Foghorn Therapeutics Provides Financial Update for 2024 and 2025 Strategic Outlook

Mar 6, 2025

First-in-class oral selective SMARCA2 (BRM) inhibitor FHD-909 (LY4050784) continues enrollment in Phase 1 trial for SMARCA4 (BRG1) mutated cancers, with non-small cell lung cancer (NSCLC) as the primary target population

FHD-909 preclinical combination data with pembrolizumab and KRAS inhibitors to be presented at AACR 2025

Selective degradation of ARID1B achieved with program update expected in 2025; continued progress of Selective CBP degrader and Selective EP300 degrader towards IND

Strong balance sheet with cash, cash equivalents, and marketable securities of $243.7 million as of December 31, 2024, provides cash runway into 2027

CAMBRIDGE, Mass., March 06, 2025 (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 update and corporate outlook in conjunction with the Company's 10-K filing for the year ending December 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.

"In 2024, we continued our strong execution across our pipeline, which has set us up for an exciting 2025. The Phase 1 trial of FHD-909, a first-in-class oral selective SMARCA2 inhibitor for SMARCA4 mutated cancers with NSCLC as the primary target population, is enrolling well. Preclinical combination data of FHD-909 with pembrolizumab and novel KRAS inhibitors will be presented at AACR," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "We are continuing to progress our Selective CBP degrader and Selective EP300 degrader towards IND and will present additional preclinical data at AACR. Our Selective ARID1B degrader program, which addresses a synthetic lethal target implicated in up to 5% of all solid tumors, continues to make exciting advancements, and we expect to provide a program update later in 2025. Our balance sheet remains strong, and we look forward to sharing progress for programs throughout the year."

Recent Corporate Updates

Dosed first patient with FHD-909 in October 2024. 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, in October 2024.

Selective degradation of ARID1B achieved. Earlier this year, Foghorn announced that the company has achieved selective degradation of ARID1B and will provide a program update during 2025.

Presented at the 7th Annual Targeted Protein Degradation (TPD) Summit. In October 2024, 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.

Program Overview and Upcoming Milestones

FHD-909 (LY4050784). FHD-909 is a first-in-class oral selective SMARCA2 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. Selectively blocking SMARCA2 activity is a promising synthetic lethal strategy intended to induce tumor death while sparing healthy cells. SMARCA4 is mutated in up to 10% of NSCLC alone and implicated in a significant number of solid tumors. Patients diagnosed with NSCLC with a SMARCA4 mutation tend to have a worse prognosis.

- **Advancing Phase 1 trial.** First patient dosed in October 2024 in the Phase 1 trial for FHD-909 in SMARCA4 mutated cancers, with NSCLC as the primary target population.
    - Ongoing first-in-human Phase 1a/b open-label, multicenter trial design for FHD-909 will be presented at the AACR Annual Meeting (April 25-30, 2025).
- **Preclinical combination data to be presented.** In 2025, preclinical data for FHD-909 in combination with pembrolizumab and KRAS inhibitors will be presented at the AACR Annual Meeting (April 25-30, 2025).

Ongoing strategic collaboration with Lilly. Collaborating 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 from Foghorn's proprietary Gene Traffic Control® platform.

Selective CBP degrader program. Selectively targets EP300 mutated cancers, including bladder, gastric, and endometrial cancers. 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.

- **Identified potent and selective CBP protein degraders.** Pharmacodynamic and pharmacokinetic preclinical data demonstrate:
    - 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.
    - Long-acting injection formulation that resulted in tumor regression from a single dose in a mouse xenograft efficacy study.
- **Preclinical combination data to be presented.** In 2025, preclinical data for the Selective CBP degrader program, in combination with approved chemotherapeutics and targeted agents, will be presented at the AACR Annual Meeting (April 25-30, 2025).

Selective EP300 degrader program. Selective degradation of EP300 for the treatment of hematopoietic malignancies and prostate cancer. Attempts to selectively drug EP300 have been challenging due to the high level of similarity between EP300 and CBP, while dual inhibition of CBP/EP300 has been limited by hematopoietic toxicity. EP300 lineage dependencies are established in multiple myeloma and diffuse large B cell lymphoma.

