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 16, 2020

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 November 16, 2020, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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	Q3 Press Release issued on November 16, 2020

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 16, 2020

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 THIRD QUARTER 2020 FINANCIAL RESULTS

Day-90 Analysis of FX-322 Phase 2a Study for Acquired Sensorineural Hearing Loss (SNHL) Planned for Late Q1 2021; End of Study Readout Planned in Late Q2 2021

Commenced Phase 1b Study of FX-322 in Patients with Age-Related Hearing Loss; Additional Phase 1b Study in Patients with Severe SNHL to Start Before Year End

Company Ends Quarter with $224.2M in Cash, Cash Equivalents and Short-Term Investments

WOBURN, Mass., November 16, 2020 – 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 third quarter ended September 30, 2020.

The Company has continued to advance the clinical development program for FX-322, its lead product candidate for the treatment of acquired SNHL, announcing last month a detailed update that includes an upcoming analysis of day-90 data from its Phase 2a study in late Q1 2021. This readout will assess all efficacy and safety endpoints following single or multiple doses of FX-322, or placebo. The Company also reiterated its plan to share end of Phase 2a data in late Q2 2021, evaluating the same metrics as at day-90, as well as the durability of the effect of FX-322 over seven months.

Further, Frequency is expanding its FX-322 development program to evaluate FX-322's clinical profile in other SNHL patient types, including those with age-related hearing loss and severe SNHL, in order to identify the broadest population that may benefit from the product candidate. The Company expects to share results from its Phase 1b age-related hearing loss study in Q2 2021 and its Phase 1b severe SNHL study in Q3 2021. SNHL is the most common form of hearing loss, impacting more than 40 million people in the US alone.

"This past quarter we continued to gain momentum, completing study enrollment and moving toward a day-90 readout of the Phase 2a study of FX-322, while expanding our development program by adding additional studies to further our understanding of the potential of FX-322 to help the broadest SNHL patient population. The analysis of day-90 data will enable us to evaluate our key goals for the Phase 2a study and provide a comparison to the hearing

improvement signal we observed in our Phase 1/2 study. These data are also expected to provide critical insights as we look ahead to the end-of-study readout late in the second quarter of next year and enable us to plan our longer-term development and regulatory strategies," said Frequency Therapeutics Chief Executive Officer David L. Lucchino. "We also expect these studies to provide us with a deeper understanding of the potential impact of FX-322 on intelligibility or clarity measures. Intelligibility of speech, which is critical for daily activities, especially in noisy environments, is the primary unmet need for tens of millions of people with hearing loss and is not effectively addressed by the current standard of care.

"We look forward to an eventful 2021, with multiple FX-322 data readouts. We also expect to move our therapeutic candidate for remyelination in multiple sclerosis to the clinic in the second half of next year and further our exploration of additional opportunities for our progenitor cell activation approach."

Recent Program and Business Updates

FX-322 Phase 2a Study and Pending Clinical Readouts: The FX-322 Phase 2a study is a double-blind, placebo-controlled single and repeat dose study in patients aged 18 to 65 with acquired SNHL. The study includes four dose cohorts, with hearing function being regularly tested in all patients over the course of the full seven months following the first dosing.

The key efficacy objectives of the study are to evaluate the potential of FX-322 to improve hearing clarity or intelligibility, as measured by improvements in tests of word recognition (WR) or words-in-noise (WIN). Data will also be analyzed for the impact of FX-322 on pure tone audiometry in the standard frequencies (0.25-8 kHz), at higher frequencies (up to 16k Hz) and on tinnitus and quality of life measures. Frequency expects to share day-90 study results in late Q1 2021 and end of study results in late Q2 2021.

In its previously disclosed Phase 1/2 study, Frequency observed improvements in key measures of hearing function, specifically speech intelligibility, following a single dose of FX-322 in patients with moderate to moderately severe acquired SNHL. The evaluation period for the Phase 1/2 study was 90 days.

At the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF) annual meeting in September 2020, Frequency presented clinical results from a follow-up durability study of patients who had shown statistically significant improvements in word recognition scores in the Phase 1/2 study. These data showed that three of four patients maintained statistically significant improvements in word recognition at time points between 13 - 21 months following initial dosing, while a fourth patient maintained some improvement. A fifth patient that had shown non-statistically significant improvements had returned to baseline.

The results of the Phase 2a end of study analysis, as well as anticipated results from the age-related hearing loss and severe SNHL studies, are expected to provide the basis for an end of Phase 2 meeting with the US Food and Drug Administration regarding potential pivotal studies of FX-322.

FX-322 Phase 1b Study for Age-Related Hearing Loss: In October, the Company announced that the first patient was dosed in a Phase 1b safety study of FX-322 for age-related hearing loss. The study is a double-blind, placebo-controlled, randomized multicenter safety study of up to 30 patients aged 66-85 with mild to moderately severe 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 the hearing response. Study participants are being randomized 4:1 to receive either FX-322 or placebo in one ear. The study is using validated measures of hearing function including WR, WIN and pure tone audiometry to assess the effect of FX-322. Safety, otologic and audiologic assessments will be conducted at days 30 and 90 following administration. Frequency expects to share these study results in Q2 2021.

FX-322 Phase 1b Study of Severe SNHL: Frequency plans to start a Phase 1b study in patients aged 18-65 with severe SNHL before year-end. Severe SNHL is defined as a pure tone average deficit between 71-90 dB. Many patients with this clinical profile typically would be candidates for cochlear implants. This study is expected to employ a similar design to the age-related Phase 1b study that is currently underway. Frequency expects to share results from this study in Q3 2021.

