

**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 10, 2023

FREQUENCY THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39062

(Commission File Number)

47-2324450
(IRS Employer
Identification No.)

75 Hayden Avenue, Suite 300
Lexington, MA 02421
(Address of principal executive offices) (Zip Code)

(781) 315-4600
(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 Stock Market LLC (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 10, 2023, Frequency Therapeutics, Inc. (the “Company”) announced its financial results for the quarter and year ended December 31, 2022 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 exhibits relate to Item 2.02, which shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on March 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 10, 2023

By: /s/ David L. Lucchino

Name: David L. Lucchino

Title: President and Chief Executive Officer



Frequency Therapeutics Provides Business Updates and Fourth Quarter and Full Year 2022 Financial Results

LEXINGTON, Mass., March 10, 2023 – Frequency Therapeutics, Inc. (Nasdaq: FREQ), a regenerative medicine company focused on developing therapeutics to activate a person’s innate potential to restore function, today announced business updates and financial results for the fourth quarter and full year ended December 31, 2022.

“The Frequency team continues to make important progress with our novel therapeutic program designed to induce remyelination for individuals living with multiple sclerosis and remains on track to initiate clinical development for a potentially first-in-class therapy for this debilitating disease in the first half of 2024. Our current cash position takes us into Q1 2025, which enables us to advance development of this program through an initial clinical study,” said David L. Lucchino, Frequency’s Chief Executive Officer. “We believe our remyelination program has the potential to produce a restorative effect by stimulating oligodendrocyte precursor cells to myelinate axons, and we are excited that our compounds have shown in *in vivo* models significantly greater remyelinating effect than prior published approaches.”

Recent Program and Business Updates

- In February, Frequency announced that the FX-322-208 study, a Phase 2b study for acquired Sensorineural Hearing Loss (SNHL), did not achieve its primary endpoint of speech perception. Based on this outcome, Frequency has discontinued both the FX-322 program and its second development program for hearing restoration, FX-345, which had been enrolling a Phase 1b study for acquired SNHL.
- The Company also announced it will now focus discovery efforts on its program to induce remyelination for individuals living with multiple sclerosis (MS), an area where there currently are no restorative options for patients. MS is characterized by demyelination, stripping axons of the myelin sheaths that support neuronal signal conduction and axonal survival. Previously, Frequency reported it had identified a novel target relevant for remyelination and that modulation of this target induced robust oligodendrocyte differentiation and expression of myelin proteins *in vitro*. The Company has identified multiple new chemical entities that induce robust remyelination following demyelination in an adult *in vivo* animal model and these novel agents substantially outperform other clinically studied remyelination agents in head-to-head *in vivo* studies.

The MS program is independent of the Frequency’s hearing efforts, with a distinct molecular target, mechanism, progenitor cell population, and small molecule drug candidates. Further, a well-defined clinical path with objective biomarkers such as visual evoked potential (VEP) and magnetic resonance imaging (MRI) exist for studying the performance of remyelination therapies in MS patients.

- Given the outcome of the FX-322-208 study, the Company has undertaken actions to reduce expenses and headcount as part of an overall restructuring, downsizing personnel by approximately 55 percent. These cuts will be completed by the end of April 2023. The
-

Company will remain at its current headquarters in Lexington where it maintains both laboratory and office space.

- CEO and President David L. Lucchino, who had been on medical leave as of February 7, 2023, returned to the Company on March 1, 2023, and has assumed all prior duties.

Fourth Quarter and Full Year 2022 Financial Results

Cash Position: As of December 31, 2022, Frequency had cash, cash equivalents and marketable securities of \$83.1 million (excluding restricted cash), or \$68.9 million net of debt.

Frequency believes that the restructuring activities will generate sufficient cost savings to extend its runway into 2025 and enable it to complete a first clinical trial of its MS Program in 2H 2024.

Research and Development Expenses: Research and development expenses were \$10.6 million for the three months ended December 31, 2022, as compared to \$12.8 million for the comparable period of 2021. Research and development expenses were \$49.4 million for the full year ended December 31, 2022, as compared to \$60.9 million for the comparable period of 2021. Excluding stock-based compensation expense of \$1.7 million for the three months ended December 31, 2022, and \$7.7 million for the full year ended December 31, 2022, research and development expenses for the three months and full year ended December 31, 2022, were \$8.9 million and \$41.7 million, respectively.

