Foghorn Therapeutics Provides Third Quarter 2022 Financial and Corporate Update

November 8, 2022

- FHD-286 Phase 1 dose escalation study in metastatic uveal melanoma continues to progress with initial data expected in the first half of 2023

- FHD-609 Phase 1 pharmacodynamic data shows degradation of BRD9 in on-treatment metastatic tumor synovial sarcoma biopsies; initial Phase 1 dose escalation efficacy and safety data expected in 2023

- Continue to advance preclinical pipeline with novel targets including BRM, ARID1B and CBP

- Cash, cash equivalents and marketable securities of $373.5 million, as of September 30, 2022, provides significant cash runway into 2025

CAMBRIDGE, Mass., Nov. 08, 2022 (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 September 30, 2022. 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 with a wide spectrum of diseases.

"This quarter, we advanced our deep pipeline of over fifteen programs including our newly disclosed selective CBP protein degrader program, BRM, and ARID1B, all having significant unmet medical need. Early clinical data for our BRD9 degrader program, FHD-609, reinforced our broad and unique capabilities in protein degradation development, further establishing Foghorn as a leader in the field," said Foghorn CEO Adrian Gottschalk. "As we look ahead, our strong balance sheet supports us through important clinical milestones including the Phase 1 dose escalation study evaluating FHD-286 in metastatic uveal melanoma, with initial data expected in the first half of 2023, and our FHD-609 program in synovial sarcoma, where we remain on track to report data in 2023."

Key Recent Updates

- **FHD-286 mUM Update**. The dose escalation Phase 1 study of FHD-286, an inhibitor of BRG1/BRM, in metastatic uveal melanoma (mUM) continues to enroll patients per protocol. Initial phase 1 clinical data is expected in the first half of 2023.

- **FHD-286 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 in relapsed and/or refractory acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS). The full clinical hold in the AML/MDS study is due to the observation, in the data submitted in response to a partial hold, of additional suspected cases of fatal differentiation syndrome believed to be associated with FHD-286. Differentiation syndrome is associated with AML/MDS therapeutics that induce differentiation, an effect that has been seen with, and is believed to be on-target for the proposed mechanism of action for, FHD-286. The FDA has additional questions and requires further analyses before the clinical hold may be lifted. The Company continues to work to resolve the clinical hold with the FDA.

- **FHD-609 Update**. Patient enrollment is continuing in the Phase 1 dose escalation clinical study of FHD-609, a potent and selective heterobifunctional protein degrader of BRD9, initially being developed for the treatment of synovial sarcoma and SMARCB1-loss tumors with initial efficacy and safety data expected in 2023.

  Initial clinical data from two patients with metastatic synovial sarcoma in the ongoing Phase 1 dose escalation study, treated with the same low dose of FHD-609, showed degradation of BRD9 in on-treatment metastatic tumor biopsies. This data was presented at Hanson Wade's 5th Annual Targeted Protein Degradation Summit on October 26. Additional preclinical data presented at the same conference demonstrated that FHD-609 is highly selective, with no off-target IMid neosubstrate impact, potentially avoiding the adverse effects associated with unwanted off-target degradation.

- **Selective CBP Program Announced**. In October 2022, Foghorn disclosed a selective CBP degrader targeting EP300 mutant cancers. The Selective CBP program is aimed at degrading the CREB binding protein and has therapeutic potential in subsets of several cancers including bladder, colorectal, breast, gastric and lung. Using selective CBP degraders, the program aims to exploit the synthetic lethal relationship it shares with its paralog EP300 to identify and treat those patients with EP300 mutated cancers. If successful, the Selective CBP program has the potential to address over 100,000 patients in many cancer types.

- **Pipeline Advancement**. Foghorn continues to expand its protein degradation capabilities and platform. Over half of the Company's programs leverage the protein degradation modality. Ongoing investments include undisclosed heterobifunctional PROTAC and non-cereblon molecular glue programs, in addition to the progression of the more advanced selective protein degrader programs of BRM, CBP, and ARID1B, all with significant unmet medical need.

- **Board of Directors Updates**. Foghorn announced the election of B. Lynne Parshall, Esq., and Thomas J. Lynch Jr.,

M.D., to its Board of Directors. Cigall Kadoch, Ph.D., a co-founder of the Company, accepted her appointment as an Investigator for the Howard Hughes Medical Institute (HHMI) and, in accordance with HHMI's rules, resigned from Foghorn's Board of Directors. Dr. Kadoch remains with the Company as a Scientific Advisor to the Board and will continue to participate on Foghorn's Scientific Advisory Board.

- **Merck Collaboration Update**. In July 2022, a research milestone was achieved under the Merck collaboration triggering a $5 million milestone payment to Foghorn, which was reflected in the financial statements for the quarter ended September 30, 2022.

Third Quarter 2022 Financial Highlights

- **Strong Balance Sheet and Cash Runway**. As of September 30, 2022, the Company had $373.5 million in cash, cash equivalents and marketable securities.
- **Collaboration Revenues**. Collaboration revenues were $6.6 million for the third quarter of 2022 compared to $0.1 million for the third quarter of 2021. The increase was primarily driven by revenue recognized under the Lilly collaboration agreement, which was executed in December 2021.
- **Research and Development Expenses**. Research and development expenses were $26.9 million for the third quarter of 2022 compared to $20.5 million for the third quarter of 2021. This increase was primarily due to costs associated with continued investment in R&D personnel and the Phase 1 studies for both FHD-286 and FHD-609, which were initiated in 2021.
- **General and Administrative Expenses**. General and administrative expenses were $8.0 million for the third quarter of 2022, compared to $5.8 million for the third quarter of 2021. This increase was primarily due to an increase in investments to support the growing business.
- **Net Loss**. Net loss was $25.8 million for the third quarter of 2022 compared to a net loss of $26.1 million for the third quarter of 2021.

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 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 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, 2021 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.

Condensed Consolidated Balance Sheets
(In thousands)

	Sept. 30, 2022	Dec. 31, 2021
Cash, cash equivalents and marketable securities	$ 373,498	$ 154,289
Collaboration receivable	—	300,000
All other assets	60,434	65,485
Total assets	**$ 433,932**	**$ 519,774**
Deferred revenue, total	$ 341,003	$ 351,047
All other liabilities	68,406	71,856
Total liabilities	**409,409**	**422,903**
Total stockholders’ equity	**24,323**	**96,871**
Total liabilities and stockholders’ equity	**$ 433,932**	**$ 519,774**

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

	Three Months Ended September 30,	
	2022	2021
Collaboration revenue	$ 6,634	$ 41
Operating expenses:		
Research and development	26,928	20,494
General and administrative	7,965	5,808
Total operating expenses	**34,893**	**26,302**
Loss from operations	**(28,259)**	**(26,261)**
Total other income, net	**2,490**	**181**
Net loss	**$ (25,769)**	**$ (26,080)**
Net loss per share attributable to common stockholders—basic and diluted	$ (0.62)	$ (0.71)
Weighted average common shares outstanding—basic and diluted	**41,672,621**	**36,971,767**

Contact:

Ben Strain, Foghorn Therapeutics Inc. (Media and Investors)
bstrain@foghorntx.com

Karin Hellsvik, Foghorn Therapeutics Inc. (Media)
khellsvik@foghorntx.com

Michael Lampe, ScientPR (Media)
michael@scientpr.com

Hans Vitzthum, LifeSci Advisors (Investors)
hans@lifesciadvisors.com