- **Identified potent and selective EP300 degraders and advancing oral degrader efforts.** Pharmacodynamic and pharmacokinetic preclinical data demonstrate candidates:
    - Are well tolerated in vivo with no observed decrease in platelet levels, and no effects on megakaryocyte viability at pharmacologically relevant concentrations in ex vivo studies.
    - Have robust anti-tumor activity in solid tumors and hematological malignancies, including prostate cancer, multiple myeloma, and diffuse large B cell lymphoma.
- **Preclinical data in hematological malignancies to be presented.** In 2025, preclinical data for the Selective EP300 degrader program demonstrating biological activity in hematological malignancies will be presented at the AACR Annual Meeting (April 25-30, 2025).

Selective ARID1B degrader program. Selectively targets and degrades ARID1B in ARID1A-mutated cancers. ARID1A is the most mutated subunit in the BAF complex and amongst the most mutated proteins in cancer. 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.

- **ARID1B is a major synthetic lethal target implicated in up to 5% of all solid tumors.**
- **Developed highly potent and selective binders.** Preclinical data demonstrated potent and selective small molecule binders to ARID1B.
- **Selective degradation of ARID1B achieved.** Foghorn has successfully selectively degraded ARID1B.
- **Selective ARID1B degrader program update expected in 2025**.

Chromatin biology and degrader platform. Foghorn continues to advance its chromatin biology and degrader platform with investments in novel ligases, long-acting injectables, oral delivery and induced proximity.

Full Year 2024 Financial Highlights

- **Collaboration revenues**. Collaboration revenues were $22.6 million for the year ended December 31, 2024, compared to $34.2 million for the year ended December 31, 2023. The decrease year-over-year was primarily driven by revenue recognized under the Merck collaboration due to the termination of the agreement in 2023 and subsequent recognition of the remaining deferred revenue.
- **Research and development expenses**. Research and development expenses were $94.5 million for the year ended December 31, 2024, compared to $109.7 million for the year ended December 31, 2023. This decrease was primarily due to costs associated with decreased headcount, partially offset by an increase in spend in our Lilly collaboration programs.
- **General and administrative expenses**. General and administrative expenses were $28.4 million for the year ended December 31, 2024, compared to $32.4 million for the year ended December 31, 2023. This decrease was primarily due to costs associated with decreased headcount.
- **Net loss**. Net loss was $86.6 million for the year ended December 31, 2024, compared to a net loss of $98.4 million for the year ended December 31, 2023.
- **Cash, cash equivalents and marketable securities**. As of December 31, 2024, the Company had $243.7 million in cash, cash equivalents and marketable securities, providing cash runway into 2027.

About FHD-909
FHD-909 (a.k.a. LY4050784) is a highly 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 tumors.

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 and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements." 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, 2024, 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)

	Dec. 31, 2024	Dec. 31, 2023
Cash, cash equivalents and marketable securities	$ 243,747	$ 234,057
All other assets	40,235	51,859
Total assets	**$ 283,982**	**$ 285,916**
Deferred revenue, total	$ 280,063	$ 302,665
All other liabilities	49,447	60,441
Total liabilities	**329,510**	**363,106**
Total stockholders' deficit	**(45,528)**	**(77,190)**
Total liabilities and stockholders' deficit	**$ 283,982**	**$ 285,916**

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

	Twelve Months Ended December 31,	
	2024	**2023**
Collaboration revenue	$ 22,602	$ 34,155
Operating expenses:		
Research and development	94,528	109,689
General and administrative	28,359	32,372
Impairment of long-lived assets	2,398	—
Total operating expenses	**125,285**	**142,061**
Loss from operations	**(102,683)**	**(107,906)**
Total other income, net	**16,063**	**13,706**
Loss before income taxes	**(86,620)**	**(94,200)**
Provision for income taxes	—	(4,226)
Net loss	**$ (86,620)**	**$ (98,426)**
Net loss per share attributable to common stockholders—basic and diluted	$ (1.58)	$ (2.34)
Weighted average common shares outstanding—basic and diluted	**54,899,432**	**41,974,484**

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