General and Administrative Expenses: General and administrative expenses were \$7.5 million for the three months ended December 31, 2022, as compared to \$8.6 million for the comparable period of 2021. General and administrative expenses were \$33.6 million for the full year ended December 31, 2022, as compared to \$37.2 million for the comparable period of 2021. Excluding stock-based compensation expense of \$2.7 million for the three months ended December 31, 2022, and \$12.1 million for the full year ended December 31, 2022, general and administrative expenses for the three months and full year ended December 31, 2022, were \$4.8 million and \$21.5 million, respectively.

Net Loss: Net loss was \$17.4 million for the three months ended December 31, 2022, as compared to \$21.5 million for the comparable period of 2021. Net loss was \$81.6 million for the full year ended December 31, 2022, as compared to \$84.7 million for the comparable period of 2021.

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 treatment potential and timing of Frequency Therapeutics' (the Company) remyelination program in MS (MS Program), including the timing of clinical development, the existence of a well-defined clinical path for the MS Program, potential application of the regenerative medicine platform to other diseases, the ability of our regenerative medicine platform to provide patient benefit, and the sufficiency of the Company's capital resources, including having sufficient resources to complete a first clinical trial in its MS Program.

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

planned clinical trials, research and development and manufacturing activities, 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 unproven approach of the PCA platform and the inability to identify additional potential product candidates; the lengthy, expensive and uncertain process of clinical drug development and regulatory approval; the Company's limited experience successfully obtaining marketing approval for and commercializing product candidates; the results of pre-clinical studies not being indicative of the results from clinical trials; adverse events or undesirable side effects; disruptions at the FDA and other regulatory agencies; failure to identify additional product candidates; new or changed legislation; costly and damaging litigation, including related to product liability or intellectual property or brought by stockholders; misconduct by employees or independent contractors; reliance on third parties, including to conduct clinical trials and manufacture product candidates; compliance with changing laws and regulations, including healthcare and environmental, health, data privacy and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property rights covering product candidates; security breaches or failure to protect private personal information; attracting and retaining key personnel; and the Company's ability to manage growth.

These and other important factors discussed under the caption "Risk factors" in the Company's Form 10-K filed with the Securities and Exchange Commission (SEC) on March 10, 2023, 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.

About Frequency Therapeutics

Headquartered in Lexington, Mass., Frequency Therapeutics is pioneering a new category in regenerative medicine that aims to restore human function by developing therapeutics that activate a person's innate regenerative potential within the body through the activation of progenitor cells. The Company's lead preclinical program is designed to activate oligodendrocyte precursor cells with the goal of driving remyelination and potential functional recovery for individuals living with multiple sclerosis. For more information, visit www.frequencytx.com and follow Frequency on Twitter @Frequencytx.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenue	\$ —	\$ —	\$ —	\$ 14,068
Operating expenses:				
Research and development	10,649	12,754	49,418	60,923
General and administrative	7,547	8,605	33,584	37,176
Total operating expenses	<u>18,196</u>	<u>21,359</u>	<u>83,002</u>	<u>98,099</u>
Loss from operations	(18,196)	(21,359)	(83,002)	(84,031)
Interest income	456	82	1,327	397
Interest expense	(312)	(182)	(961)	(764)
Realized gain (loss) on investments	—	—	3	(23)
Foreign exchange gain (loss)	2	—	(5)	16
Other income (expense), net	695	(39)	1,056	(266)
Loss before income taxes	<u>\$ (17,355)</u>	<u>\$ (21,498)</u>	<u>\$ (81,582)</u>	<u>\$ (84,671)</u>
Tax (provision) benefit	(7)	(2)	2	(15)
Net loss	<u>\$ (17,362)</u>	<u>\$ (21,500)</u>	<u>\$ (81,580)</u>	<u>\$ (84,686)</u>
Net loss per share attributable to common stockholders- basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.62)</u>	<u>\$ (2.33)</u>	<u>\$ (2.47)</u>
Weighted-average shares of common stock outstanding- basic and diluted	<u>35,262,083</u>	<u>34,596,227</u>	<u>35,075,924</u>	<u>34,351,274</u>

Frequency Therapeutics, Inc.
Consolidated Balance Sheet Data
(in thousands)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	\$ 83,097	\$ 142,426
Working capital	66,467	123,319
Total assets	121,238	185,358
Total liabilities	52,043	54,534
Accumulated deficit	(261,665)	(180,085)
Total stockholders' equity	69,195	130,824

Contacts:

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

Media Contact:
Frequency Therapeutics
Email: media@frequencytx.com

###

