Foghorn Therapeutics Provides Second Quarter 2024 Financial and Corporate Update

August 8, 2024

Topline Phase 1 dose escalation data for FHD-286 in combination with decitabine, in relapsed and/or refractory AML patients, anticipated in the fourth quarter of 2024

Dosing of first patient in a Phase 1 trial for FHD-909, a potential first-in-class SMARCA2 selective inhibitor, anticipated in the second half of 2024; primary target population in SMARCA4 mutated NSCLC

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

Successful $110 million financing strengthens balance sheet with cash, cash equivalents and short-term investments of $285.2 million as of June 30, 2024 and extends expected cash runway into 2027

CAMBRIDGE, Mass., Aug. 08, 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 June 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 anticipate topline data from our Phase 1 combination trial with FHD-286 in patients with relapsed and/or refractory AML in the fourth quarter of 2024. We believe FHD-286 has the potential to be a first-in-class, mutation-agnostic differentiation therapeutic," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "Additionally, the IND for FHD-909 cleared in May and we anticipate FHD-909 to be the first SMARCA2 selective inhibitor to enter the clinic. Dosing of the first patient in our Phase 1 trial, with primary target population in SMARCA4 mutated NSCLC, is planned for the second half of the year. We are also on track to initiate IND-enabling studies in the fourth quarter of 2024 for our Selective CBP degrader program targeting tumors harboring EP300 mutations including bladder, gastric and endometrial cancers."

Mr. Gottschalk continued, "The biological foundation for the development of therapeutics targeting the chromatin regulatory system in oncology and other disease areas continues to get stronger. In April, we were pleased to present preclinical data at AACR reinforcing the potential of our platform to deliver innovative medicines across cancers by selectively drugging historically very challenging targets. The conviction in our pipeline was further strengthened by our recent successful financing with new and long-term investors, which extended our expected cash runway into 2027 and through key inflection points, strongly positioning us for continued advancement."

Corporate Updates

Strengthened Balance Sheet to Advance Pipeline. In May, Foghorn successfully closed an approximately $110 million registered direct offering to advance the Company's pipeline. The offering included new investors BVF Partners, Deerfield Management and other leading healthcare specialist investors as well as current investors, including founding investor Flagship Pioneering.

Presented at AACR Annual Meeting. In April, Foghorn presented preclinical data highlighting pipeline progress on the advancement of multiple potential first-in-class medicines, including the first presentation of preclinical data for FHD-909, at the 2024 American Association for Cancer Research (AACR) Annual Meeting.

Hosted Chromatin Regulation Summit. In April, Foghorn hosted the first Future of Disease and Chromatin Regulation Summit at the Foghorn corporate headquarters in Cambridge, Massachusetts. The live event featured presentations and panel discussions with world-renowned industry and academic key opinion leaders on therapeutic opportunities in chromatin regulatory biology.

Strengthened Executive Leadership. In April, Foghorn appointed Kristian Humer as Chief Financial Officer. Mr. Humer joined Foghorn with over 14 years of diversified financial strategy and business development experience in the life science industry and more than 20 years of experience in the financial industry.

Key Recent Program Updates 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), non-small cell lung cancer (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 previous courses of therapy. FHD-286 previously demonstrated a promising mutation-agnostic differentiation effect in a single-agent dose escalation trial.
    - Topline clinical data are anticipated in the fourth quarter. We anticipate this will include topline safety, tolerability, initial efficacy and PK/PD data.

- **Overcoming Tyrosine Kinase Inhibitor Resistance**. Data published in *Cancer Cell* in August 2023, together with additional preclinical studies conducted by Foghorn, suggest that FHD-286 may play an important role in overcoming resistance in EGFR/KRAS tumors. Preclinical data profiling the ability of FHD-286 to amplify and/or restore tumor sensitivity will be presented with FHD-286 Phase 1 dose escalation data.

FHD-909. FHD-909 is a first-in-class oral SMARCA2 (BRM) selective inhibitor that has demonstrated in preclinical studies to have high selectivity over its closely related paralog SMARCA4 (BRG1), 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.