Continued Progress on Earlier Stage Pipeline: The Company continued to make progress in its program for remyelination in multiple sclerosis, advancing the program from discovery into the pre-clinical phase. The program remains on track for an anticipated regulatory submission in H2 2021.

Cynthia Feldmann Appointed to Board of Directors: In September, Cynthia Feldmann joined the Company's Board of Directors. Ms. Feldmann is an experienced finance and accounting professional who brings to Frequency several decades of experience in life sciences and public company board leadership. She was formerly a partner at KPMG LLP, where she held leadership roles in the firm's medical technology and health care and life sciences industry groups, and was the lead partner in the life sciences practice for Coopers & Lybrand (now PricewaterhouseCoopers LLP) during her 19-year career there. Currently, she is a member of the board of directors at STERIS PLC (NYSE: STE) and at UFP Technologies (Nasdaq: UFPT).

New England Innovation Awards Life Science Winner: In October, Frequency was named the winner in the life sciences category of the New England Innovation Awards for its research into and development of FX-322 for sensorineural hearing loss. The award recognizes companies for their efforts to develop transformative innovations that can have a positive impact on patients, industry and society.

Boston Patent Law Association (BPLA) Honoree: In November, Frequency Therapeutics scientific co-founders Dr. Robert Langer of the Massachusetts Institute of Technology and Dr. Jeff Karp of Harvard Medical School, along with their co-inventors Dr. Xiaolei Yin and Dr. Nitin Joshi, were recognized by the BPLA for U.S. Patent No. 10,568,883 titled *"Compositions, Systems, and Methods for Generating Inner Ear Hair Cells For Treatment Of Hearing Loss,"* work that was foundational for some of Frequency's drug discovery programs.

Third Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and short-term investments on Sept. 30, 2020 were $224.2 million, as compared to $217.4 million on December 31, 2019. In July, the Company completed a private placement, resulting in $40.1 million in net proceeds, after deducting placement agent fees and other offering expenses.

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 $11.2 million and $27.0 million for the three- and nine-month periods ended Sept. 30, 2020, respectively. The Company had revenue of $24.2 million in each of the comparable periods of 2019.

Research & Development Expenses: Research and development expenses were $10.2 million and $25.6 million for the three- and nine-month periods ended Sept. 30, 2020, respectively, as compared to $5.2 million and $12.6 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 $6.5 million and $18.7 million for the three- and nine-month periods ended Sept. 30, 2020, respectively, as compared to $4.3 million and $9.8 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 $5.3 million and $16.3 million for the three- and nine-month periods ended Sept. 30, 2020, respectively, as compared to $0.6 million and $13.3 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. In a FX-322 Phase 1/2 study, statistically significant and clinically meaningful improvements in key measures of hearing function in patients with sensorineural hearing loss were observed. 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 The Scripps Research Institute, Massachusetts Eye and Ear, Cambridge Enterprises Limited, Mass General Brigham and the Massachusetts Institute of Technology. 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 Phase 2a clinical trial, the Phase 1b study of age-related hearing loss, the Phase 1b study of severe SNHL, including timing of commencement thereof, design, pace and timing of enrollment and results for the Phase 1b studies in age-related hearing loss and severe SNHL, the timing and completion of analysis of Phase 2 clinical trial data and data readouts from the Phase 2a clinical trial and the Phase 1b studies in age-related hearing loss and severe SNHL, the expected insights of such readouts and resulting developments, the effectiveness of the current standard of care to address the

primary unmet need of patients with acquired SNHL, the timing of a regulatory submission of a product candidate for remyelination in MS and commencement of clinical trials, the ability of our technology platform to provide patient benefit, the impact of COVID-19 on the Company's on-going and planned clinical trials and business, increases in headcount, future milestone and royalty payments under the license and collaboration agreement with Astellas, 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 potential application of the PCA platform to other diseases and expectations regarding cash, cash equivalents and short-term investments.

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-Q filed with the Securities and Exchange Commission (SEC) on November 16, 2020 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,	
	2020	2019	2020	2019
Revenue	$ 11,247	$ 24,238	$ 27,034	$ 24,238
Operating expenses:				
Royalty	—	16,000	—	16,000
Research and development	10,153	5,221	25,587	12,588
General and administrative	6,512	4,269	18,720	9,837
Total operating expenses	16,665	25,490	44,307	38,425
Loss from operations	(5,418)	(1,252)	(17,273)	(14,187)
Interest income	74	624	962	842
Realized gain on investments	—	62	65	88
Foreign exchange gain (loss)	18	(9)	27	4
Loss before income taxes	(5,326)	(575)	(16,219)	(13,253)
Income taxes	(15)	-	(60)	-
Net loss	(5,341)	(575)	(16,279)	(13,253)
Cumulative Series C convertible preferred stock dividends	-	(1,014)	-	(1,014)
Net loss attributable to common stockholders	$ (5,341)	$ (1,589)	$ (16,279)	$ (14,267)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.16)	$ (0.73)	$ (0.51)	$ (7.17)
Weighted-average shares of common stock outstanding-basic and diluted	33,073,889	2,163,289	31,729,702	1,990,106

Frequency Therapeutics, Inc.

Consolidated Balance Sheet Data

(in thousands)
(unaudited)

	September 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 224,231	$ 217,355
Working capital	194,424	168,575
Total assets	234,320	223,218
Total liabilities	34,728	55,860
Accumulated deficit	(85,167)	(68,888)
Total stockholders' equity	199,592	167,358

###

Contacts:

Investor Contact:
Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com
617-914-0008

Media Contact:
Suzanne Day
Frequency Therapeutics
Tel: 781-496-2211
Email: sday@frequencytx.com