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 26, 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 March 26, 2020, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2019 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) Exhibit

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 26, 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: March 26, 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 Fourth Quarter and Full Year 2019 Financial Results

Phase 2a Study of FX-322 for Sensorineural Hearing Loss Remains Ongoing

Strong Cash Position at End of 2019 Providing Runway into 2022;
Potential for Meaningful FX-322 Development Milestones

WOBURN, Mass., March 26, 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 fourth quarter and year ended December 31, 2019.

"2019 was an important year in Frequency's growth and evolution and we believe our business remains well positioned as we work to develop the first restorative, disease-modifying treatment for the millions of patients with sensorineural hearing loss," said Frequency Therapeutics Chief Executive Officer David Lucchino. "We are continuing our Phase 2a exploratory study of FX-322, building upon the statistically significant hearing signal we observed in our Phase 1/2 safety study. Phase 2a study enrollment has been steady. However, the COVID-19 pandemic has had an impact and we are working closely with our principal investigators, who are based primarily at private clinics across the U.S., to advance the trial. We will provide updated timing on the reporting of top-line data from this study as we learn more. We do believe that, if necessary, we could achieve the key objectives of the study with fewer subjects than originally designed. We deeply appreciate the ongoing engagement and collaboration with the sites and their focus on ensuring patient safety while maintaining study integrity. Our top priority is the well-being of study patients, the site investigators, their staff and our employees."

Mr. Lucchino added, "We also continue to make progress toward advancing a candidate to the clinic for remyelination in multiple sclerosis, for which we intend to file an investigational new drug application in the second half of 2021, while we further explore a wide range of potential new degenerative disease targets where we can leverage our progenitor cell activation approach."

Recent Program and Business Updates

- **FX-322 Phase 2a Study for Sensorineural Hearing Loss**: The FX-322 Phase 2a study is a randomized, double-blind, placebo-controlled, single- and repeat-dose study in which the Company may enroll up to 96 patients aged 18 to 65 with stable sensorineural hearing loss (SNHL). The objectives of the study are to further establish the hearing signal observed in the Phase 1/2 study; evaluate the impact of multiple doses; and provide insights on endpoints and patient population for future

studies. Study subjects are randomized to receive either FX-322 or placebo in one ear, with the untreated ear acting as an additional measure of control. The study is using validated measures of hearing function including word recognition, words-in-noise, and pure tone audiometry. Tinnitus and quality-of-life measures will also be subjectively evaluated using the Tinnitus Functional Index and the Hearing Handicap Inventory for Adults, respectively. This study builds upon the Phase 1/2 safety study in which the Company observed statistically significant and clinically meaningful improvements in word recognition (clarity of sound) in some subjects with a single dose of FX-322. The Phase 2a study has four dose cohorts and hearing function will be regularly tested over the course of seven months.

The Company believes the Phase 2a study is the first of its kind in which all enrolled subjects are carefully screened to ensure that their hearing deficit has remained stable. Unlike the Phase 1/2 safety study, where most patients had near-perfect word recognition scores, this stringent enrollment criterion was implemented to help ensure that study subjects have a SNHL deficit that FX-322 may address. As of today, study enrollment is approximately at the halfway point based on its original design.

Frequency already has observed an impact to study operations from COVID-19 as several study sites have informed Frequency that they have temporarily halted enrollment in the study. The Company expects the pandemic may result in other clinical sites being similarly affected for an unknown period of time, slowing or temporarily halting patient enrollment and potentially impacting patient retention. The Company believes, if necessary, that it would be able to achieve the key objectives of the study with fewer subjects than originally designed. Frequency intends to provide more specific guidance regarding the timing of the reporting of top-line data from the Phase 2a study once the impact of the pandemic is better understood.

- **Strengthened Leadership Team**: In February 2020, Frequency announced new appointments to its leadership team with the addition of Wendy Arnold as Chief People Officer and Dr. Lisa Geller as the Company's Head of Intellectual Property. Ms. Arnold has held senior human resources roles at Kaleido BioSciences, Moderna Therapeutics, Celgene, Predictive Biosciences and Inotek Pharmaceuticals. Dr. Geller is an experienced patent attorney with both law firm and in-house experience in the biotechnology and pharmaceutical sectors. Prior to joining Frequency, she held senior roles at Casebia Therapeutics, Seres Therapeutics, Eleven Biotherapeutics and Biogen, and worked at the law firms of Wilmer Cutler Pickering Hale & Dorr and Fish & Richardson P.C.

