Foghorn Therapeutics Provides Third Quarter 2024 Financial and Corporate Update

November 4, 2024

First patient dosed with first-in-class SMARCA2(BRM) selective inhibitor FHD-909 (LY4050784) in Phase 1 trial with primary target population in SMARCA4(BRG1) mutated NSCLC

Topline Phase 1 dose escalation data for FHD-286 plus decitabine in patients with relapsed and/or refractory AML expected by year-end 2024

IND-enabling studies for Selective CBP degrader program on track to begin by year-end 2024

Strong balance sheet with cash, cash equivalents, and marketable securities of $267.4 million as of September 30, 2024, provides cash runway into 2027

CAMBRIDGE, Mass., Nov. 04, 2024 (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, 2024. 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.

"We continue to advance our pipeline of multiple therapeutics targeting novel biology in the chromatin regulatory system. The first patient was recently dosed with FHD-909, a highly selective SMARCA2 (BRM) inhibitor, that targets the SMARCA2 synthetic lethal relationship with SMARCA4 (BRG1) mutated NSCLC. We look forward to further clinical progress with the FHD-909 program in collaboration with our partner Lilly," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "By year-end, we expect data from our FHD-286 combination study in AML and expect to initiate IND-enabling studies for our Selective CBP degrader program targeting tumors harboring EP300 mutations, including bladder, gastric, and endometrial cancers. With our strong cash position and runway into 2027, we are poised to advance our clinical and preclinical pipeline."

Recent Corporate Updates

Presented at 7th Annual Targeted Protein Degradation (TPD) Summit. In October, Foghorn participated in multiple sessions at the 7th Annual TPD Summit, including a CEO Think Tank keynote session entitled "A Strategic Look at Targeted Protein Degradation & Induced Proximity Field" featuring Foghorn's CEO Adrian Gottschalk, and a presentation by Steve Bellon, Foghorn's Chief Scientific Officer, on the recent developments from Foghorn's degrader pipeline.

Dosed First Patient with FHD-909. In October, the first patient was dosed with FHD-909 in the Phase 1 open-label, multicenter trial for SMARCA4 mutated cancers, with non-small cell lung cancer (NSCLC) as the primary target patient population.

Strengthened Executive Leadership. In September, Foghorn appointed Anna Rivkin, Ph.D., as Chief Business Officer. Dr. Rivkin brings over two decades of expertise establishing strategic alliances, R&D partnerships, in-licensing and M&A. Most recently, she held leadership roles at Bristol Myers Squibb where she successfully oversaw a broad range of complex business transactions across multiple disease areas.

Program Overview and Upcoming Milestones

FHD-286. FHD-286 is a potent, first-in-class, selective inhibitor of the SMARCA2 (BRM) and SMARCA4 (BRG1) subunits of the BAF chromatin remodeling complex where dependency on SMARCA2/SMARCA4 is well-established preclinically with multiple tumor types, including acute myeloid leukemia (AML)/myelodysplastic syndrome (MDS), NSCLC and prostate cancer.

- **AML Phase 1 trial.** The ongoing Phase 1 dose escalation trial is evaluating the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary clinical activity of FHD-286 in combination with decitabine or low-dose cytarabine in patients with relapsed and/or refractory AML who have failed multiple courses of therapy. FHD-286 previously demonstrated a promising mutation-agnostic differentiation effect in a single-agent dose escalation trial.
- Topline safety, tolerability, initial efficacy, and PK/PD data expected by year-end 2024.

FHD-909 (LY4050784). FHD-909 is a first-in-class oral SMARCA2 selective inhibitor that has demonstrated in preclinical studies to have high selectivity over its closely related paralog SMARCA4, two proteins that are the catalytic engines across all forms of the BAF complex. SMARCA4 mutations are common across tumor types, including approximately 10% of NSCLC, and result in tumors being dependent on SMARCA2 activity for their survival. Selectively blocking SMARCA2 activity is a promising synthetic lethal strategy intended to induce tumor death while sparing healthy cells.

- **Dosed first patient.** In October 2024, the first patient was dosed in the Phase 1 trial for FHD-909 in SMARCA4 mutated cancers, with NSCLC as the primary target patient population.
- **Strategic collaboration with Lilly.** In December 2021, Foghorn announced a strategic collaboration with Lilly to create novel oncology medicines that includes a U.S. 50/50 co-development and co-commercialization agreement for Foghorn's Selective SMARCA2 oncology program, agreements for a selective inhibitor and a selective degrader, and an additional undisclosed oncology target. The collaboration also includes three discovery programs using Foghorn's proprietary Gene Traffic Control platform.

Selective CBP degrader program. Foghorn is advancing its Selective CBP degrader program to selectively target CBP in EP300 mutated cancer cells. CBP and EP300 are highly similar acetyltransferases that create a synthetic lethal relationship when EP300 is mutated. Attempts to selectively drug CBP have been challenging due to the high level of similarity between the two proteins, while dual inhibition of CBP/EP300 has been limited by hematopoietic toxicity.

- **Robust antitumor activity in EP300 loss tumors.** In April, Foghorn presented new pharmacodynamic and pharmacokinetic preclinical data at the 2024 AACR Annual Meeting and during a pipeline update call. In October, Foghorn presented additional data on efficacy, tolerability, and formulation at the 7th Annual TPD & Induced Proximity Summit. These data include:
  - Deep and sustained CBP degradation significantly inhibited tumor growth in mouse xenograft solid tumor models.
  - Robust monotherapy preclinical anti-tumor activity that was not associated with significant body weight loss, thrombocytopenia or anemia.
  - Identification of potent and selective CBP protein degraders with first-in-class potential to address tumors harboring EP300 mutations in many types of cancer, including bladder, gastric and endometrial cancers.
  - Identification of long-acting injection formulation that resulted in tumor regression from a single dose in a mouse xenograft efficacy study.
- Investigational New Drug (IND)-enabling studies are on track to initiate by the fourth quarter of 2024.

