Foghorn Therapeutics Provides Second Quarter 2023 Financial and Corporate Update

August 4, 2023

— Initiating FHD-286 combination study in AML in the third quarter of 2023

— Selective BRM, ARID1B, EP300, and CBP, targeting key regulators of gene expression, continue to advance toward IND

— Cash, cash equivalents, and marketable securities of $284.3 million, as of June 30, 2023, provides cash runway into the second half of 2025

CAMBRIDGE, Mass., Aug. 04, 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 June 30, 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.

"Foghorn made important progress across both our clinical and preclinical pipeline in the second quarter. We successfully resolved the clinical hold for FHD-286 in AML and disclosed the clinical data from the Phase 1 study which suggested that FHD-286 is a potent, broad-based differentiation agent. We are on track to initiate dosing in a combination study of FHD-286 in AML in the third quarter. We continue to advance our selective BRM, selective CBP, selective EP300, and selective ARID1B programs, demonstrating our ability to repeatedly drug important targets in oncology," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn.

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 preclinically with multiple tumor types, including acute myelogenous leukemia (AML)/myelodysplastic syndrome (MDS), non–small cell lung cancer (NSCLC) and prostate cancer.
  - **AML/MDS Update.** Foghorn plans to commence a Phase 1 study of FHD-286 in combination with decitabine or low-dose cytarabine (LDAC) in relapsed and/or refractory AML patients. The decision to advance to the Phase 1 combination study is based on clinical data demonstrating FHD-286's effect as a broad-based differentiation agent, its safety profile, as well as supportive preclinical combination data, including robust efficacy data in multiple CDX and PDX models.
  - **mUM Update.** On June 28, 2023, Foghorn announced data from the Phase 1 dose escalation safety study of FHD-286 in metastatic uveal melanoma (mUM). These data reinforced the safety and tolerability profile of FHD-286. At this time, the company does not plan to advance FHD-286 in uveal melanoma independently.

- **Differentiated Pipeline Advancement.** Foghorn continues to expand its platform and pipeline. The Company anticipates the potential for six new 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.

- **Strategic Collaborations.** Foghorn continued to progress its strategic collaborations with 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 Foghorn is 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. Through the first two quarters of 2023, Foghorn continued 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.

Second Quarter 2023 Financial Highlights

- **Strong Balance Sheet and Cash Runway.** As of June 30, 2023, the Company had $284.3 million in cash, cash equivalents and marketable securities, which provides a cash runway into the second half of 2025.

- **Collaboration Revenues.** Collaboration revenue was $5.6 million for the three months ended June 30, 2023, compared to $4.5 million for the three months ended June 30, 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 $29.2 million for the three months ended June 30, 2023, compared to $26.0 million for the three months ended June 30, 2022. This increase was primarily due to costs associated with continued investment in R&D personnel and platform and early-stage research investments, modestly offset by a decline in clinical trial spend

- **General and Administrative Expenses.** General and administrative expenses were $8.4 million for the three months ended June 30, 2023, compared to $7.7 million for the three months ended June 30, 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 $29.5 million for the three months ended June 30, 2023, compared to a net loss of $27.3 million for the three months ended June 30, 2022.

About FHD-286
FHD-286 is a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 (SMARCA4) and BRM (SMARCA2), two highly similar proteins that are the ATPases, or the catalytic engines of the BAF complex, one of the key regulators within 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. FHD-286 is being developed for relapsed and/or refractory AML, and the company plans to commence a Phase 1 study, in combination with decitabine or cytarabine, in the third quarter of 2023.

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 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, including its initiation of a Phase 1 study of FHD-286 in combination with decitabine or low-dose cytarabine (LDAC) in relapsed and/or refractory AML patients, 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)

	June 30, 2023	Dec. 31, 2022
Cash, cash equivalents and marketable securities	$ 284,311	$ 345,798
All other assets	55,265	59,085
Total assets	**$ 339,576**	**$ 404,883**
Deferred revenue, total	$ 325,912	$ 336,820
All other liabilities	63,014	67,951
Total liabilities	**388,926**	**404,771**
Total stockholders’ equity (deficit)	**(49,350)**	**112**
Total liabilities and stockholders’ equity	**$ 339,576**	**$ 404,883**

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

	Three Months Ended June 30,	
	2023	**2022**
Collaboration revenue	$ 5,599	$ 4,490
Operating expenses:		
Research and development	29,248	25,974
General and administrative	8,401	7,704
Total operating expenses	**37,649**	**33,678**
Loss from operations	**(32,050)**	**(29,188)**
Total other income, net	**3,505**	**1,875**
Provision for income taxes	**(942)**	**—**
Net loss	**$ (29,487)**	**$ (27,313)**
Net loss per share attributable to common stockholders—basic and diluted	$ (0.70)	$ (0.66)
Weighted average common shares outstanding—basic and diluted	**41,825,555**	**41,515,305**

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