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): August 12, 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 August 12, 2020, Frequency Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 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	Q2 Press Release issued on August 12, 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: August 12, 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 SECOND QUARTER 2020 FINANCIAL RESULTS

Expects to Complete Enrollment of FX-322 Phase 2a Study for Sensorineural Hearing Loss by Early Q4 2020; Study Readout Anticipated in Q2 2021

Recently Announced Clinical Data Show FX-322 Delivery to the Cochlea and Preliminary Evidence of a Durable Clinical Benefit; Plans New Studies in Additional Patient Populations

Raised $42.3 Million Private Placement, Providing Company Runway into 2023

WOBURN, Mass., August 12, 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 second quarter ended June 30, 2020.

"We are pleased with the steady progress in our Phase 2a study, despite the challenges of the pandemic, and we anticipate completing enrollment early in the fourth quarter of 2020 and sharing data from the study in the second quarter of 2021," said Frequency Therapeutics Chief Executive Officer David L. Lucchino. "In the last quarter, we generated compelling cochlear drug delivery data for FX-322, as well as important durability data suggesting that some patients who were given a single injection of FX-322 in our original Phase 1/2 study maintained statistically significant improvements in word recognition between 12 and 21 months following administration. We believe that these clinical advances are important building blocks as we work to further our understanding of FX-322 drug activity and the patient populations we hope to treat.

I also want to thank the medical professionals and patients who have enabled the study to move forward in these difficult conditions. Their commitment, and compliance, gives us great confidence in the quality of data that will be produced."

Recent Program and Business Updates

FX-322 Phase 2a Study for Sensorineural Hearing Loss: Patient enrollment for Frequency's FX-322 Phase 2a study has been steady over the second quarter of 2020 and based on current projections, the Company expects to achieve target enrollment by early in the fourth quarter of 2020. Based on this timeline, the Company expects to report study data in the second quarter

of 2021. The 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). In addition, in order to evaluate additional potential patient populations that FX-322 may treat, later this year the Company plans to commence a safety study of FX-322 in patients with age-related hearing loss, and also is evaluating other potential studies.

The objectives of the Phase 2a study are to further establish the hearing signal observed in the completed Phase 1/2 study, evaluate the impact of multiple doses and provide deeper insights on endpoints and the appropriate patient population for future studies. FX-322 Phase 2a 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 (WR), words-in-noise and pure tone audiometry. Tinnitus and quality-of-life measures will also be evaluated using the Tinnitus Functional Index and the Hearing Handicap Inventory for Adults, respectively. The Phase 2a study has four dose cohorts, and hearing function will be regularly tested over the course of seven months following the first dosing.

FX-322 Phase 1/2 Durability of Clinical Response Data: In June 2020, the Company shared preliminary findings from a longer-term, follow-up study of five patients that had been treated with FX-322 in the randomized portion of the Phase 1/2 study, and where the Company observed improvement in certain key measures of hearing loss. WR tests were performed for five patients at timepoints between 12- and 21-months following FX-322 administration.

Four of the patients that were observed to have statistically significant WR scores during the Phase 1/2 study were observed to have maintained the hearing benefit, three of which remained at statistically significant levels. An additional patient who did not achieve a statistically significant improvement in WR during the Phase 1/2 study was also retested and it was observed that the WR score had returned to baseline. The Company plans to share results of this follow-up study at the upcoming American Academy of Otolaryngology – Head & Neck Surgery meeting in September 2020.

Exploratory Clinical Pharmacokinetic Study Data: In May 2020, Frequency 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 drug delivery approach, study results showed measurable concentrations of FX-322 in all samples measured 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, based on computer models.

Private Placement: In July 2020, the Company completed the issuance and sale of 2,350,108 shares of its common stock in a private placement to institutional and accredited investors, including Wasatch Global, Federated Hermes Kaufmann Funds, RTW Investments, Perceptive Advisors, Driehaus Capital Management, Maven Investment Partners US and Alexandria Venture Investments. The transaction resulted in gross proceeds of $42.3 million and net proceeds to the Company of $40.1 million, after deducting placement agent fees and other offering expenses.