- In December 2021, Foghorn announced a strategic collaboration with Lilly to create novel oncology medicines. The collaboration includes a U.S. 50/50 co-development and co-commercialization agreement for Foghorn's Selective SMARCA2 oncology program, which includes a selective inhibitor and a selective degrader, and an additional undisclosed oncology target. In addition, the collaboration includes three discovery programs using Foghorn's proprietary Gene Traffic Control platform.
- In April 2024, Foghorn and Lilly presented new preclinical data as a poster presentation at the AACR Annual Meeting and during a pipeline update call demonstrating at tolerable doses high SMARCA2 selectivity and dose-dependent single agent activity in SMARCA4 mutated cancers.
- In May 2024, the investigational new drug (IND) application was approved by the Food and Drug Administration. The primary target patient population is SMARCA4 mutated NSCLC.
- Dosing of the first patient in the Phase 1 trial for FHD-909 is planned to begin in the second half of 2024.

Selective CBP degrader program and Selective EP300 degrader program.
Foghorn is advancing two separate programs targeting either CBP or EP300, paralog histone acetyltransferases with a synthetic lethal relationship in tumor cells. Attempts to selectively drug CBP or EP300 have been challenging due to the high level of similarity between the two proteins. Additionally, dual inhibition of CBP/EP300 has been historically limited by hematopoietic toxicity.

Selective CBP degrader program. In April, Foghorn presented new pharmacodynamic and pharmacokinetic preclinical data at the 2024 AACR Annual Meeting and during a pipeline update call highlighting:

- 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.
- IND-enabling studies on track to initiate by the fourth quarter of 2024.

Selective EP300 degrader program. 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 (DLBCL).

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.

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

Second Quarter 2024 Financial Highlights

- **Collaboration Revenues.** Collaboration revenue was $6.9 million for the three months ended June 30, 2024, compared to $5.6 million for the three months ended June 30, 2023. The increase year-over-year was primarily driven by the continued advancement of programs under the Lilly Collaboration Agreement.

- **Research and Development Expenses.** Research and development expenses were $23.8 million for the three months ended June 30, 2024, compared to $29.2 million for the three months ended June 30, 2023. This decrease was primarily due to lower personnel-related costs and lower development program spend following the shutdown of two clinical studies (FHD-286 in metastatic uveal melanoma and FHD-609 (BRD9 degrader) in synovial sarcoma).

- **General and Administrative Expenses.** General and administrative expenses were $7.3 million for the three months ended June 30, 2024, compared to $8.4 million for the three months ended June 30, 2023. This decrease was primarily due to lower personnel-related costs.

- **Net Loss.** Net loss was $23.0 million for the three months ended June 30, 2024, compared to a net loss of $29.5 million for the three months ended June 30, 2023.

- **Cash, Cash Equivalents and Marketable Securities.** As of June 30, 2024, the Company had $285.2 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 BAF function. 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 study of FHD-286 in combination with decitabine in relapsed and/or refractory AML patients and the planned Phase 1 trial of FHD-909, 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)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 285,177	$ 234,057
All other assets	43,408	51,859
Total assets	**$ 328,585**	**$ 285,916**
Deferred revenue, total	$ 290,726	$ 302,665
All other liabilities	52,181	60,441
Total liabilities	**$ 342,907**	**$ 363,106**
Total stockholders' deficit	**$ (14,322)**	**$ (77,190)**
Total liabilities and stockholders' deficit	**$ 328,585**	**$ 285,916**

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended June 30,	
	2024	2023
Collaboration revenue	$ 6,888	$ 5,599
Operating expenses:		
Research and development	23,797	29,248
General and administrative	7,325	8,401
Impairment of long-lived assets	2,398	—

Total operating expenses	**$ 33,520**	**$ 37,649**
Loss from operations	**$ (26,632)**	**$ (32,050)**
Total other income, net	**$ 3,653**	**$ 3,505**
Provision for income taxes	**$ —**	**$ (942)**
Net loss	**$ (22,979)**	**$ (29,487)**
Net loss per share attributable to common stockholders—basic and diluted	(0.45)	(0.70)
Weighted average common shares outstanding—basic and diluted	**51,580,310**	**41,825,555**

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