Foghorn Therapeutics Provides First Quarter 2023 Financial and Corporate Update

May 8, 2023

- Data from Phase 1 dose escalation study of FHD-286, a BRG1/BRM inhibitor, in metastatic uveal melanoma expected in the second quarter of 2023
- Selective BRM, ARID1B, EP300 and CBP, targeting key regulators of gene expression, continue to advance towards IND
- Cash, cash equivalents and marketable securities of $316.0 million, as of March 31, 2023, provides cash runway into the second half of 2025

CAMBRIDGE, Mass., May 08, 2023 (GLOBE NEWSWIRE) -- 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 provided a financial and corporate update in conjunction with the Company's 10-Q filing for the quarter ended March 31, 2023. With an initial focus in oncology, Foghorn's Gene Traffic Control® Platform and resulting broad pipeline have the potential to transform the lives of people suffering from a wide spectrum of diseases.

"In the coming months, we anticipate the initial Phase 1 results for FHD-286 in metastatic uveal melanoma and we continue to advance our exciting early-stage oncology programs—including our BRM selective inhibitor, CBP, EP300 and ARID1B—toward the clinic while showcasing our ability to repeatedly generate selective chemical matter against important targets in oncology," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "These programs have the potential to deliver novel therapies that hold tremendous value for large patient populations in a broad range of different cancers."

Key Recent Updates and Upcoming Milestones

- **FHD-286.** FHD-286 is a potent, selective inhibitor of the BRG1 and BRM subunits of the BAF chromatin remodeling complex where dependency on BRG1/BRM is well-established pre-clinically with multiple tumor types, including uveal melanoma, acute myelogenous leukemia (AML)/myelodysplastic syndrome (MDS), non-small cell lung cancer (NSCLC) and prostate cancer.
  - **mUM Update.** Phase 1 dose escalation of FHD-286 in metastatic uveal melanoma (mUM) continues to enroll patients per protocol. Top-line Phase 1 safety and efficacy data is expected in the second quarter of 2023.
  - **AML/MDS Update.** In August 2022, the U.S. Food and Drug Administration (FDA) placed a full clinical hold on the Phase 1 dose escalation study of FHD-286 in relapsed and/or refractory AML and MDS. The Company anticipates providing a regulatory update for FHD-286 in AML/MDS in the second quarter of 2023.

- **FHD-609 Update.** On April 24, 2023, Foghorn provided an update on the FHD-609 Phase 1 program in synovial sarcoma and SMARCB1-deleted tumors. (Link to press release here).

- **Differentiated Pipeline Advancement.** Foghorn continues to expand its platform and pipeline. The Company anticipates the potential for six new molecular investigational new drug (IND) applications in the next four years. The Company continues to progress programs for multiple targets which include chromatin remodeling complexes, transcription factors, helicases and other chromatin related factors. These targets include Selective BRM* and wholly owned programs including CBP, EP300 and ARID1B, as well as other undisclosed targets, which combined could address more than 20 tumor types impacting more than 500,000 new patients annually.

- **Medical Conference Participation.** In April 2023, Foghorn participated at the 2023 American Association for Cancer Research Annual Meeting and the 18th Annual Drug Discovery Chemistry Meeting, highlighting preclinical data from its selective CBP and EP300 protein degrader programs, preclinical data for FHD-286 and its transcription factor and protein degradation capabilities. To access the presentations, please visit the "Our Data" section of the Foghorn website.

- **Strategic Collaborations.** During the first quarter of 2023, Foghorn continued to progress the Company's strategic collaborations with two world-leading pharmaceutical companies, which validate the rigor of our science, highlight the importance of the targets we are tackling and confirm the relevance of the biology on which we are focused.
  - In December 2021, Foghorn entered into a strategic collaboration with Loxo@Lilly. In 2023, Foghorn anticipates continued progress across the collaboration including a co-development and co-commercialization agreement on the Selective BRM program*, an additional undisclosed oncology target and three additional discovery programs. The Selective BRM program is on track to transition to Loxo@Lilly in the second half of 2023.
  - In July 2020, Foghorn entered into a strategic collaboration with Merck Sharp & Dohme. In 2023, Foghorn will

continue to utilize its Gene Traffic Control platform to discover and develop novel therapeutics under the collaboration based on disruptors of a specified transcription factor target.

*In December 2021, Foghorn announced a strategic collaboration with Loxo@Lilly to create novel oncology medicines. 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 discovery programs using Foghorn's proprietary Gene Traffic Control platform.

First Quarter 2023 Financial Highlights

- **Strong Balance Sheet and Cash Runway.** As of March 31, 2023, the Company had $316.0 million in cash, cash equivalents and marketable securities, which provides a cash runway into the second half of 2025.

- **Collaboration Revenues.** Collaboration revenue was $5.3 million for the three months ended March 31, 2023, compared to $3.9 million for the three months ended March 31, 2022. The increase year-over-year was primarily driven by revenue recognized under the Lilly collaboration agreement.

- **Research and Development Expenses.** Research and development expenses were $30.0 million for the three months ended March 31, 2023, compared to $24.5 million for the three months ended March 31, 2022. This increase was primarily due to costs associated with continued investment in R&D personnel and platform and early-stage research investments.

- **General and Administrative Expenses.** General and administrative expenses were $8.6 million for the three months ended March 31, 2023, compared to $7.2 million for the three months ended March 31, 2022. This increase was primarily due to an increase in investments to support the growing business which included increases in personnel-related costs and stock-based compensation expense.

- **Net Loss.** Net loss was $30.5 million for the three months ended March 31, 2023, compared to a net loss of $26.9 million for the three months ended March 31, 2022.

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 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 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 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.foghorntx.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 programs for FHD-286 and FHD-609, including its efforts to resolve the full clinical hold relating to FHD-286 in AML and MDS, the anticipated timing of release of clinical data, its collaborations with Lilly and Merck and its research pipeline, including the status of its Selective BRM program, the filing of INDs and its protein 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, 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.

Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2023	Dec. 31, 2022
Cash, cash equivalents and marketable securities	$ 315,970	$ 345,798
All other assets	56,913	59,085
Total assets	**$ 372,883**	**$ 404,883**
Deferred revenue, total	$ 331,511	$ 336,820
All other liabilities	65,958	67,951
Total liabilities	**397,469**	**404,771**
Total stockholders' equity (deficit)	**(24,586)**	**112**
Total liabilities and stockholders' equity	**$ 372,883**	**$ 404,883**

Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	$ 5,309	$ 3,920
Operating expenses:		
Research and development	29,985	24,508
General and administrative	8,641	7,216
Total operating expenses	**38,626**	**31,724**
Loss from operations	**(33,317)**	**(27,804)**
Total other income, net	**3,389**	**890**
Provision for income taxes	**(560)**	**—**
Net loss	**$ (30,488)**	**$ (26,914)**
Net loss per share attributable to common stockholders—basic and diluted	$ (0.73)	$ (0.65)
Weighted average common shares outstanding—basic and diluted	**41,811,087**	**41,370,186**

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