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 15, 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 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 15, 2021, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 "Current Report").

The information in this Item 2.02 of this Current Report, including Exhibit 99.1, is intended to be furnished and 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 (the "Securities Act"), 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 15, 2021
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 15, 2021

By: /s/ David L. Lucchino

Name: David L. Lucchino

Title: President and Chief Executive Officer

Frequency Therapeutics Provides Business Updates and Third Quarter 2021 Financial Results

Enrollment Underway for FX-322-208 Phase 2b Study in Subjects with Sudden and Noise-Induced Sensorineural Hearing Loss; Aligns with FDA on Speech Perception as Primary Endpoint for FX-322 Studies

Expands Pipeline with New Pre-Clinical Program for Hearing Restoration that May Provide Broader Cochlear Exposure and the Potential to Address Expanded SNHL Patient Populations

Introduces Remyelination Program in Multiple Sclerosis (MS), Sharing In Vivo Data Showing Substantially Greater Activity than Biologic or Small Molecule Comparators

LEXINGTON, Mass., Nov. 15, 2021 – 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 third quarter ended September 30, 2021.

"Frequency has made significant operational progress throughout this year, highlighted by the initiation of a Phase 2b study (FX-322-208) of FX-322, our lead program for sensorineural hearing loss (SNHL). We have designed this study following careful analysis of multiple completed FX-322 exploratory clinical studies, and through this work, we've increased our understanding of the specific patient etiologies and severities where hearing benefits were observed. We have also reached alignment with the U.S. Food and Drug Administration (FDA) on speech perception as the primary efficacy endpoint that we believe helps de-risk future development activities," said David L. Lucchino, Frequency's Chief Executive Officer.

"At our recent R&D event, we detailed results from our completed FX-322 clinical studies, showing all of the data demonstrating a clear signal of clinical benefit in a significant segment of individuals with SNHL. We also showed how the breadth of our clinical efforts informed the inclusion criteria of our ongoing FX-322-208 Phase 2b study. Furthermore, we were excited to introduce two new research programs, the first a pre-clinical development candidate to treat SNHL that can reach deeper into the cochlea and which may provide the opportunity to treat different patient populations. The second is a novel candidate for remyelination in MS that has shown significant remyelinating effect *in vivo* and has the potential to provide a highly differentiated offering compared to currently approved MS treatments."

FX-322 Clinical Study Overview and Recent Corporate Highlights

FX-322-208 Phase 2b Study in Acquired SNHL: In October, Frequency announced that the first subject was dosed in a new Phase 2b study of acquired 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. FX-322-208 will include subjects with hearing loss associated with either noise-induced or sudden SNHL. The 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. Based on learnings from prior studies, extensive study design elements have been included in FX-322-208 to mitigate potential bias and help ensure the consistency of baseline hearing assessments.

Since 2018, Frequency has run exploratory learning studies with the aim of determining the optimal patient populations where FX-322 may restore lost hearing. Given the diversity of etiologies and severities and the heterogeneity of hearing loss, this comprehensive approach was utilized to narrow in on the target population for further development. Data from these studies has enabled Frequency to design the FX-322-208 study inclusive of the hearing loss etiologies and severities where speech perception improvements were observed in prior FX-322 clinical studies.

To date, 169 individuals have been dosed with FX-322 across previous studies and no drug-related serious adverse events have been reported. The Company is also planning in Q4 2021 to report data from its FX-322-113 Phase 1b study in subjects with severe SNHL.

Introduction of FX-345, a Second Sensory Hair Cell Regeneration Program for SNHL: In November, Frequency announced a new, highly potent, investigational therapeutic candidate for SNHL called FX-345. 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 would enable Frequency to explore the potential for a hearing restoration therapeutic that could address a broad set of hearing loss severities and etiologies. FX-345 is a combination of two small molecules, including a more potent GSK3 inhibitor. An investigational new drug (IND) application for FX-345 is anticipated in Q2 2022.

Pre-clinical Program for Remyelination in Multiple Sclerosis: In November, Frequency also 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*.

