Foghorn Therapeutics Provides 2023 Outlook and Full Year 2022 Corporate Update

March 9, 2023

- Phase 1 dose escalation study of FHD-286, a BRG1/BRM inhibitor, in metastatic uveal melanoma continues to progress with initial safety and efficacy data expected in the first half of 2023

- Phase 1 dose escalation study of FHD-609, a selective degrader of BRD9, in synovial sarcoma continues to progress with initial safety and efficacy data expected mid-2023

- Advancing preclinical pipeline targeting key regulators of gene expression, including newly disclosed EP300 program, and selective BRM, ARID1B, CBP and other undisclosed programs, setting up the potential for six INDs over the next four years

- Cash, cash equivalents and marketable securities of $345.8 million, as of December 31, 2022, provide cash runway into the second half of 2025

CAMBRIDGE, Mass., March 09, 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 corporate update including the Company's 2023 strategic priorities and 2022 key achievements in conjunction with its 10-K filing for the year ending December 31, 2022. With an initial focus in oncology, Foghorn's Gene Traffic Control ® Platform and resulting broad pipeline has the potential to transform the lives of people suffering from a wide spectrum of diseases.

"2022 was a productive year for Foghorn as we made significant progress advancing our robust preclinical and clinical pipeline," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "Specifically, we advanced more than 15 programs, which include selective inhibitors and degraders for some of the most challenging targets in oncology – BRM, CBP, EP300 and ARID1B. This year, we expect Phase 1 clinical data for our BRG1/BRM inhibitor FHD-286 in metastatic uveal melanoma in the first half of 2023 and aim to provide clarity on the path forward for FHD-286 in AML/MDS. We also expect to share clinical data for our BRD9 degrader FHD-609 mid-year. Our cash position remains strong and supports our R&D investments as we continue to advance our pipeline through late 2025."

2023 Outlook and Key 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 pre-clinically with multiple tumor types, including uveal melanoma, acute myelogenous leukemia (AML) / myelodysplastic syndrome (MDS), non-small cell lung cancer (NSCLC) and prostate cancer.
    - **mUM Update**. Phase 1 dose escalation of FHD-286 in metastatic uveal melanoma (mUM) continues to enroll patients per protocol. Initial Phase 1 safety and efficacy data are expected in the first half of 2023.
    - **AML/MDS Update.** In August 2022, the U.S. Food and Drug Administration (FDA) placed a full clinical hold on the Phase 1 dose escalation study of FHD-286 in relapsed and/or refractory AML and MDS. The Company anticipates providing clarity on the development path for FHD-286 in AML/MDS in the first half of 2023.
- **FHD-609 Update**. FHD-609 is a potent and selective heterobifunctional protein degrader of BRD9, which is a component of the BAF chromatin remodeling complex and a protein synovial sarcoma cells rely on for survival. Patient enrollment is continuing in the Phase 1 dose escalation clinical study of FHD-609 in synovial sarcoma and SMARCB1-loss tumors, with initial safety and efficacy data expected in mid-2023.
- **Newly Disclosed Selective EP300 Degrader**. Foghorn disclosed a selective EP300 degrader targeting CBP mutant cancers and subsets of EP300 dependent malignancies. The Selective EP300 program has potential in various cancers which include bladder, NSCLC and various lymphomas and leukemias, and could provide a new therapeutic option for more than 100,000 people a year.
- **Differentiated Pipeline Advancement**. Foghorn continues to expand its platform and pipeline. The Company has the potential for six new molecular investigational new drug (IND) applications in the next four years. The Company continues to progress programs for multiple targets which include chromatin remodeling complexes, transcription factors, helicases and other chromatin related factors. These targets include Selective BRM, 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 people annually.
- **Strategic Collaborations**. Foghorn expects continued progress across its strategic collaborations with two leading pharmaceutical companies.

- In December 2021, Foghorn entered into a strategic collaboration with Loxo Oncology, and in 2023 the Company anticipates continued progress across the collaboration, including the co-development and co-commercialization agreement on the selective BRM program, an additional undisclosed oncology target and three additional discovery programs.

- In July 2020, Foghorn entered into a strategic collaboration with Merck. In 2023, Foghorn will continue to leverage its Gene Traffic Control platform to discover and develop novel therapeutics based on disruptors of an undisclosed transcription factor target.

- **Strong Balance Sheet and Cash Runway**. As of December 31, 2022, the Company had $345.8 million in cash, cash equivalents and marketable securities, providing cash runway into the second half of 2025.

2022 Key Achievements

- **Selective CBP Program Announced**. In October 2022, Foghorn disclosed a selective CBP degrader targeting EP300 mutant cancers. The Selective CBP program is aimed at degrading the CREB binding protein and has therapeutic potential in subsets of several cancers including bladder, colorectal, breast, gastric and lung. Using selective CBP degraders, the program aims to exploit the synthetic lethal relationship it shares with its paralog EP300 to identify and treat those patients with EP300 mutated cancers. If successful, the Selective CBP program has the potential to address more than 100,000 people per year across many cancer types.

- **Advanced Top Synthetic Lethal Relationship Targets**. BRM and ARID1B represent two of the top synthetic lethal targets in cancer, where the mutation occurs in BRG1 and ARID1A paralogues, respectively. We continued to make progress on our BRM selective program with Loxo Oncology. Additionally, we continued to advance our ARID1B program with validated selective chemical matter.

- **Merck Collaboration Progress**. In July 2022, a research milestone on the transcription factor target was achieved under the Merck collaboration triggering a $5 million milestone payment to Foghorn.

