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 18, 2019

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 18, 2019, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 18, 2019

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 18, 2019

By: /s/ David L. Lucchino

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

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Exhibit 99.1

Frequency Therapeutics Provides Business Updates and Reports Third Quarter 2019 Financial Results

Initiated FX-322 Phase 2a clinical study for sensorineural hearing loss

Granted FDA Fast Track designation for FX-322

Completed an $88.6 million initial public offering in October 2019, providing Company runway into 2022

WOBURN, Mass., November 18, 2019 - 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 ending September 30, 2019.

"This has been a tremendously productive period for Frequency as we commenced our Phase 2a study, received Fast Track designation for FX-322, and completed key financings that we believe will enable us to advance our hearing program and further diversify our portfolio as we apply our progenitor cell activation platform in numerous disease areas," said Frequency Therapeutics Chief Executive Officer David Lucchino. "We have opened all U.S. sites for our Phase 2a study of FX-322 and remain on track to report top-line data in the second half of next year. We believe FX-322 has the potential to be a restorative, disease-modifying treatment for the millions of patients with hearing loss, with the aim of improving hearing function, including speech intelligibility. We also continue to advance our multiple sclerosis development efforts and remain focused on moving our remyelination program into the clinic in the second half of 2021."

Recent Business 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, expected to enroll approximately 96 adults aged 18 to 65 with stable sensorineural hearing loss at 12 sites in the U.S. Patients will be randomized to one of four groups, each of which will receive four injections, once per week, at weekly intervals starting at the initial visit. The key efficacy endpoints of this trial are word recognition (WR), words-in-noise (WIN), and standard pure tone audiometry. Exploratory efficacy endpoints are extended high frequency pure tone audiometry, the Tinnitus Functional Index (TFI), and the Hearing Handicap Inventory in Adults (HHIA).

- **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 Initial Public Offering (October 2019)**: Frequency completed an initial public offering of 6,325,000 shares of common stock, which included the partial exercise of the underwriters' over-allotment option for 325,000 shares, at the offering price of $14.00 per share for total gross proceeds of approximately $88.6 million, before deducting underwriting discounts and commissions and other offering expenses. Frequency common stock began trading on the Nasdaq Global Select Market on October 3, 2019 under the ticker symbol "FREQ." J.P. Morgan, Goldman Sachs and Cowen were joint book-running managers for the offering.

- **Presentation of FX-322 Phase 1/2 Data (September 2019)**: At the American Academy of Otolyrangology – Head and Neck Surgery annual meeting, Frequency presented data from the Phase 1/2 study of FX-322 in which a statistically significant and clinically meaningful improvement in key measures of hearing loss, including clarity of sound and word understanding, was observed. In addition, FX-322 was observed to be well-tolerated with no serious adverse effects. The Company also presented preclinical and clinical data from the Phase 1/2 study at the 2nd Annual International Symposium on Inner Ear Therapeutics (ISIET) in Hanover, Germany in November.

- **Strengthened Leadership Team (August 2019)**: Frequency expanded its leadership team with the addition of Dana Hilt, M.D., as Chief Medical Officer, William Chin, M.D. as head of Clinical and Translational Science; Jason Glashow as head of Corporate Affairs; Jeff Hrkach, Ph.D., as head of Technology Development; and Michael Bookman as Deputy General Counsel.

- **Completion of Crossover Financing (July 2019)**: The Company completed a $62 million private financing led by Perceptive Advisors and a syndicate that included Deerfield Management, RTW Investments, and Mizuho Securities Principal Investment.

- **License and Collaboration Agreement with Astellas (July 2019)**: Frequency entered into a license and collaboration agreement with Astellas Pharma, Inc. (Astellas) for FX-322. Frequency received an $80 million upfront payment with the potential of up to $545 million in future milestone payments as well as double-digit royalties. Astellas obtained the exclusive rights to develop and commercialize FX-322 in ex-U.S. markets; Frequency retains U.S. rights.