- **New Corporate Headquarters:** in January 2020, Frequency entered into an agreement for the lease of new space in Lexington, Mass., for its headquarters, which it plans to occupy beginning in early 2021. The new site will include laboratory facilities for research and development and will accomodate employees from the Company's current Farmington, CT labs. As of February 29, 2020, Frequency had 64 employees.

2019 Highlights:

- **Initiation of FX-322 Phase 2a Study for Sensorineural Hearing Loss (October 2019)**: The Phase 2a clinical trial is a multi-center, randomized, double-blind, placebo-controlled, single- and repeat-dose study of FX-322, which may enroll up to 96 adults aged 18 to 65 with stable sensorineural hearing loss.

- **FX-322 Fast Track Designation (October 2019)**: The United States Food and Drug Administration (FDA) granted Fast Track designation for FX-322. This designation is intended to facilitate development of new therapies for serious conditions with unmet medical need, expedite review, and enable more frequent engagement between the Company and the FDA regarding study planning and design.

- **Completion of Two Equity Financings Including Initial Public Offering (October and July 2019)**: Frequency raised $150.6 million in gross proceeds in 2019 through equity financings. Its initial public offering of 6,325,000 shares of common stock, at the offering price of $14.00 per share, yielded total gross proceeds of approximately $88.6 million. Frequency common stock began trading on the Nasdaq Global Select Market on October 3, 2019 under the ticker symbol “FREQ”. J.P. Morgan Securities, LLC, Goldman Sachs & Co. LLC and Cowen and Company, LLC were joint book-running managers for the offering. Earlier in the year, the Company closed a $62.0 million Series C financing, led by Perceptive Advisors and a syndicate that included new investors Deerfield Management, RTW Investments and Mizuho Securities Principal Investment, as well as existing investors.

- **Astellas License and Collaboration Agreement for FX-322 (July 2019)**: Frequency and Astellas Pharma Inc. entered into an exclusive license agreement to develop and commercialize FX-322, for the treatment of SNHL. Under the terms of the agreement, Astellas is responsible for the development and commercialization of FX-322 outside of the U.S. and Frequency is responsible for U.S. development and commercialization. The companies are jointly responsible for conducting global clinical studies and coordinating commercial launch activities. Frequency received an upfront payment of $80 million and may also receive up to an additional $545 million based on development and commercial milestones, as well as royalties on any future product sales in the licensed territory. Specifically, the Company would receive development milestone payments of $65.0 million and $25.0 million upon the first dosing of a patient in a Phase 2b clinical trial for SNHL in Europe and Asia, respectively, and $100.0 million and $40.0 million upon the first dosing of a patient in a Phase 3 clinical trial for SNHL in Europe and Asia, respectively. If the Astellas licensed products are successfully commercialized, Frequency would be eligible for up to $315.0 million in potential commercial milestone payments plus tiered royalties at rates ranging from low- to mid-teen percentages. Frequency continues to maintain all FX-322 product rights for the United States.

Fourth Quarter and Full Year 2019 Financial Results

Cash Position: Cash, cash equivalents and short-term investments at December 31, 2019 were $217.4 million, as compared to $42.2 million at December 31, 2018. Cash, cash equivalents and short-term investments at December 31, 2019 reflect the net proceeds of the Company’s initial public offering, $79.7 million, which closed in October 2019, the $80.0 million upfront payment received from Astellas in July 2019 under the license and collaboration agreement and the $62.0 million Series C financing closed in July 2019. Based on its current plans and assumptions, the Company expects its existing cash, cash equivalents and short-term investments, will be sufficient to fund its operations into 2022. This guidance does not include potential future milestones which could be received from Astellas for continued FX-322 development.

Revenue: Revenue was $4.7 million for the fourth quarter of 2019 and $28.9 million for the year ended December 31, 2019. The Company had no revenue in the comparable periods of 2018. In accordance with the Company's revenue recognition policy, the $80.0 million upfront payment received from Astellas under the license and collaboration agreement in July 2019 is being recognized as revenue over the period from the execution of the agreement until Frequency meets its obligation to complete a Phase 2a clinical trial for FX-322.

Royalties: Royalty expense was $16.0 million for the year ended December 31, 2019 representing the royalty due to the Massachusetts Institue of Technology on the $80.0 million upfront payment from Astellas. This was paid and expensed in the third quarter of 2019 upon entering into the license and collaboration agreement with Astellas.

