

Foghorn Therapeutics Provides Third Quarter 2023 Financial and Corporate Update

Nov 2, 2023

- First patient dosed in FHD-286 combination study in AML; data expected in the second half of 2024
- Transitioned the BRM Selective inhibitor program to Loxo@Lilly
- Presented preclinical data demonstrating tumor growth inhibition and favorable safety profiles for Selective EP300 and Selective CBP programs
- Cash, cash equivalents, and marketable securities of \$259.9 million, as of September 30, 2023, provides cash runway into the first half of 2026

CAMBRIDGE, Mass., Nov. 02, 2023 (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, 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 suffering from a wide spectrum of diseases.

"During the third quarter, we continued to enroll patients in our FHD-286 combination study in AML and expect to have data 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," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "We also made important progress with our Loxo@Lilly collaboration transitioning the BRM Selective inhibitor program to them."

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. Data are expected in the second half 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 EP300 and Selective CBP programs.** Foghorn presented new preclinical data for its EP300 and CBP selective degrader programs at Hanson Wade's 6th Annual Targeted Protein Degradation Summit on October 31st.
 - EP300 selective degraders showed potent cellular antiproliferation and in vivo tumor growth inhibition in an AR+ enzalutamide prostate in vivo model.
 - CBP selective degraders demonstrated 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.
 - At preclinical efficacious doses, neither the EP300 nor the CBP selective degraders caused thrombocytopenia, commonly observed safety liability for dual CBP/EP300 inhibitors.
- **Loxo@Lilly Collaboration.** Foghorn continues to progress its strategic collaboration with Loxo@Lilly.
 - During Q3 2023, the Company transitioned the BRM Selective inhibitor program to Loxo@Lilly.

*In December 2021, Foghorn announced a strategic collaboration with Loxo@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.

Third Quarter 2023 Financial Highlights

- **Strong Balance Sheet and Cash Runway.** As of September 30, 2023, the Company had \$259.9 million in cash, cash equivalents and marketable securities, which provides cash runway into the first half of 2026.

- **Collaboration Revenues.** Collaboration revenue was \$17.5 million for the three months ended September 30, 2023, compared to \$6.6 million for the three months ended September 30, 2022. The increase year-over-year was primarily driven by revenue realized upon termination of the Merck collaboration.
- **Research and Development Expenses.** Research and development expenses were \$26.3 million for the three months ended September 30, 2023, compared to \$26.9 million for the three months ended September 30, 2022. This decrease was primarily due to costs associated with continued investment in R&D personnel and platform and early-stage research investments, modestly offset by a decline in clinical trial spend.
- **General and Administrative Expenses.** General and administrative expenses were \$8.3 million for the three months ended September 30, 2023, compared to \$8.0 million for the three months ended September 30, 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 \$14.3 million for the three months ended September 30, 2023, compared to a net loss of \$25.8 million for the three months ended September 30, 2022.

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 pre-clinical 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 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.foghornrx.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, 2022, 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, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	\$ 259,888	\$ 345,798
All other assets	53,535	59,085
Total assets	\$ 313,423	\$ 404,883
Deferred revenue, total	\$ 308,434	\$ 336,820
All other liabilities	62,377	67,951
Total liabilities	\$ 370,811	\$ 404,771
Total stockholders’ equity (deficit)	\$ (57,388)	\$ 112
Total liabilities and stockholders’ equity	\$ 313,423	\$ 404,883

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

	Three Months Ended September 30,	
	2023	2022
Collaboration revenue	\$ 17,478	\$ 6,634
Operating expenses:		
Research and development	26,251	26,928
General and administrative	8,308	7,965
Total operating expenses	\$ 34,559	\$ 34,893
Loss from operations	\$ (17,081)	\$ (28,259)
Total other income, net	\$ 3,474	\$ 2,490
Provision for income taxes	\$ (738)	\$ —
Net loss	\$ (14,345)	\$ (25,769)
Net loss per share attributable to common stockholders—basic and diluted	(0.34)	(0.62)
Weighted average common shares outstanding—basic and diluted	42,025,938	41,672,621

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