Third Quarter 2019 Financial Results

Cash Position: Cash, cash equivalents and short-term marketable securities at September 30, 2019 were $165.3 million, as compared to $42.2 million at December 31, 2018. Cash, cash equivalents and short-term marketable securities at September 30, 2019 do not include the net proceeds of the Company's initial public offering, $79.2 million, which closed in October 2019. Based on its current plans, the Company expects its existing cash, cash equivalents and short-term marketable securities, including the proceeds from its October initial public offering, will be sufficient to fund its operations into 2022.

Revenue: Revenue was $24.2 million for the third quarter of 2019. The Company had no revenue in the comparable period 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 third quarter of 2019, representing the royalty to the Massachusetts Institute of Technology on the $80 million upfront payment from Astellas.

Research & Development Expenses: Research and development expenses were $5.2 million for the third quarter of 2019 as compared to $3.5 million for the third quarter of 2018. The increase of $1.7 million was primarily due to increased costs related to the Company's lead product candidate, FX-322, including external development costs as the Company prepared to commence a Phase 2a clinical trial 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.

General and Administrative Expenses: General and administrative expenses were $4.3 million for the third quarter of 2019 as compared to $1.5 million for the third quarter of 2018. The increase of $2.8 million 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 increased cost for consulting and professional fees.

Net Loss: Net loss was $0.6 million for the third quarter of 2019 as compared to $5.1 million for the third quarter of 2018. The decrease of $4.5 million was primarily due to the impact of recognizing $24.2 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 development 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 agreements with academic and nonprofit research organizations including The Scripps Research Institute, Massachusetts Eye and Ear, 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 sufficiency of the Company's cash, cash equivalents and short-term marketable securities, the intended purpose of Fast Track designation, the treatment potential of FX-322, the design and enrollment of the Phase 2a clinical trial of FX-322, the timing of top-line data from the Phase 2a clinical trial, estimates of the size of the hearing loss population and population at risk for hearing loss, future milestone payments under the license and collaboration agreement with Astellas, the Company's ability to advance its hearing program and further diversify its portfolio, the timing of the remyelination program, 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; 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, 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 final prospectus filed with the Securities and Exchange Commission (SEC) on October 4, 2019 relating to its Registration Statement on Form S-1 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)
(unaudited)

	September 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities [1]	$ 165,321	$ 42,189
Working capital [1]	$ 94,517	$ 39,164
Total Assets [1]	$ 170,849	$ 44,548
Deferred revenue	$ 55,762	—
Convertible preferred stock and non-controlling interest [2, 3]	$ 151,675	$ 88,708
Stockholders' deficit	$ (59,652)	$ (48,282)

1 Excludes the net proceeds of $79.2 million from the completion of the Company's IPO in October 2019.

2 The convertible preferred stock was converted into common stock in conjunction with the Company's IPO in October 2019.

3 Non-controlling interest represents the preferred stock of the Company's Japanese subsidiary which was converted into Company common stock in conjunction with the Company's IPO in October 2019.

Frequency Therapeutics, Inc.

Consolidated Statements of Operations
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Month Ended September 30,	
	2019	2018	2019	2018
Revenue	$ 24,238	$ —	$ 24,238	$ —
Operating expenses:				
Royalty	16,000	—	16,000	—
Research and development	5,221	3,550	12,588	8,959
General and administrative	4,269	1,507	9,837	4,660
Total operating expenses	25,490	5,057	38,425	13,619
Loss from operations	(1,252)	(5,057)	(14,187)	(13,619)
Interest income	624	—	842	—
Interest expense	—	(63)	—	(95)
Realized gain on investments	62	—	88	—
Foreign exchange gain (loss)	(9)	(16)	4	(7)
Net loss	(575)	(5,136)	(13,253)	(13,721)
Cumulative Series C convertible preferred stock dividends	(1,014)	—	(1,014)	—
Net loss attributable to common stockholders	$ (1,589)	$ (5,136)	$ (14,267)	$ (13,721)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.73)	$ (3.26)	$ (7.17)	$ (9.29)
Weighted average shares outstanding-basic and diluted	2,163,289	1,575,728	1,990,106	1,476,678