Update of COVID-19 Impact on Operations: Frequency's offices are located in states that are currently operating under a phased re-opening plan in response to the COVID-19 pandemic. At present, the majority of employees continue to work from home, while nearly a quarter of Frequency's workforce, consisting of mainly laboratory personnel, have periodically worked in rotating teams to ensure the continuation of essential experiments. The Company's Farmington, CT research site, co-located with the University of Connecticut, has resumed activity at a 50 percent level after a period of paused activity due to state lock down orders. Thus, while the Company has resumed experiments at its Farmington site, certain key experiments have been transitioned to its offices in Woburn, MA, while third party and contract research organizations also have been engaged to advance certain projects. The Company also has taken steps consistent with the FDA's updated industry guidance for conducting clinical trials.

Upcoming Conferences and Investor Events: Frequency executives plan to present at the following upcoming (virtual) events:

- American Academy of Otolyrangology – Head and Neck Surgery 2020 Meeting and OTO Experience: September 13 – 16, 2020
- Cantor Fitzgerald Virtual Global Healthcare Conference: September 15 – 17, 2020
- Oppenheimer Healthcare Fall Summit: September 22 – 23, 2020
- 2020 Cell and Gene Meeting on the Mesa: October 12 – 16, 2020

Second Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and short-term investments on June 30, 2020 were $195.4 million, as compared to $217.4 million on December 31, 2019. Subsequent to the end of the second quarter, the Company completed a private placement, resulting in $42.3 million in gross proceeds and $40.1 million in net proceeds to the Company, after deducting placement agent fees and other offering expenses.

Based on current plans and assumptions, the Company expects its existing cash and cash equivalents, short-term investments, and net proceeds from the private placement will be

sufficient to fund its operations into 2023. This guidance does not include potential future milestones which could be received from Astellas for continued FX-322 development.

Revenue: Revenue was $8.5 million and $15.8 million for the three- and six-month periods ended June 30, 2020, respectively. The Company had no revenue in the comparable periods of 2019.

Research & Development Expenses: Research and development expenses were $8.8 million and $15.4 million for the three- and six-month periods ended June 30, 2020, respectively, as compared to $3.9 million and $7.4 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 $6.0 million and $12.2 million for the three- and six-month periods ended June 30, 2020, respectively, as compared to $3.1 million and $5.6 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 $6.0 million and $10.9 million for the three- and six-month periods ended June 30, 2020, respectively, as compared to $6.9 million and $12.7 million for the comparable periods of 2019. The decrease in net loss in 2020 reflects the recognition of revenue under the agreement with Astellas partially offset by the increase in operating expenses.

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 an ongoing Phase 2a clinical study in patients with sensorineural hearing loss. 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 Phase 2a clinical trial, pace and timing of enrollment for the Phase 2a clinical trial, the timing of top-line data from the Phase 2a clinical trial, the novelty of the exploratory pharmacokinetic study, the implications of the results of the exploratory pharmacokinetic study in combination with our other trials, the results and implications of the Phase 1/2 durability of response data, expected presentation of such results, the therapeutic levels of FX-322 predicted in the exploratory pharmacokinetic study, the timing of the FX-322 clinical study in patients with age related hearing loss, 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 expected use of proceeds from the private placement, the sufficiency of the Company's cash, cash equivalents, short-term investments and private placement funds, 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 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 May 14, 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	$ 8,523	$ —	$ 15,787	$ —
Operating expenses:				
Research and development	8,764	3,921	15,434	7,367
General and administrative	5,959	3,098	12,208	5,568
Total operating expenses	14,723	7,019	27,642	12,935
Loss from operations	(6,200)	(7,019)	(11,855)	(12,935)
Interest income	178	119	888	218
Realized (loss) gain on investments	(4)	26	65	26
Foreign exchange gain	8	22	9	13
Loss before income taxes	$ (6,018)	$ (6,852)	$ (10,893)	$ (12,678)
Income taxes	(7)	—	(45)	—
Net loss	$ (6,025)	$ (6,852)	$ (10,938)	$ (12,678)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.19)	$ (3.42)	$ (0.35)	$ (6.67)
Weighted-average shares of common stock outstanding-basic and diluted	31,066,686	2,005,054	30,967,453	1,902,092

Frequency Therapeutics, Inc.

Consolidated Balance Sheet Data

(in thousands)
(unaudited)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 195,379	$ 217,355
Working capital	157,259	168,575
Total assets	204,786	223,218
Total liabilities	43,085	55,860
Accumulated deficit	(79,826)	(68,888)
Total stockholders' equity	161,701	167,358

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