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 29, 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.)**

19 Presidential Way, 2nd Floor
Woburn, MA 01801
(Address of principal executive offices) (Zip Code)

(866) 389-1970
(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 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 29, 2021 Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2020 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 exhibit relates to Item 2.02, which shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on March 29, 2021

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 29, 2021

By: /s/ David L. Lucchino

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

Exhibit 99.1

Frequency Therapeutics Provides Business Updates and Reports Fourth Quarter and Full Year 2020 Financial Results

Recent FX-322 Study Readouts Support Single-Dose Administration as Part of Future Trial Designs; Company Planning Additional Single Injection Studies

Results from Exploratory FX-322 Phase 1b Studies in Patients with Age-Related and Severe Hearing Loss Anticipated in Q2 and Q3 Respectively

Company Ends Year with $220 Million in Unrestricted Cash Providing Runway Into 2023

WOBURN, Mass., March 29, 2021 – Frequency Therapeutics, Inc. (Nasdaq: FREQ), a clinical-stage biotechnology company focused on harnessing the body's innate biology to repair or reverse damage caused by a broad range of degenerative diseases, today announced business updates and financial results for the fourth quarter and year ended December 31, 2020.

"We recently obtained valuable data from two clinical studies in patients with sensorineural hearing loss that have provided us with important learnings that already are informing our future development plans for FX-322, specifically around trial design and using a single administration approach in our studies," said David L. Lucchino, Frequency's President and CEO. "Combined with data from our published Phase 1/2 results, we have now shown statistically significant and clinically meaningful improvements in speech intelligibility from two independent, single injection studies that we believe provide encouraging support for FX-322 as a potential novel treatment option as we drive forward in this new area of regenerative medicine."

Mr. Lucchino continued: "Upcoming readouts from our ongoing studies will be further clarifying, and we will use these insights as we plan for future placebo-controlled FX-322 clinical studies using a single administration regimen. We have utilized a multi-study development approach that enables us to continually learn more about the clinical profile of FX-322, its potential application in different potential populations, as well as how to carry out trials most effectively in this emerging therapeutic area. In Q2, we anticipate results of a FX-322 Phase 1b study in patients with age-related hearing loss and in Q3 results of a FX-322 Phase 1b study of patients with severe sensorineural hearing loss, which will further inform our path forward. There is a tremendous need to advance the standard of care for people with sensorineural hearing loss, and we are are grateful to the patient community and all of those that have participated in our clinical studies for their continued support as we work to advance a medicine for hearing restoration."

FX-322 Day-90 Study Detail and Ongoing Program

- **FX-322 Phase 2a Study Day 90 Topline Results**: The Company recently shared interim data from its four-arm, Phase 2a study of FX-322 conducted in 95 subjects aged 18-65 with mild to moderately severe sensorineural hearing loss (SNHL). In the study, all subjects were administered a total of four weekly intratympanic injections comprised of zero, one, two, or four

doses of FX-322 with the balance of injections comprised of placebo doses. Subjects were evaluated for hearing improvement using Word Recognition (WR), Words-In-Noise (WIN), pure tone audiometry and additional exploratory measures. While WR scores increased across all groups, repeated weekly injections appeared to dampen the hearing benefit observed compared to other single-injection studies. The Phase 2a interim results also showed an unexpected apparent level of hearing benefit in the placebo group that did not occur in previous trials and exceeded well-established published standards, suggesting bias due to trial design. Given these challenges observed in the Phase 2a study design, there was no discernible hearing benefit of FX-322 over placebo. No treatment-related serious adverse events were observed in the study.