Research & Development Expenses: Research and development expenses were $6.2 million for the fourth quarter of 2019 and $18.8 million for the year ended December 31, 2019, as compared to $2.9 million for the fourth quarter of 2018 and $11.9 million for the year ended December 31, 2018. The increase was primarily due to increased costs related to the Company's lead product candidate, FX-322, including external development costs as the Company commenced a Phase 2a clinical trial for FX-322 in October 2019, 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 $5.0 million for the fourth quarter of 2019 and $14.8 million for the year ended December 31, 2019, as compared to $2.4 million for the fourth quarter of 2018 and $7.1 million for the year ended December 31, 2018. 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 insurance and consulting and professional fees.

Net Loss: Net loss was $5.5 million for the fourth quarter of 2019 and $18.7 million for the year ended December 31, 2019, as compared to $5.4 million for the fourth quarter of 2018 and $19.2 million for the year ended December 31, 2018. The decrease was primarily due to the impact of recognizing $28.9 million of revenue under the Astellas license and collaboration agreement which was partially offset by the $16.0 million royalty expense and increases in research and development and general and administrative expenses.

About Sensorineural Hearing Loss

Sensorineural hearing loss (SNHL) is the most common form of hearing loss, resulting from damage to the hair cells in the inner ear or problems with the nerve pathways that convert sound waves from the inner ear to the brain. Hair cells are commonly lost due to chronic noise exposure, or as a result of aging, certain viral infections or exposure to ototoxic drugs. The World Health Organization (WHO) estimates that there are currently more than 800 million adults with hearing loss globally and that 1.1 billion children and adults ages 12 to 35 years old are at risk for hearing loss from recreational noise exposure. According to the U.S. National Institutes of Health, more than 90 percent of those with hearing loss are affected by SNHL.

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. The Company also is evaluating additional diseases where its PCA approach could create functional tissue, including a discovery program in multiple sclerosis.

Headquartered in Woburn, Mass., Frequency has a license and collaboration agreement with Astellas Pharma Inc. for FX-322, for which it retains U.S. rights, as well as additional collaboration and licensing agreements with academic and nonprofit research organizations including The Scripps Research Institute, Massachusetts Eye and Ear, Partners Healthcare 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 novelty of the Phase 2a clinical trial, the timing of top-line data from the Phase 2a clinical trial, the initiation of clinical studies in additional hearing loss patients, the timing of filing an IND for the remyelination program, the ability of our technology platform to provide patient benefit, the data from the Phase 2a trial informing future studies, the impact of COVID-19 on the Company's on-going and planned clinical trials and business, the timing for occupying, and the intended use of, the Company's new corporate headquarters, increases in headcount, the intended purpose of Fast Track designation, 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 sufficiency of the Company's cash, cash equivalents and short-term investments, the Company's ability to advance its hearing program and further diversify its portfolio, 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 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 18, 2019 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 Balance Sheet Data
(in thousands)

	As of December 31,	
	2019	2018
Cash, cash equivalents and short-term investments	$ 217,355	$ 42,189
Working capital	168,575	39,164
Total assets	223,218	44,548
Total liabilities	55,860	4,122
Convertible preferred stock and non-controlling interest	—	88,708
Accumulated deficit	(68,888)	(49,088)
Total stockholders' (deficit) equity	167,358	(48,282)

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenue	$ 4,709	$ —	$ 28,947	$ —
Operating expenses:				
Royalty	—	—	16,000	—
Research and development	6,196	2,921	18,784	11,880
General and administrative	5,001	2,404	14,838	7,064
Total operating expenses	11,197	5,325	49,622	18,944
Loss from operations	(6,488)	(5,325)	(20,675)	(18,944)
Interest income (expense)	942	(106)	1,784	(106)
Loss on extinguishment of debt	—	(174)	—	(269)
Realized gain on investments	50	—	138	—
Foreign exchange gain (loss)	3	158	7	151
Net loss	$ (5,493)	$ (5,447)	$ (18,746)	$ (19,168)
Cumulative Series C preferred stock dividends	(40)	—	(1,054)	—
Net loss attributable to common shareholders	$ (5,533)	$ (5,447)	$ (19,800)	$ (19,168)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.19)	$ (3.23)	$ (2.29)	$ (12.53)
Weighted-average shares of common stock outstanding-basic and diluted	28,409,518	1,689,094	8,649,245	1,530,218