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, 2022

Foghorn Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39634**	**47-5271393**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

500 Technology Square, Ste 700

Cambridge, MA	**02139**
(Address of principal executive offices)	(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 2.02 Results of Operations and Financial Condition.

On March 10, 2022, Foghorn Therapeutics Inc. (the "Company") issued a press release announcing certain of the Company's financial results for the year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and 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 into any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filling.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Foghorn Therapeutics Inc. on March 10, 2022

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: March 10, 2022

Exhibit 99.1

Foghorn Therapeutics Provides Full Year 2021 Corporate Update and 2022 Outlook

– Initial clinical data for FHD-286 expected in H1'22 and FHD-609 as early as H1'22

– Advancing broad therapeutic pipeline of oncology programs including protein degraders, enzymatic inhibitors and transcription factor disruptors

– Entered strategic collaboration in December 2021 with Loxo Oncology at Lilly for five novel oncology targets using Foghorn's proprietary Gene Traffic Control® Platform, including $380 million in upfront consideration

– Significant cash runway including $154.3 million in cash, cash equivalents and marketable securities at year end plus the $300 million received in January as part of the Lilly collaboration equating to $454.3 million in pro forma year-end cash, cash equivalents and marketable securities.

CAMBRIDGE, Mass.--(GLOBE NEWSWIRE)— March 10, 2022—Foghorn Therapeutics Inc. (Nasdaq: FHTX), a clinical stage biotechnology company pioneering a new class of medicines that modulate gene expression through selectively targeting the chromatin regulatory system, today provided a corporate update including the Company's 2021 key achievements and 2022 strategic priorities in conjunction with its 10-K filing for the year ended December 31, 2021. With an initial focus in oncology, Foghorn's Gene Traffic Control® Platform and resulting broad pipeline has the potential to transform the lives of people suffering from a wide spectrum of diseases.

"The Company completed 2021 with an important strategic collaboration with Lilly for multiple novel oncology targets to come from our Gene Traffic Control® Platform, helping to set up a transformative 2022 and beyond. Our strong balance sheet allows us to invest through multiple inflection points, including advancing our clinical stage pipeline, with initial phase 1 data anticipated for both FHD-286 and FHD-609 this year, while also progressing our platform and earlier stage pipeline towards INDs and clinical studies," said Foghorn CEO Adrian Gottschalk.

Gottschalk continued, "Foghorn made significant progress in 2021, and we continue to execute on our strategy to systematically drug the chromatin regulatory system and build our capabilities to support the different modalities we use including targeted protein degradation, enzymatic inhibition, and protein disruptors, and all supported by a strong financial position."

2022 Outlook; Key Milestones

- **FHD-286 data.** Foghorn expects to provide initial Phase 1 clinical data for FHD-286, an inhibitor of BRG1/BRM, in metastatic uveal melanoma (mUM), relapsed and/or refractory acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), in the first half of 2022.

- **FHD-609 data.** Foghorn anticipates providing initial Phase 1 clinical data for FHD-609, a potent and selective heterobifunctional protein degrader of BRD9, initially being developed for the treatment of synovial sarcoma, as early as the first half of 2022.

- **BRM-selective Progress.** Foghorn is advancing its BRM-selective program in collaboration with Loxo Oncology at Lilly, with the BRM-selective inhibitor in lead optimization and the protein

degrader program in the hit-to-lead stage. BRG1 is mutated in ~5% of tumors. Over 30 different cancer types have BRG1 mutations, including up to 10% of NSCLC.

- **Pipeline Advancement.** Foghorn anticipates advancing its broad therapeutic pipeline of which the majority are wholly owned including protein degraders, enzymatic inhibitors and transcription factor disruptors targeting cancers impacted by breakdowns in the chromatin regulatory system.

- **Protein Degrader Platform**. In January 2022, Foghorn added Dannette Daniels as our Vice President, Protein Degrader Platform, continuing our investment in and expansion of our protein degrader capabilities.

- **Financial**. Foghorn significantly strengthened its balance sheet and cash runway in 2021. As of December 31, 2021, the Company had $154.3 million in cash, cash equivalents and marketable securities at year-end, plus the $300 million received as part of the Lilly collaboration in January equating to $454.3 million in year-end pro forma cash, cash equivalents and marketable securities.
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2021 Key Achievements

- **Dosed First Patient with FHD-286**. In May 2021, Foghorn announced the first patient was dosed in a first-in-human Phase 1 clinical trial of FHD-286, a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 and BRM, being developed as a treatment in i) metastatic uveal melanoma (mUM) and ii) relapsed and/or refractory acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS).

- **Dosed First Patient with FHD-609**. In August 2021, Foghorn announced the first patient was dosed in a first-in-human Phase 1 clinical trial of FHD-609, a potent, selective protein degrader of BRD9 (bromodomain-containing protein 9), a subunit of ncBAF (non-canonical BAF complex), which is being developed as a treatment for synovial sarcoma.

