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): April 30, 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, 2 nd 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 7.01. Regulation FD Disclosure.

On April 30, 2020, in connection with the distribution of proxy materials for the Frequency Therapeutics, Inc. (the "Company") annual meeting of stockholders, the Company included in its 2019 Annual Report a letter to stockholders from its President and Chief Executive Officer. A copy of the letter to stockholders is furnished as Exhibit 99.1 to this Current Report on Form 8-K and the 2019 Annual Report is available on the Investors & Media section of the Company's website at https://investors.frequencytx.com/.

The information contained in Item 7.01 of this Current Report on 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 filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibit

Exhibit No.	Description
99.1	Letter to Stockholders dated April 30, 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: April 30, 2020

By: /s/ Michael D. Bookman
Name: Michael D. Bookman
Title: Deputy General Counsel and Secretary

A letter from David L. Lucchino

Chief Executive Officer

Dear fellow shareholders,

This past year was one of tremendous progress for Frequency Therapeutics, and I could not be more proud to lead an organization that may redefine the landscape for regenerative therapeutics and transform the treatment paradigm for those suffering from the most common form of hearing loss.

We achieved several major milestones in 2019, advancing our hearing program, executing a global licensing and collaboration agreement, expanding our organization for the demands of future growth and taking the company public. We reported data from our Phase 1/2 study of FX-322, our lead product candidate for the treatment of sensorineural hearing loss (SNHL), in which we observed a hearing signal and the potential return of function in patients with hearing loss. We believe these results have never before been seen in hearing research and have positioned Frequency to advance what may be the first restorative, disease-modifying treatment for the millions of patients with SNHL. Our approach may potentially transform how this debilitating condition is treated beyond the device-based standard of care.

We entered into a global licensing and collaboration agreement for FX-322 with Astellas Pharma Inc. in a deal worth more than $600 million, including an $80 million up-front payment. Astellas has the rights to develop and commercialize FX-322 outside of the U.S., while Frequency maintains rights in the U.S. market.

Our Phase 2a trial of FX-322 commenced dosing in October 2019 and was followed by the U.S. Food and Drug Administration (FDA) granting FX-322 Fast Track designation, increasing our ability to engage with the agency regarding our ongoing development efforts.

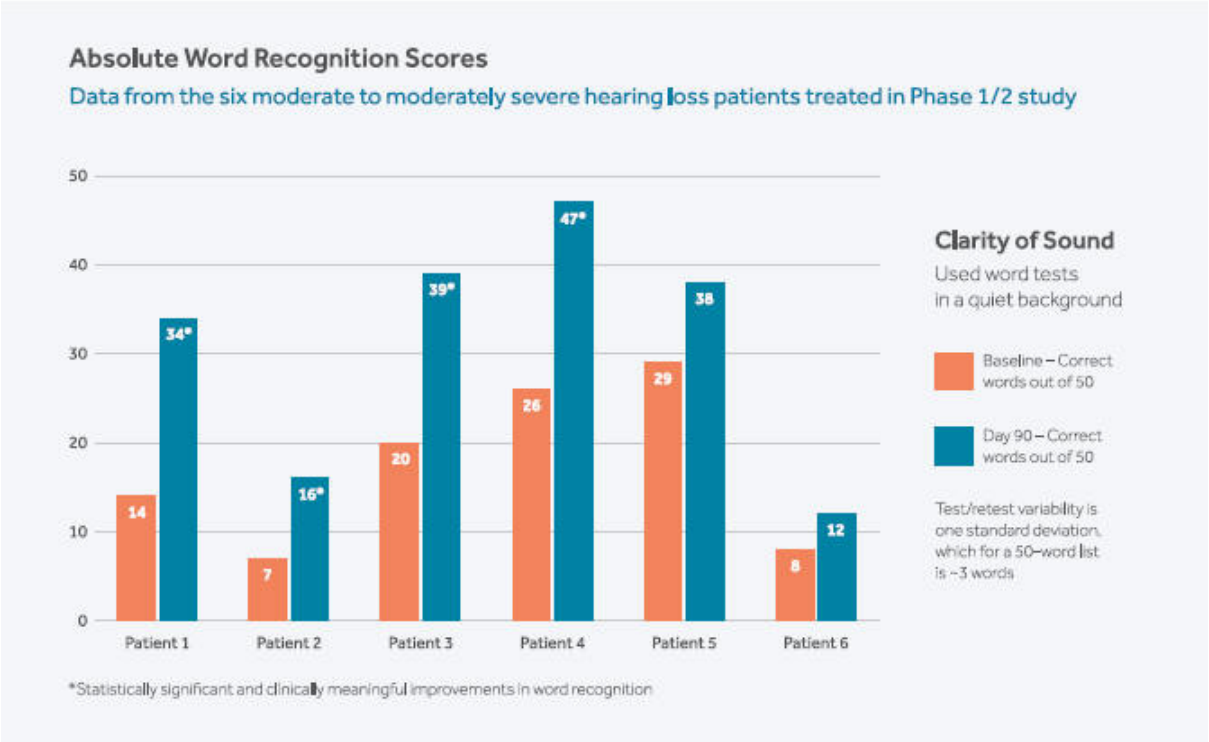
Looking ahead, we believe 2020 will be a year critical to the growth of Frequency. As of this writing, we are still assessing the impact of COVID-19 on our business and Phase 2a clinical study, but we believe that we are in a strong position, both in terms of resources and study design, to meet our objectives. We will continue to drive our leadership in hearing regeneration, advance our program for remyelination in multiple sclerosis (MS), as well as actively evaluate new opportunities where we can leverage our progenitor cell activation (PCA) platform to further expand this emerging area of regenerative medicine.