- **FX-322 - 111 Phase 1b:** The Company also shared preliminary data from a recently completed open-label, single-dose study of FX-322 (FX-322-111) designed to evaluate the impact of injection conditions on tolerability. In the multi-center, randomized study, subjects with mild to severe SNHL (n=33) were injected in one ear with FX-322, with the untreated ear as the control. Hearing function was tested over the course of 90 days following dosing. At day 90 following dosing, thirty-four percent (34%) of subjects achieved a ten percent (10%) or greater absolute improvement in WR scores in the treated ear, which was clinically meaningful and statistically significant compared to the untreated ear ($p < 0.05$). This included a subset of subjects that more than doubled their WR scores. These data were based on results from 32 of 33 subjects that completed the 90-day clinical assessment period. The single dose had a favorable safety profile and was well tolerated.
- **FX-322 - 112 Phase 1b Study in Age-Related Hearing Loss**: In October 2020, Frequency commenced a Phase 1b safety study of FX-322 (FX-322-112) for individuals with age-related hearing loss. The study, which has completed enrollment, is a double-blind, placebo-controlled, randomized, multicenter safety study of 30 individuals aged 66-85 with age-related hearing loss. The primary objectives of the Phase 1b study are to assess the local and systemic safety of a single dose of FX-322 and evaluate hearing responses in an older adult cohort. Study participants were randomized 4:1 to receive either FX-322 or placebo in one ear. Validated measures of hearing including WR, WIN and pure tone audiometry are being evaluated. Safety, otologic and audiologic assessments are also being conducted at day 30 and 90 following administration of FX-322 or placebo. Frequency expects to obtain topline results from this study in Q2 2021.
- **FX-322 - 113 Phase 1b Study in Severe SNHL:** In November 2020, Frequency commenced a Phase 1b study in patients aged 18-65 with severe SNHL (FX-322-113). Enrollment is continuing for the study of up to 30 individuals. This study employs a similar design and endpoints to the ongoing age-related Phase 1b study. Frequency expects to obtain topline results from this study in Q3 2021.

Other FX-322 Program Highlights

- **FX-322 Phase 1/2 Publication and Presentation:** In February 2021, the results from the completed FX-322 Phase 1/2 study were published in *Otology & Neurotology*, a leading peer-reviewed journal focused on disorders of the ear. The data demonstrate hearing improvements

in adults with acquired SNHL, and the first known linkage of pharmacokinetics and pharmacodynamics for a potential hearing restoration therapy. The Phase 1/2 study data were also presented at the leading international hearing research conference, the Association for Research in Otolaryngology (ARO) 44th Annual Midwinter Meeting on February 22, 2021.

- **Key Opinion Leader Webcast on Potential for Restorative Treatments for SNHL**: In January 2021, Company management and leading hearing loss researchers and clinicians held an investor event to discuss current interventions for the treatment of acquired sensorineural hearing loss (SNHL), unmet medical needs for hearing loss patients and the potential of FX-322 to transform the current standard of care.
- **FX-322 Phase 1/2 Durability Data:** In September 2020 at the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) Annual Meeting, data from a Phase 1/2 follow-up study showed that some patients with chronic SNHL had maintained significant improvements in key measures of hearing following a single injection of FX-322. Susan King, M.D., FACS, the lead investigator on both studies, outlined data which showed sustained improvements 13 – 21 months after initial dosing in measures of speech intelligibility (clarity) and in some patients, increased audibility (volume) threshold values at the highest tested frequency.
- **Clinical Data from Exploratory Study Confirming Delivery of FX-322 to the Cochlea:** In May 2020, the Company announced top-line data from an exploratory clinical study designed to show whether drug levels of FX-322 in the cochlea can be directly measured. In addition to confirming the viability of the approach, study results showed measurable concentrations of FX-322 in every sample analyzed and that anatomical factors did not prevent the active agents of FX-322 from reaching the cochlea. Further, the levels of FX-322 in the cochlea were predicted to reach the therapeutically active range of the treatment.

2020 and Recent Business Activity:

- **Expanded Leadership Team:** The Company recently has made several important leadership hires, building out its finance, manufacturing and pre-commercial functions:
  - Peter P. Pfreundschuh was appointed to the role of Chief Financial Officer in December 2020 to oversee the Company's financial strategy and activities related to accounting, investor relations, business development and business operations. He joined Frequency from UroGen Pharma Ltd., where he served as Chief Financial Officer, Chief Compliance Officer and Corporate Secretary.
  - Quentin McCubbin, Ph.D. was appointed as Chief Manufacturing Officer in January 2021. Dr. McCubbin is overseeing Company technical operations, leading drug product formulation, chemistry manufacturing and controls (CMC) and supply chain, to support the development of Frequency's pipeline of product candidates. He joined Frequency from Cerevel Therapeutics, a clinical-stage biotechnology company where he served as Head of Technical Operations.
  - Kevin Franck, Ph.D. was appointed to the role Senior Vice President of Strategic Marketing and New Product Planning in February 2021. Dr. Franck will lead pre-commercial strategy and launch planning for Frequency's clinical pipeline. A licensed audiologist, Dr. Franck

joined Frequency from Massachusetts Eye and Ear, where he served as Director of Audiology and was on the Harvard Medical School faculty in the Department of Otolaryngology-Head and Neck Surgery.

- **Progress on Remyelination Program for Multiple Sclerosis:** The Company continues to advance preclinical programs to support the advancement of a therapeutic candidate for remyelination in multiple sclerosis into the clinic.

