

**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 24, 2023

Foghorn Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39634
(Commission
File Number)

47-5271393
(IRS Employer Identification No.)

500 Technology Square, Ste 700
Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

(Registrant's telephone number, including area code): (617) 586-3100

Not Applicable
(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:

- 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, \$0.0001 par value per share	FHTX	The Nasdaq Global 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 8.01 Other Events.

On April 24, 2023, Foghorn Therapeutics Inc. (the "Company") issued a press release providing an update on the Company's FHD-609 program in synovial sarcoma and SMARCB1-deleted tumors. The Company announced that enrollment of the dose escalation portion of the study has been completed and a maximum tolerated dose has been identified. The Company also announced that it is pausing enrollment in the study following a grade 4 QTc prolongation event in a synovial sarcoma patient at the second highest dose. After communicating the enrollment pause to U.S. and European regulators, the Food and Drug Administration placed the study on partial clinical hold in the United States, while allowing patients currently enrolled and benefiting from therapy to continue dosing. The Company further announced that it is not at this time planning to pursue a dose expansion study independently.

A copy of the press release is attached to this Current Report as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued on April 24, 2023

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.

FOGHORN THERAPEUTICS INC.

By: /s/ Allan Reine
Allan Reine, M.D.
Chief Financial Officer

Date: April 24, 2023

Foghorn Therapeutics Provides an Update on FHD-609

CAMBRIDGE, Mass.--(GLOBE NEWSWIRE)--April 24, 2023--Foghorn[®] Therapeutics Inc. (Nasdaq: FHTX), a clinical-stage biotechnology company pioneering a new class of medicines that treat serious diseases by correcting abnormal gene expression, today announced an update on the FHD-609 program in synovial sarcoma and SMARCB1-deleted tumors.

Foghorn is pausing enrollment in the FHD-609 study in synovial sarcoma and SMARCB1-deleted tumors due to a grade 4 QTc prolongation event in a synovial sarcoma patient at the second highest dose. Enrollment of the dose escalation portion of the study has been completed and a maximum tolerated dose has been identified. Patients in the affected cohort were dose reduced and additional safety measures have been discussed with and provided to the study investigators. The Company promptly communicated the enrollment pause and risk mitigation actions to the FDA and European regulatory authorities. Consequently, the FDA placed the study on partial clinical hold in the United States, while allowing patients currently enrolled and benefiting from therapy to continue dosing and to remain on FHD-609. The Company is not at this time planning to pursue a dose expansion study independently.

About Foghorn Therapeutics

Foghorn[®] Therapeutics Inc. is discovering and developing a novel class of medicines targeting genetically determined dependencies within the chromatin regulatory system. Through its proprietary scalable Gene Traffic Control[®] platform, Foghorn is systematically studying, identifying and validating potential drug targets within the chromatin regulatory system. The Company is developing multiple product candidates in oncology. Visit our website at www.foghornrx.com for more information on the Company, and follow us on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

This press release contains “forward-looking statements” regarding the Company’s clinical program for FHD-609. Forward-looking statements include statements regarding the Company’s clinical trials, product candidates and research efforts and other statements identified by words such as “could,” “may,” “might,” “will,” “likely,” “anticipates,” “intends,” “plans,” “seeks,” “believes,” “estimates,” “expects,” “continues,” “projects” and similar references to future periods. Forward-looking statements are based on our current expectations and assumptions regarding capital market conditions, our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions, including risks relating to our clinical trials and other factors set forth under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission. Any forward-looking statement made in this press release speaks only as of the date on which it is made.

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