Foghorn Therapeutics Provides Financial Update for 2023 and 2024 Strategic Outlook

Mar 7, 2024

• Dose escalation in FHD-286 combination study in AML continues to progress; clinical data anticipated in the second half of 2024

• FHD-909, a first-in-class BRM selective inhibitor, selected for clinical development by partner Lilly; preclinical data to be presented at AACR with IND planned for the second quarter, primary target patient population in non-small cell lung cancer

• Selective CBP and EP300 degrader preclinical data to be presented at AACR; IND-enabling studies for CBP degrader program planned to begin by end of 2024

• Foghorn anticipates at least six new INDs targeting significant oncology patient populations over the next four years, reflecting the continued productivity of its precision medicine platform

• Cash, cash equivalents, and marketable securities of $234.1 million, as of December 31, 2023, provide cash runway into the first half of 2026

CAMBRIDGE, Mass., March 07, 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 update and corporate outlook in conjunction with the Company's 10-K filing for the year ending December 31, 2023. 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 with a wide spectrum of diseases.

"The research and clinical advances we made in 2023 set the stage for Foghorn to deliver significant value with the potential for several differentiated, high-impact medicines in 2024 and beyond," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "In 2023 we initiated a combination study with FHD-286 in AML, with data anticipated in the second half of 2024. Based on the mutation-agnostic differentiation effect observed in our single-agent escalation study, we believe FHD-286 has the potential to be a first-in-class broad-based differentiation therapeutic in AML. We are also making progress with our selective BRM program with FHD-909, a first-in-class BRM selective inhibitor, selected for clinical development by partner Lilly. The IND is planned for the second quarter of 2024, with an initial focus in non-small cell lung cancer. Finally, we are excited by the preclinical efficacy and safety data for our CBP and EP300 selective degrader programs and target IND-enabling studies for CBP by the end of the year. Our cash position remains strong with runway into the first half of 2026."

Key Recent Updates and Upcoming Milestones

- **FHD-286.** FHD-286 is a potent, selective inhibitor of the BRG1 and BRM subunits of the BAF chromatin remodeling complex where dependency on BRG1/BRM is well-established preclinically with multiple tumor types, including acute myelogenous leukemia (AML)/myelodysplastic syndrome (MDS), non-small cell lung cancer (NSCLC) and prostate cancer.
    - **AML Update**. Foghorn commenced a Phase 1 study 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, and the first clinical data are expected in the second half of 2024.
    - **TKI Resistance**. Recently published data, along with Foghorn's work, suggest that FHD-286 may play an important role in overcoming resistance in EGFR/KRAS tumors. The Company is conducting preclinical work to further explore the opportunity and expects data in the second quarter of 2024.

- **Differentiated Pipeline Advancement.** Foghorn continues to expand its platform and pipeline. The Company anticipates the potential for six new investigational new drug (IND) applications in the next four years. The Company continues to progress programs for multiple targets that include chromatin remodeling complexes, transcription factors, helicases, and other chromatin-related factors. These targets include selective BRM and wholly owned programs including CBP, EP300, and ARID1B, as well as other undisclosed targets, which combined could address more than 20 tumor types impacting more than 500,000 new patients annually.

    - **Selective CBP and Selective EP300 programs.** Foghorn is presenting new preclinical data for its CBP and EP300 selective degrader programs at the 2024 AACR Annual Meeting, April 5-10, 2024.
        - CBP selective degraders have shown significant tumor growth inhibition in a colorectal cancer *in vivo* model. Antiproliferative effects were also observed for numerous cancer cell lines, including colorectal, gastric and bladder cancers.
        - EP300 selective degraders have shown potent cellular antiproliferation and *in vivo* tumor growth inhibition in an AR+ enzalutamide prostate *in vivo* model.
        - At preclinical efficacious doses, neither the CBP nor the EP300 selective degraders cause

thrombocytopenia, a commonly observed safety liability for dual CBP/EP300 inhibitors.

- **Lilly Collaboration.** Foghorn is engaged in a strategic collaboration with Lilly and continues to advance the BRM selective inhibitor and degrader programs along with other undisclosed programs.
    - In the first quarter of 2024, Lilly selected FHD-909, a first-in-class oral BRM selective inhibitor, for clinical development. Lilly plans to file an IND for FHD-909 in the second quarter of 2024. The primary target patient population is BRG1-mutated NSCLC.
    - Selective BRM inhibition has been a sought-after objective in cancer research for many years. A variety of tumor types, including NSCLC, are known to have mutations in BRG1, which we believe make them dependent on BRM activity for their survival. Selective blocking of BRM activity is considered a promising strategy for causing tumor cell death while sparing healthy cells.
    - Preclinical data will be presented in 2024, including at AACR with a poster presentation on April 8.

In December 2021, Foghorn announced a strategic collaboration with Lilly to create novel oncology medicines. The collaboration includes a 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.

Full Year 2023 Financial Highlights

- **Collaboration Revenues**. Collaboration revenues were $34.2 million for the year ended December 31, 2023, compared to $19.2 million for the year ended December 31, 2022. The increase year-over-year was primarily driven by revenue recognized under the Merck collaboration due to the termination of the agreement and the subsequent recognition of the remaining deferred revenue.

- **Research and Development Expenses**. Research and development expenses were $109.7 million for the year ended December 31, 2023, compared to $105.6 million for the year ended December 31, 2022. This increase was primarily due to costs associated with continued investment in R&D personnel, platform, and other early-stage research, partially offset by a decrease in spend on FHD-286 and FHD-609.

- **General and Administrative Expenses**. General and administrative expenses were $32.4 million for the year ended December 31, 2023, compared to $30.7 million for the year ended December 31, 2022. This increase was primarily due to an increase in investments to support the growing business, which included increases in personnel-related costs and stock-based compensation expense.

- **Net Loss**. Net loss was $98.4 million for the year ended December 31, 2023, compared to a net loss of $108.9 million for the year ended December 31, 2022.

- **Cash, cash equivalents and marketable securities**. As of December 31, 2023, the Company had $234.1 million in cash, cash equivalents and marketable securities, providing cash runway into the first half of 2026.

About FHD-286

FHD-286 is a highly 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 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 (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, 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, 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)

	Dec. 31, 2023	Dec. 31, 2022
Cash, cash equivalents and marketable securities	$ 234,057	$ 345,798
Collaboration receivable	—	—
All other assets	51,859	59,085
Total assets	**$ 285,916**	**$ 404,883**
Deferred revenue, total	$ 302,665	$ 336,820
All other liabilities	60,441	67,951
Total liabilities	**363,106**	**404,771**
Total stockholders' equity	**(77,190)**	**112**
Total liabilities and stockholders' equity	**$ 285,916**	**$ 404,883**

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

	Twelve Months Ended December 31,	
	2023	2022
Collaboration revenue	$ 34,155	$ 19,228
Operating expenses:		
Research and development	109,689	105,618
General and administrative	32,372	30,747
Total operating expenses	**142,061**	**136,365**
Loss from operations	**(107,906)**	**(117,137)**
Total other income, net	**13,706**	**8,255**
Loss before income taxes	**(94,200)**	**(108,882)**
Provision for income taxes	(4,226)	—
Net loss	**$ (98,426)**	**$ (108,882)**
Net loss per share attributable to common stockholders —basic and diluted	$ (2.34)	$ (2.62)
Weighted average common shares outstanding —basic and diluted	**41,974,484**	**41,591,433**

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