Frequency developed multiple novel chemical entities that induce robust remyelination *in vivo*, including FREQ-162, which is its most advanced compound to date. A single dose of FREQ-162 induces robust increases in oligodendrocyte differentiation throughout the brain and significant remyelination in extensively demyelinated, aged mice. The Company is progressing these assets in dose range finding studies and IND-enabling toxicology studies in order to advance the program into clinical trials. FREQ-162 is one of several compounds Frequency has discovered that show potent remyelination activity. Remyelination is believed to slow or even reverse progression of disability in MS patients.

November 9 R&D Event: Frequency hosted an investor event on November 9, where management and key opinion leaders reviewed detailed FX-322 clinical study results and discussed the design of the ongoing FX-322-208 Phase 2b study. Management also presented research findings for FX-345 and its remyelination program. An archived replay of the webcast is available on the Investors & Media section of the Frequency Therapeutics website.

Third Quarter 2021 Financial Results

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2021 were $160.5 million (excluding restricted cash), as compared to $220.3 million as of December 31, 2020. Based on current plans and assumptions, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into late 2023. This guidance does not include potential future milestones which could be received from Astellas for continued FX-322 development.

Revenue: Revenue was $14.1 million for the nine months ending September 30, 2021 compared to $27.0 million in the comparable period of 2020. The Company had no revenue in the three months ending September 30, 2021 compared to $11.2 million in the comparable period of 2020.

Research & Development Expenses: Research and development expenses were $15.7 million and $48.2 million for the three and nine month periods ending September 30, 2021, respectively, as compared to $10.2 million and $25.6 million for the comparable periods 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 $2.8 million and $7.4 million for the three and nine months ending September 30, 2021, research and development expenses for the three and nine months ending September 30, 2021 were $12.9 million and $40.8 million, respectively.

General and Administrative Expenses: General and administrative expenses were $9.3 million and $28.6 million for the three and nine months ending September 30, 2021, respectively, as compared to $6.5 million and $18.7 million for the comparable periods 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 and $9.2 million for the three and nine months ending September 30, 2021, general and administrative expenses for the three and nine months ending September 30, 2021 were $6.2 million and $19.4 million, respectively.

Net Loss: Net loss was $25.2 million and $63.2 million for the three and nine months ending September 30, 2021, as compared to $5.3 million and $16.3 million for the comparable periods 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 leading a new category in regenerative medicine that aims to restore 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 design of the new Phase 2b trial of FX-322, including the type of SNHL that the enrolled patients will have 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 acceptance by the FDA of particular endpoints in the Company's trials, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in multiple sclerosis, the timing and progress of the FX-345 and remyelination programs, the ability of our technology platform to provide patient benefit, the ability to continue to develop our Progenitor Cell Activation (PCA) platform and identify additional product candidates, the potential application of the PCA platform to other diseases, the license and collaboration with Astellas Pharma Inc., 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 15, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ —	$ 11,247	$ 14,068	$ 27,034
Operating expenses:				
Research and development	15,662	10,153	48,169	25,587
General and administrative	9,328	6,512	28,571	18,720
Total operating expenses	24,990	16,665	76,740	44,307
Loss from operations	(24,990)	(5,418)	(62,672)	(17,273)
Interest income	172	74	315	962
Interest (expense)	(182)	—	(582)	—
Realized (loss) gain on investments	(9)	—	(23)	65
Foreign exchange (loss) gain	(4)	18	16	27
Other (expense), net	(139)	—	(227)	—
Loss before income taxes	(25,152)	(5,326)	(63,173)	(16,219)
Income taxes	(3)	(15)	(13)	(60)
Net loss	$ (25,155)	$ (5,341)	$ (63,186)	$ (16,279)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.73)	$ (0.16)	$ (1.84)	$ (0.51)
Weighted-average shares of common stock outstanding-basic and diluted	34,448,746	33,073,889	34,268,736	31,729,702

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 160,471	$ 220,341
Working capital	139,424	198,430
Total assets	202,185	264,722
Total liabilities	55,069	72,231
Accumulated deficit	(158,585)	(95,399)
Total stockholders' equity	147,116	192,491

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