Our hearing program and the importance of "clarity"

The cochlea is the organ within the ear that controls hearing. Within the cochlea are rows of inner and outer sensory (or hair) cells that help filter and tune sounds while also providing connections to the brain. When theses cells are damaged – either by noise, age or infection – they do not naturally regenerate. This damage can lead to sensorineural hearing loss, the primary cause of 90 percent of all hearing loss.

But underneath these rows of sensory cells are the progenitor cells that created the original hair cells when we were *in utero* . FX-322 is made of two small molecules that, when combined, aim to turn on these progenitor cells and enable the growth of new sensory cells (while also creating new progenitor cells) and potentially restore hearing.

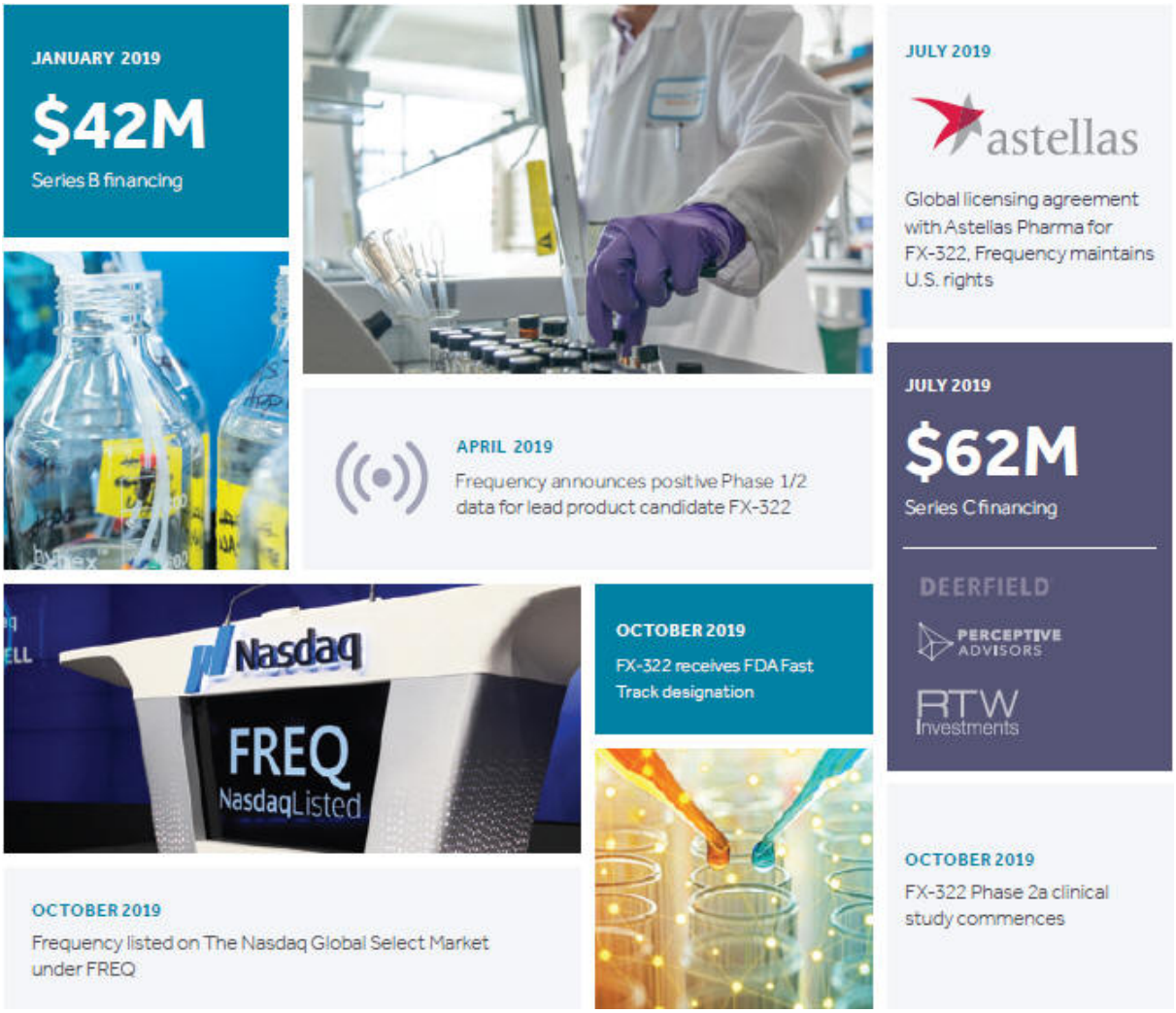
In our Phase 1/2 study of FX-322, we observed clinically meaningful improvements in key measure of hearing function in SNHL patients. Most compelling were the increases we observed in certain subjects in their word recognition scores, an indication that these individuals were hearing more clearly. Clarity of sound is essential for hearing health – and we believe remains the largest unmet need in the treatment of hearing loss. While wearing devices such as hearing aids can increase volume, they increase sound into a broken system. FX-322 aims to repair that system to improve audibility and clarity.