Selective EP300 degrader program. Foghorn is advancing its Selective EP300 degrader program for CBP mutant and EP300-dependent cancers. Attempts to selectively drug EP300 have been challenging due to the high level of similarity between the two proteins, while dual inhibition of CBP/EP300 has been limited by hematopoietic toxicity.

- **Robust anti-tumor activity in CBP mutant and EP300 dependent cancers.** In April, Foghorn presented new pharmacodynamic and pharmacokinetic preclinical data at the 2024 AACR Annual Meeting and during a pipeline update call highlighting:
  - Well-tolerated *in vivo* with no observed decrease in platelet levels, with no effects on megakaryocyte viability at pharmacologically relevant concentrations in *ex vivo* studies.
  - Identification of potent and selective EP300 degraders with anti-tumor activity in prostate and hematological malignancies, including prostate cancer, multiple myeloma, and diffuse large B cell lymphoma.

Selective ARID1B degrader program.
ARID1A is the most mutated subunit in the BAF complex and amongst the most mutated proteins in oncology. These mutations lead to a dependency on ARID1B in several types of cancer, including ovarian, endometrial, colorectal, and bladder. Attempts to selectively drug ARID1B have been challenging because of the high degree of similarity between ARID1A and ARID1B and the fact that ARID1B has no enzymatic activity to target.

- **Highly potent and selective binders developed.** In April, Foghorn presented data demonstrating potent and selective small molecule binders to ARID1B. The Company is in the process of converting these selective binders into heterobifunctional degraders.

Third Quarter 2024 Financial Highlights

- **Collaboration Revenues.** Collaboration revenue was $7.8 million for the three months ended September 30, 2024, compared to $17.5 million for the three months ended September 30, 2023. The three months ended September 30, 2023 included $16.1 million revenue from a Merck collaboration that ended in August 2023. The revenue in the three months ended September 30, 2024 was driven by the continued advancement of programs under the Lilly Collaboration Agreement.
- **Research and Development Expenses.** Research and development expenses were $24.7 million for the three months ended September 30, 2024, compared to $26.3 million for the three months ended September 30, 2023. The decrease is attributed to an increase in Lilly partnered programs of $3.3 million, partially offset by decreases in personnel-related costs, early development and other research external costs and facilities and IT related expenses of $5.0 million.

General and Administrative Expenses. General and administrative expenses were $7.0 million for the three months ended September 30, 2024, compared to $8.3 million for the three months ended September 30, 2023. This decrease was primarily due to lower personnel-related costs.

- **Net Loss.** Net loss was $19.1 million for the three months ended September 30, 2024, compared to a net loss of $14.3 million for the three months ended September 30, 2023.
- **Cash, Cash Equivalents and Marketable Securities.** As of September 30, 2024, the Company had $267.4 million in cash, cash equivalents and marketable securities, providing expected cash runway into 2027.

About FHD-286

FHD-286 is a highly potent, first-in-class, selective, allosteric, and orally available small-molecule, enzymatic inhibitor of SMARCA2 (BRM) and SMARCA4 (BRG1), 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.

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 FHD-909
FHD-909 (LY4050784) is a potent, first-in-class, allosteric, and orally available small molecule that selectively inhibits the ATPase activity of SMARCA2 (BRM) over its closely related paralog SMARCA4 (BRG1), two proteins that are the catalytic engines across all forms of the BAF complex, one of the key regulators of the chromatin regulatory system. In preclinical studies, tumors with mutations in SMARCA4 rely on SMARCA2 for their survival. FHD-909 has shown significant anti-tumor activity across multiple SMARCA4 mutant lung tumor models.

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 X (formerly Twitter) and LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking statements." Forward-looking statements include statements regarding the Company's clinical trials, including its ongoing Phase 1 trial of FHD-286 in combination with decitabine in relapsed and/or refractory AML patients and the ongoing Phase 1 trial of FHD-909 in SMARCA4-mutated cancers , pre-clinical product candidates, expected timing of clinical data, expected cash runway, expected timing of regulatory filings, 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, 2023, 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)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 267,397	$ 234,057
All other assets	40,975	51,859
Total assets	**$ 308,372**	**$ 285,916**
Deferred revenue, total	$ 282,919	$ 302,665
All other liabilities	53,740	60,441
Total liabilities	**$ 336,659**	**$ 363,106**
Total stockholders' deficit	**$ (28,287)**	**$ (77,190)**
Total liabilities and stockholders' deficit	**$ 308,372**	**$ 285,916**

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

	Three Months Ended September 30,	
	2024	2023
Collaboration revenue	$ 7,808	$ 17,478
Operating expenses:		
Research and development	24,689	26,251
General and administrative	6,971	8,308
Total operating expenses	**$ 31,660**	**$ 34,559**
Loss from operations	**$ (23,852)**	**$ (17,081)**
Total other income, net	**$ 4,730**	**$ 3,474**
Provision for income taxes	**$ —**	**$ (738)**
Net loss	**$ (19,122)**	**$ (14,345)**
Net loss per share attributable to common stockholders—basic and diluted	(0.31)	(0.34)
Weighted average common shares outstanding—basic and diluted	**62,602,848**	**42,025,938**

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