- **Key Leadership Updates**. In 2022, Foghorn announced Steven Bellon, Ph.D., former Senior Vice President of Drug Discovery, was promoted to Chief Scientific Officer. Dr. Bellon joined Foghorn Therapeutics in 2016 as head of drug discovery, bringing more than 20 years of drug discovery experience from multiple drug classes. During his tenure at Foghorn, Dr. Bellon has been instrumental in building Foghorn's Gene Traffic Control® platform and advancing the Company's broad therapeutic pipeline of more than 15 programs including protein degraders, enzymatic inhibitors and transcription factor disruptors.

- **Board of Directors Updates**. During 2022, Foghorn announced the election of B. Lynne Parshall, Esq., and Thomas J. Lynch Jr., M.D., to its Board of Directors. Ms. Parshall brings nearly three decades of experience in finance and operations in the biotechnology industry and served as the Senior Strategic Advisor for Ionis Pharmaceuticals. Dr. Lynch is currently the president and director of Fred Hutchinson Cancer Center, where he holds the Raisbeck Endowed Chair and sets the strategic direction of the center, oversees center-wide initiatives and represents the center's interests to major partners and governmental bodies.

Full Year 2022 Financial Highlights

- **Collaboration Revenues**. Collaboration revenues were $19.2 million for the year ended December 31, 2022, compared to $1.3 million for the year ended December 31, 2021. The increase year-over-year was primarily driven by revenue recognized under the Lilly collaboration agreement, which was executed in December 2021.

- **Research and Development Expenses**. Research and development expenses were $105.6 million for the year ended December 31, 2022, compared to $80.3 million for the year ended December 31, 2021. This increase was primarily due to costs associated with continued investment in R&D personnel and the Phase 1 studies for both FHD-286 and FHD-609, which were initiated in 2021.

- **General and Administrative Expenses**. General and administrative expenses were $30.7 million for the year ended December 31, 2022, compared to $21.7 million for the year ended December 31, 2021. 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 $108.9 million for the year ended December 31, 2022, compared to a net loss of $101.3 million for the year ended December 31, 2021.

- **Cash, cash equivalents and marketable securities**. As of December 31, 2022, the Company had $345.8 million in cash, cash equivalents and marketable securities, providing cash runway into the second half of 2025.

About FHD-286

FHD-286 is a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 and BRM, two highly similar proteins that are the ATPases, or the catalytic engines across all forms of the BAF complex, one of the key regulators of 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. To learn more about these studies, please visit ClinicalTrials.gov. (Link here for metastatic uveal melanoma and here for AML and MDS).

About Uveal Melanoma

Uveal (intraocular) melanoma (UM) is a rare eye cancer that forms from cells that make melanin in the iris, ciliary body and choroid. It is the most common eye cancer in adults. It is diagnosed in about 2,000 adults every year in the United States and occurs most often in lightly pigmented individuals with a median age of 55 years. However, it can occur in all races and at any age. UM metastasizes in approximately 50% of cases, leading to very poor prognosis.

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-609

FHD-609 is a potent, selective, intravenously administered protein degrader of BRD9, a component of the ncBAF complex. Preclinical studies have demonstrated tumor growth inhibition in synovial sarcoma and SMARCB1-loss tumors, cancers genetically dependent on BRD9. To learn more about this study, please visit ClinicalTrials.gov.

About Synovial Sarcoma

Synovial sarcoma is a rare, often aggressive soft tissue sarcoma that originates from different types of soft tissue, including muscle or ligaments. Synovial sarcoma can occur at any age but is most common among adolescents and young adults. It represents around 5-10% of all soft tissue sarcomas, with ~800 new cases each year in the United States. Surgery remains the most effective treatment for synovial sarcoma, and there are limited therapeutic treatment options.

About Foghorn Therapeutics

Foghorn® Therapeutics Inc. 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 Twitter and LinkedIn.

Forward-Looking Statements

This press release contains “forward-looking statements” regarding the Company’s clinical programs for FHD-286 and FHD-609, including its efforts to resolve the full clinical hold relating to FHD-286 in AML and MDS, the anticipated timing of release of clinical data, its collaborations with Lilly and Merck and its research pipeline, including the filing of INDs and its protein degrader efforts. 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, 2021 and subsequent Quarterly Reports on Form 10-Q, 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, 2022	Dec. 31, 2021
Cash, cash equivalents and marketable securities	$ 345,798	$ 154,289
Collaboration receivable	—	300,000
All other assets	59,085	65,485
Total assets	**$ 404,883**	**$ 519,774**
Deferred revenue, total	$ 336,820	$ 351,047
All other liabilities	67,951	71,856
Total liabilities	**404,771**	**422,903**

Total stockholders' equity	**112**	**96,871**
Total liabilities and stockholders' equity	**$ 404,883**	**$ 519,774**

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

	Twelve Months Ended December 31,	
	2022	**2021**
Collaboration revenue	$ 19,228	$ 1,319
Operating expenses:		
Research and development	105,618	80,325
General and administrative	30,747	21,728
Total operating expenses	**136,365**	**102,053**
Loss from operations	**(117,137)**	**(100,734)**
Total other income, net	**8,255**	**(586)**
Net loss	**$ (108,882)**	**$ (101,320)**
Net loss per share attributable to common stockholders—basic and diluted	$ (2.62)	$ (2.73)
Weighted average common shares outstanding—basic and diluted	**41,591,433**	**37,171,147**

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