of audiometric measures and anticipates the study commencing in the fourth quarter of this year.

Pre-clinical Program for Remyelination in Multiple Sclerosis (MS): The Company is advancing to IND-enabling studies its program for remyelination in MS. As announced late last year, the Company 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 an *in vivo* animal model. The Company plans to advance a candidate into clinical studies in 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.

Second Quarter 2022 Financial Results

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2022, were $111.0 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 six months ended June 30, 2022, compared to $9.4 million and $14.1 million in the comparable periods of 2021.

Research and Development Expenses: Research and development expenses were $13.3 million for the three months ended June 30, 2022, as compared to $17.4 million for the comparable period of 2021. Research and development expenses were $27.1 million for the six months ended June 30, 2022, as compared to $32.5 million for the comparable period of 2021. Excluding stock-based compensation expense of $1.6 million for the three months ended June 30, 2022 and $3.9 million for the six months ended June 30, 2022, research and development expenses for the three and six months ended June 30, 2022, were $11.7 million and $23.2 million, respectively.

General and Administrative Expenses: General and administrative expenses were $8.0 million for the three months ended June 30, 2022, as compared to $9.5 million for the comparable period of 2021. General and administrative expenses were $17.5 million for the six months ended June 30, 2022, as compared to $19.2 million for the comparable period of 2021. Excluding stock-based compensation expense of $3.0 million for the three months ended June 30, 2022 and $5.9 million for the six months

ended June 30, 2022, general and administrative expenses for the three and six months ended June 30, 2022 were $5.0 million and $11.6 million, respectively.

Net Loss: Net loss was $21.3 million for the three months ended June 30, 2022, as compared to $17.7 million for the comparable period of 2021. Net loss was $44.7 million for the six months ended June 30, 2022, as compared to $38.0 million for the comparable period of 2021. The period over period increases in net loss were primarily due to a decrease in revenue for the three and six months ended June 30, 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 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 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 and clinical trials, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in MS, the sufficiency of the Company's laboratory and other workspaces, the sufficiency of the Company's capital resources, the acceptance by the FDA of particular endpoints in the Company's trials, 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 August 9, 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	$ —	$ 9,417	$ —	$ 14,068
Operating expenses:				
Research and development	13,273	17,401	27,054	32,507
General and administrative	8,000	9,499	17,477	19,243
Total operating expenses	21,273	26,900	44,531	51,750
Loss from operations	(21,273)	(17,483)	(44,531)	(37,682)
Interest income	425	118	520	143
Interest expense	(208)	(182)	(386)	(400)
Realized gain (loss) on investments	2	(10)	2	(14)
Foreign exchange (loss) gain	(3)	(1)	(2)	20
Other expense, net	(226)	(88)	(260)	(88)
Loss before income taxes	(21,283)	(17,646)	(44,657)	(38,021)
Income taxes	(2)	(10)	(14)	(10)
Net loss	$ (21,285)	$ (17,656)	$ (44,671)	$ (38,031)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.61)	$ (0.52)	$ (1.28)	$ (1.11)
Weighted-average shares of common stock outstanding-basic and diluted	34,976,409	34,238,394	34,894,001	34,177,262

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	111,016	142,426
Working capital	96,660	123,319
Total assets	149,658	185,358
Total liabilities	53,805	54,534
Accumulated deficit	(224,756)	(180,085)
Total stockholders' equity	95,853	130,824

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