Foghorn Therapeutics Provides First Quarter 2024 Financial and Corporate Update

May 6, 2024

Dose escalation in FHD-286 combination trial in AML continues to progress with clinical data expected in the second half of 2024; potential to be a first-in-class oral broad-based differentiation therapeutic in AML

IND filing submitted for FHD-909, a first-in-class oral BRM (SMARCA2) selective inhibitor; Phase 1 trial planned to begin in the second half of 2024 with primary target population in BRG1 mutated non-small cell lung cancer; first BRM selective inhibitor to enter the clinic

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

Data presented at AACR support monotherapy activity and first-in-class potential for historically challenging targets including FHD-909, Selective CBP degrader and Selective EP300 degrader programs

Cash, cash equivalents, and marketable securities of $206.7 million, as of March 31, 2024, providing cash runway into the first half of 2026

CAMBRIDGE, Mass., May 06, 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 March 31, 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 are excited about the progress and strength of data presented this quarter which includes robust preclinical anti-tumor monotherapy activity at tolerable doses for multiple pipeline programs. We believe these data demonstrate the potential of our platform to generate novel medicines against very challenging targets, as well as our leadership in the development of therapeutics in chromatin biology," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn.

Mr. Gottschalk added, "In the second half of the year, we expect initial data from our FHD-286 combination study in AML. The IND for FHD-909 was recently submitted and would be the first selective BRM inhibitor to enter the clinic, with a Phase 1 trial planned to begin in the second half of this year. Earlier this year, we also shared data from our Selective CBP degrader program demonstrating tumor growth inhibition in solid tumors without thrombocytopenia or anemia that have been observed with dual CBP/EP300 inhibition. Our Selective EP300 degrader program also demonstrated promising preclinical efficacy with no thrombocytopenia, which is often seen in dual approaches. Our cash balance remains strong, and with multiple programs advancing, we are expected to deliver near- and mid-term value for both patients and shareholders."

Corporate Updates

Presented at AACR Annual Meeting. In April 2024, Foghorn presented preclinical data highlighting pipeline progress from 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 held April 5-10, 2024.

Hosted Chromatin Regulation Summit. In April 2024, 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 Financial Leadership. In April 2024, Foghorn appointed Kristian Humer as Chief Financial Officer. Mr. Humer joins 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, selective inhibitor of the BRG1 (SMARCA4) and BRM (SMARCA2) subunits of the BAF chromatin remodeling complex where dependency on BRG1/BRM 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 Update**. Foghorn initiated a Phase 1 trial of FHD-286 in combination with decitabine or low-dose cytarabine (LDAC) in relapsed and/or refractory AML patients, with the first patient dosed during the third quarter of 2023. Dose escalation is ongoing with initial clinical data expected in the second half of 2024 .
- **Tyrosine Kinase Inhibitor Resistance.** Data published in *Cancer Cell* in August 2023, along with Foghorn's work, suggest that FHD-286 may play an important role in overcoming and delaying resistance in EGFR/KRAS tumors. Preclinical data is expected in the second quarter of 2024.

FHD-909. FHD-909 is a first-in-class oral BRM (SMARCA2) selective inhibitor that has been demonstrated in preclinical studies to have high selectivity over its closely related paralog BRG1 (SMARCA4), two proteins that are the catalytic engines across all forms of the BAF complex. BRG1 mutations are common across tumor types, including approximately 10% of NSCLC, and result in tumors being dependent on BRM activity for their survival. Selectively blocking BRM 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 US 50/50 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.
- In the first quarter of 2024, Lilly selected FHD-909 for clinical development and in April the investigational new drug (IND) application was submitted. The primary target patient population is BRG1-mutated NSCLC.
- In April 2024, Foghorn and Lilly presented new preclinical data as a poster presentation at the AACR Annual Meeting demonstrating, at tolerable doses, high BRM selectivity and dose-dependent single agent activity in BRG1-mutated cancers.
- Dosing of first patient in Phase 1 trial for FHD-909 in BRG1-mutated NSCLC is expected 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, both of which are paralog histone acetyltransferases with a synthetic lethal relationship in tumor cells. Attempts to selectively drug CBP or EP300 have been historically challenging due to the high level of similarity between the two proteins. Additionally, dual inhibition of CBP/EP300 is limited by hematopoietic toxicity.