Also, several subjects saw improvements in their pure tone audiometry scores at higher frequencies – which was a key finding as it is high frequencies where hearing loss typically starts.

The objectives of our double-blind, placebo-controlled, single- and repeat-dose Phase 2a 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. Subjects are carefully screened to ensure that their hearing deficit has not changed over several months, and only one ear is dosed, adding a third control in what we believe is a rigorously designed study.

We believe that quality of life for those using hearing aids (and for millions of untreated patients) can be transformed if FX-322 continues to show an impact on clarity – and may also potentially reduce the risks of other co-morbidities, as hearing loss is the largest modifiable risk factor for developing dementia and is also associated with depression and broader cognitive decline.



Building our pipeline beyond hearing

We continue to make progress in our efforts to advance a clinical candidate for remyelination in multiple sclerosis and intend to file an investigational new drug application in the second half of 2021. Our discovery efforts in MS also use a combination of small molecules, further building on our PCA approach.

Today, more than a dozen treatments slow MS disease progression or treat symptoms, but there are no therapies to reverse or repair damage. We see remyelination as the next frontier in MS research.

Beyond hearing and MS, we are also exploring the potential of our PCA approach in other disease areas, engaging with biopharma companies and academic labs, as we consider a wide range of potential new targets where we believe our technology platform can provide benefit for patients with devastating degenerative disease – and over time create a repeatable model for sustained, long-term growth.

Becoming FREQ

Our ambitious development efforts require significant capital, and we have secured funding that will enable us to pursue our immediate near-term opportunities.

On the heels of our Phase 1/2 data for FX-322, we closed a $62.0 million crossover round, led by Perceptive Advisors and a syndicate that included several new and existing investors.

Our agreement with Astellas last July yielded an additional $80 million for our FX-322 development efforts, and now our companies are working closely together toward conducting global clinical studies. There is the potential of $90 million in milestone payments when Astellas commences a Phase 2b study in Europe and Asia and an additional $140 million for a Phase 3 start in those regions.

In October of 2019, we raised gross proceeds of $88.6 million in our initial public offering, and Frequency began trading on the Nasdaq Global Select Market with the ticker symbol “FREQ.” We are thankful to J.P. Morgan, Goldman Sachs and Cowen, which were joint book-running managers for the offering. We ended 2019 with more than $217 million in cash, cash equivalents and short-term investments, funds that enable us to run our company into 2022.

As a research and development company, we are focusing these proceeds on innovation and science, being careful stewards of our investors’ capital as we carefully build our team with recognized leaders in hearing and MS research. In 2021, we plan to move to a new headquarters in Lexington, Mass., which will include laboratory facilities and will bring together employees from our Woburn, Mass., and Farmington, Conn., sites.

We are grateful to all clinical investigators and their staff and all of the individuals participating in our clinical studies. We deeply appreciate those who have invested their capital in our vision. And finally, I am amazed and inspired by the contributions of our team and their commitment to science and to finding new treatments for patients with debilitating diseases. It is an honor to work with this group.

What was once an audacious idea – creating a drug to help those with hearing loss – is now a unique opportunity to impact millions around the world.

I believe we are on our way to doing just that.

David L. Lucchino
Chief Executive Officer