- **Established Strategic Collaboration with Loxo Oncology at Lilly**. In December 2021, Foghorn and Lilly announced a strategic collaboration for novel oncology targets using Foghorn's proprietary Gene Traffic Control® Platform. The collaboration established a co-development and co-commercialization agreement on Foghorn's BRM-selective program and an undisclosed program, as well as three discovery programs. Foghorn received upfront consideration of $300 million in cash under the collaboration agreement and an equity investment by Lilly of $80 million in Foghorn common stock at a price of $20 per share. Foghorn is eligible to receive up to $1.3 billion in potential milestones and retains significant financial upside through profit-sharing agreements in the U.S. on several programs coupled with significant royalties ex-U.S.

- **Advanced Top Synthetic Lethal Relationship Targets**. BRM and ARID1B represent two of the top synthetic lethal targets in cancer, where the mutation occurs in BRG1 and ARID1A paralogues, respectively. In June Foghorn announced its BRM selective inhibitor program transitioned into lead optimization. This program is now part of the Lilly collaboration. During 2021, Foghorn screens led to validated selective chemical matter against ARID1B and the Company is now using its degrader capabilities to convert these protein hits into novel selective protein degraders.

About FHD-286

FHD-286 is a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 and BRM, two highly similar proteins that are the ATPases, or the catalytic engines across all forms of the BAF complex, one of the key regulators of the chromatin regulatory system. In preclinical studies, FHD-286 has shown anti-tumor activity across a broad range of malignancies including both hematologic and solid tumors. To learn more about these studies please visit ClinicalTrials.gov. (Link here for metastatic uveal melanoma and here for AML and MDS).

About AML

Adult acute myeloid leukemia (AML) is a cancer of the blood and bone marrow and the most common type of acute leukemia in adults. AML is a diverse disease associated with multiple genetic mutations. It is diagnosed in about 20,000 people every year in the United States.

About Uveal Melanoma

Uveal (intraocular) melanoma (UM) is a rare eye cancer that forms from cells that make melanin in the iris, ciliary body, and choroid. It is the most common eye cancer in adults. It is diagnosed in about 2,000 adults every year in the United States and occurs most often in lightly pigmented individuals with a median age of 55 years. However, it can occur in all races and at any age. UM metastasizes in approximately 50% of cases, leading to very poor prognosis.

About FHD-609

FHD-609 is a potent, selective, intravenously administered protein degrader of BRD9, a component of the ncBAF complex. Preclinical studies have demonstrated tumor growth inhibition in synovial sarcoma, a cancer genetically dependent on BRD9. To learn more about the first-in-human clinical trial of FHD-609 in synovial sarcoma, please visit ClinicalTrials.gov.

About Synovial Sarcoma

Synovial sarcoma is a rare, often aggressive soft tissue sarcoma that originates from different types of soft tissue, including muscle or ligaments. Synovial sarcoma can occur at any age but is most common among adolescents and young adults. It represents around 5-10% of all soft tissue sarcomas, with ~800 new cases each year in the United States. Surgery remains the most effective treatment for synovial sarcoma, and there are limited therapeutic treatment options.

About the Strategic Collaboration with Loxo Oncology at Lilly

In December 2021, Foghorn and Loxo Oncology at Lilly entered into a strategic collaboration for novel oncology targets. Under the terms of the agreement, Foghorn received upfront consideration of $300 million in cash for the collaboration agreement and an equity investment by Lilly of $80 million in Foghorn common shares at a price of $20 per share. The collaboration includes a co-development and co-commercialization agreement for Foghorn's selective BRM oncology program and an additional undisclosed oncology target. In addition, the collaboration includes three additional discovery programs using Foghorn's proprietary Gene Traffic Control platform.

For the BRM-selective program and the additional undisclosed target program, Foghorn will lead discovery and early research activities, while Lilly will lead development and commercialization activities with participation from Foghorn in operational activities and cost sharing. Foghorn and Lilly will share 50/50 in the U.S. economics, and Foghorn is eligible to receive royalties on ex-U.S. sales starting in the low double-digit range and escalating into the twenties based on revenue levels.

For the additional discovery programs, Foghorn will lead discovery and early research activities. Foghorn may receive up to a total of $1.3 billion in potential development and commercialization milestones. Additionally, Foghorn will have an option to participate in a percentage of the U.S. economics and is eligible to receive tiered royalties from the mid-single digit to low-double digit range on sales outside the U.S. that may be exercised after the successful completion of the dose-finding toxicity studies.

About Foghorn Therapeutics

Foghorn® Therapeutics 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.

Forward-Looking Statements

This press release contains "forward-looking statements" regarding the Company's clinical programs for FHD-286 and FHD-609, including anticipated timing of receipt of initial clinical data, its collaboration with Lilly and its research pipeline, including its degrader efforts. 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, 2020 and subsequent Quarterly Reports on Form 10-Q, 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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