Fourth Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and short-term investments on Dec. 31, 2020 were $220.3 million.

Based on current plans and assumptions, the Company expects its existing cash and cash equivalents, and short-term investments will be sufficient to fund its operations into 2023. This guidance does not include potential future milestones which could be received from Astellas Pharma for continued FX-322 development.

Revenue: Revenue was $10.0 million and $37.0 million for the three- and twelve-month periods ended Dec. 31, 2020, respectively. The Company had revenue of $4.7 million and $28.9 million in each of the comparable periods of 2019.

Research & Development Expenses: Research and development expenses were $11.8 million and $37.4 million for the three- and twelve-month periods ended Dec. 31, 2020, respectively, as compared to $6.2 million and $18.8 million for the comparable periods of 2019. The increases are due to increased costs related to the Company's lead product candidate, FX-322, including external development costs related to the Company's ongoing Phase 2a clinical trial, as well as increased personnel-related costs due to additional headcount to support the growth of Frequency's research and development organization.

General and Administrative Expenses: General and administrative expenses were $8.4 million and $27.1 million for the three- and twelve-month periods ended Dec. 31, 2020, respectively, as compared to $5.0 million and $14.8 million for the comparable periods of 2019. The increases are 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 insurance, consulting and professional fees.

Net Loss: Net loss was $10.2 million and $26.5 million for the three- and twelve-month periods ended Dec. 31, 2020, respectively, as compared to $5.5 million and $18.7 million for the comparable periods of 2019. The increase in net loss in 2020 reflects the increase in research and development costs associated with the growth of Frequency's research and development organization and the increase in general and administrative expenses required to support the growth of the Company and the cost associated with operating as a public company.

About Frequency Therapeutics

Frequency Therapeutics is a leader in the development of medicines designed to activate progenitor cells within the body to treat degenerative diseases. The Company's progenitor cell activation (PCA) approach stimulates progenitor cells to create functional tissue with the aim of developing disease modifying therapies. The Company's lead product candidate, FX-322, is designed to regenerate auditory

hair cells to restore hearing function. FX-322 is being evaluated in multiple ongoing clinical studies in patients with sensorineural hearing loss. The Company also is evaluating additional diseases where its PCA approach could create functional tissue, including in a pre-clinical program in multiple sclerosis.

Headquartered in Woburn, 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 interpretation and implications of the results of the interim day-90 Phase 2a data and the FX-322-111 data, including advancing FX-322 as a single-dose regimen and re-treatment at longer intervals, the impact of the trial design of the Phase 2a study on clinical data, the timing of results of the Company's clinical studies, the treatment potential of FX-322, the ability of our technology platform to provide patient benefit, estimates of the size of the hearing loss population and population at risk for hearing loss, the Company's ability to advance its hearing program and further diversify its portfolio, the timing of the Company's remyelination program, the sufficiency of the 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 relocation of the Company's offices and laboratory facilities, 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; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; 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; 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 laws and regulations, including healthcare and environmental, health, and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property; security breaches or failure to protect private personal information; attracting and retaining key personnel; and 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 29, 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.

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

	Three Months Ended December 31,		Year Ended December	
	2020	2019	2020	
Revenue	$ 9,950	$ 4,709	$ 36,984	$
Operating expenses:				
Royalty	—	—	—	
Research and development	11,828	6,196	37,415	
General and administrative	8,399	5,001	27,119	
Total operating expenses	20,227	11,197	64,534	
Loss from operations	(10,277)	(6,488)	(27,550)	
Interest income	32	942	994	
Realized gain on investments	19	50	84	
Foreign exchange gain (loss)	(31)	3	(4)	
Loss before income taxes	(10,257)	(5,493)	(26,476)	
Income taxes	25	-	(35)	
Net loss	(10,232)	(5,493)	(26,511)	
Cumulative Series C convertible preferred stock dividends	-	(40)	-	
Net loss attributable to common stockholders	$ (10,232)	$ (5,533)	$ (26,511)	$
Net loss per share attributable to common stockholders-basic and diluted	$ (0.30)	$ (0.19)	$ (0.82)	$
Weighted-average shares of common stock outstanding-basic and diluted	33,807,943	28,409,518	32,253,227	

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 220,341	$ 217,355
Working capital	198,430	168,575
Total assets	264,722	223,218
Total liabilities	72,231	55,860
Accumulated deficit	(95,399)	(68,888)
Total stockholders' equity	192,491	167,358

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