- **Selective CBP Degrader Program**. In April, Foghorn presented new pharmacodynamic and pharmacokinetic preclinical data at the 2024 AACR Annual Meeting 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.
    - Long-acting CBP-selective protein degrader formulations with first-in-class potential for patients with tumors harboring EP300 mutations.
    - IND-enabling studies on track to initiate by year-end 2024.

- **Selective EP300 Degrader Program**. In April, Foghorn presented new pharmacodynamic and pharmacokinetic preclinical data at the 2024 AACR Annual Meeting highlighting:
    - No observed thrombocytopenia *in vivo*.
    - Identification of potent and selective EP300 protein degraders with first-in-class potential to address tumors harboring CBP mutations and tumors with dependency on EP300 in several types of cancer, including prostate, 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.

Drug Discovery Platform. Foghorn's synthesis of deep chromatin expertise, protein biochemistry and screening, and degrader expertise uniquely positions the Company to successfully drug historically challenging targets.

- Potential for five additional INDs in the next four years.
- Targets combined have the potential to address more than 20 tumor types impacting over 500,000 new patients annually.

First Quarter 2024 Financial Highlights

- **Collaboration Revenues.** Collaboration revenue was $5.1 million for the three months ended March 31, 2024, compared to $5.3 million for the three months ended March 31, 2023. The decrease year-over-year was primarily driven by the termination of the Merck collaboration agreement.
- **Research and Development Expenses.** Research and development expenses were $25.5 million for the three months ended March 31, 2024, compared to $30.0 million for the three months ended March 31, 2023. This decrease was primarily due to lower personnel-related costs.
- **General and Administrative Expenses.** General and administrative expenses were $7.7 million for the three months ended March 31, 2024, compared to $8.6 million for the three months ended March 31, 2023. This decrease was primarily due to lower personnel-related costs.
- **Net Loss.** Net loss was $25.0 million for the three months ended March 31, 2024, compared to a net loss of $30.5 million for the three months ended March 31, 2023.
- **Cash, Cash Equivalents and Marketable Securities.** As of March 31, 2024, the Company had $206.7 million in cash, cash equivalents and marketable securities, which providing expected cash runway into the first half of 2026.

About FHD-286

FHD-286 is a 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.

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 (a.k.a. LY4050784) is a potent, allosteric and orally available small molecule that selectively inhibits the ATPase activity of BRM (SMARCA2) over its closely related paralog BRG1 (SMARCA4), 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 BRG1 rely on BRM for BAF function. FHD-909 has shown significant anti-tumor activity across multiple BRG1-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 or low-dose cytarabine (LDAC) in relapsed and/or refractory AML patients, pre-clinical product candidates, including the planned Phase 1 study of FHD-909, expected timing of clinical data, 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)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 206,661	$ 234,057
All other assets	48,343	51,859
Total assets	**$ 255,004**	**$ 285,916**
Deferred revenue, total	$ 297,615	$ 302,665
All other liabilities	54,875	60,441
Total liabilities	**$ 352,490**	**$ 363,106**
Total stockholders' equity (deficit)	**$ (97,486)**	**$ (77,190)**
Total liabilities and stockholders' equity	**$ 255,004**	**$ 285,916**

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

	Three Months Ended March 31,	
	2024	2023
Collaboration revenue	$ 5,050	$ 5,309
Operating expenses:		
Research and development	25,534	29,985
General and administrative	7,710	8,641
Total operating expenses	**$ 33,244**	**$ 38,626**
Loss from operations	**$ (28,194)**	**$ (33,317)**
Total other income, net	**$ 3,178**	**$ 3,389**
Provision for income taxes	**$ —**	**$ (560)**
Net loss	**$ (25,016)**	**$ (30,488)**
Net loss per share attributable to common stockholders—basic and diluted	(0.59)	(0.73)

Weighted average common shares outstanding—basic and diluted	**42,428,813**	**41,811,087**

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