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): March 15, 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 March 15, 2022, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter and year ended December 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 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 March 15, 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: March 15, 2022

By: /s/ David L. Lucchino

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

Frequency Therapeutics Provides Business Updates and Reports Fourth Quarter and Full Year 2021 Financial Results

Company Reports Steady Enrollment for FX-322-208 Phase 2b Study in Individuals with Sudden and Noise-Induced Sensorineural Hearing Loss; Topline Results Anticipated in Q4 2022 or Q1 2023

Continued Progress on Second Program for Hearing Restoration, FX-345; Phase 1b Start Anticipated in H2 2022

Advances Lead Optimization for Remyelination Program in Multiple Sclerosis (MS); Selection of Lead Clinical Candidate in 2022; IND Planned in 2023

LEXINGTON, Mass., March 15, 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 fourth quarter and full year ended December 31, 2021.

"The year ahead has numerous milestones for Frequency and our lead program FX-322, as we plan to complete enrollment and work toward a readout of our FX-322-208 Phase 2b study of individuals with sudden and noise-induced sensorineural hearing loss (SNHL). The design of the study is based on key insights from having built what we believe to be the largest clinical data set in the hearing restoration space, enabling us to hone-in on the severities and etiologies where we have observed FX-322 to have shown clinically meaningful outcomes. We are also aligned with the U.S. Food and Drug Administration on speech perception as the primary endpoint for this study, which we believe increases the likelihood of future technical and regulatory success. We remain on track to report study results by the end of this year, or in the first quarter of next year," said David L. Lucchino, Frequency's Chief Executive Officer.

Lucchino continued: "2021 was also a highly productive year for our research engine as we worked to expand our clinical pipeline with a second program in hearing restoration. Our new hearing asset, FX-345, has shown pre-clinically to be highly potent, potentially enabling the drug candidate to exert its activity further into the cochlea and treat more and different types of SNHL. We also shared compelling data from our pre-clinical program for remyelination in MS, where we have discovered a novel target and demonstrated a powerful remyelinating effect *in vivo*. With significant readouts and milestones in the year ahead, we believe we have multiple opportunities to advance new regenerative approaches in hearing loss and MS while working to transform the standard of care for both of these conditions."

Recent Pipeline Progress and Corporate Highlights

FX-322-208 Phase 2b Study in Acquired SNHL: In October 2021, 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. FX-322-208 includes subjects with hearing loss associated with either noise-induced or sudden SNHL. The study's primary endpoint is speech perception, a measure of sound clarity and understanding speech. Study enrollment is progressing to plan with more than 25 clinical sites in operation. The Company recently amended the study protocol, adding six- and nine-month visits to assess durability and provide further insight into potential redosing. Topline FX-322-208 study results are planned for either late 2022 or early 2023.

Based on learnings from five prior FX-322 studies, extensive design elements have been included in FX-322-208 to mitigate potential bias and 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 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 being evaluated in investigational new drug (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 Multiple Sclerosis: 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 lead remyelination development candidate for advancement into clinical development in 2022 with plans for an IND in 2023.

Recent Investor Events and Corporate Presentations

Oppenheimer 32nd Annual Healthcare Conference: On March 16 at 3:20 p.m. ET, Frequency CEO David L. Lucchino will present a Company overview. A replay will be available on the Company investor site at www.frequency.com/investors.

Cowen 42nd Annual Health Care Conference: On March 7, CEO David L. Lucchino participated in a panel discussion with executives from other leading audiology and ophthalmology companies. A replay of the program can be found here.

40th Annual J.P. Morgan Healthcare Conference: On January 13, CEO David L. Lucchino and Frequency management provided a Company update and near-term timelines and milestones. A replay of the program can be found here.

Virtual R&D Event: On November 9, 2021, Frequency hosted a virtual investor event that reviewed advances of the Company's FX-322 program for SNHL, as well as new potential restorative treatment programs for hearing loss and remyelination in MS. A replay of the program and of each individual presentation can be found here.

Fourth Quarter 2021 Financial Results

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2021, were $142.4 million (excluding restricted cash). Based on current plans and assumptions, the Company believes its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations through the end of 2023. This guidance does not include potential future milestones which could be received from Astellas for continued FX-322 development.

Revenue: As all revenue related to the Astellas Agreement was recognized as of June 30, 2021, there was no revenue recognized in the three months ending December 31, 2021, compared to $10.0 million in the comparable period of 2020. Revenue was $14.1 million for the twelve months ending December 31, 2021, compared to $37.0 million in the comparable period of 2020.

Research & Development Expenses: Research and development expenses were $12.8 million and $60.9 million for the three- and twelve-month periods ending December 31, 2021, respectively, as compared to $11.8 million and $37.4 million for the comparable periods of 2020. The increase was due to increased costs related to the Company's lead product candidate, FX-322, as well as costs related to the Company's new investigational therapeutic programs in hearing restoration and MS. Excluding stock-based compensation expense of $2.2 million and $9.6 million for the three- and twelve-months ending December 31, 2021, research and development expenses for the three- and twelve-months ending December 31, 2021, were $10.6 million and $51.3 million, respectively.

General and Administrative Expenses: General and administrative expenses were $8.6 million and $37.2 million for the three- and twelve-months ending December 31, 2021, respectively, as compared to $8.4 million and $27.1 million for the comparable periods of 2020. The increase was primarily due to an increase in personnel-related costs including stock-based compensation, as well as costs associated with being a public company, primarily comprised of professional fees. Excluding stock-based compensation expense of $3.0 million and $12.2 million for the three- and twelve-months ending December 31, 2021, general and administrative expenses for the three- and twelve-months ending December 31, 2021, were $5.7 million and $25.1 million, respectively.

Net Loss: Net loss was $21.5 million and $84.7 million for the three- and twelve-months ending December 31, 2021, as compared to $10.2 million and $26.5 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 human function – first in hearing loss and then in multiple sclerosis (MS) – 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 and clinical trials, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in MS, the acceptance by the Food and Drug Administration of particular endpoints in the Company's trials, the sufficiency of 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 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-K filed with the Securities and Exchange Commission (SEC) on March 15, 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue	$ —	$ 9,950	$ 14,068	$ 36,984
Operating expenses:				
Research and development	12,754	11,828	60,923	37,415
General and administrative	8,605	8,399	37,176	27,119
Total operating expenses	21,359	20,227	98,099	64,534
Loss from operations	(21,359)	(10,277)	(84,031)	(27,550)
Interest income	82	32	397	994
Interest expense	(182)	—	(764)	—
Realized gain on investments	—	19	(23)	84
Foreign exchange gain (loss)	—	(31)	16	(4)
Other expense, net	(39)	—	(266)	—
Loss before income taxes	$ (21,498)	$ (10,257)	$ (84,671)	$ (26,476)
Income taxes	(2)	25	(15)	(35)
Net loss	$ (21,500)	$ (10,232)	$ (84,686)	(26,511)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.62)	$ (0.30)	$ (2.47)	$ (0.82)
Weighted-average shares of common stock outstanding-basic and diluted	34,596,227	33,807,943	34,351,274	32,253,227

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 142,426	$ 220,341
Working capital	123,319	198,430
Total assets	185,358	264,722
Total liabilities	54,534	72,231
Accumulated deficit	(180,085)	(95,399)
Total stockholders' equity	130,824	192,491

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