Foghorn Therapeutics Provides Second Quarter 2022 Financial and Corporate Update

Aug 9, 2022

- FHD-286 dose escalation Phase 1 study in metastatic uveal melanoma continues to progress per protocol; working to resolve partial clinical hold in AML and MDS

- On track to report initial Phase 1 clinical data for FHD-609 in synovial sarcoma in 2023

- Research milestone achieved under Merck collaboration in July, triggering $5 million milestone payment to Foghorn in the third quarter 2022

- Cash, cash equivalents and marketable securities of $394.7 million, as of June 30, 2022, provides significant cash runway

CAMBRIDGE, Mass., Aug. 09, 2022 (GLOBE NEWSWIRE) -- Foghorn® Therapeutics Inc. (Nasdaq: FHTX), a clinical stage biotechnology company pioneering a new class of medicines that modulate gene expression through selectively targeting the chromatin regulatory system, today provided a financial and corporate update in conjunction with the Company's 10-Q filing for the quarter ended June 30, 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.

"During the second quarter, supported by a strong balance sheet, Foghorn continued to advance its broad and deep pipeline of more than a dozen highly differentiated programs while making important progress towards our goal of becoming a fully integrated biotech company," said Foghorn CEO Adrian Gottschalk. "We continue to enroll patients in the Phase 1 dose escalation study of FHD-286 in uveal melanoma and FHD-609 in synovial sarcoma, and we have been working diligently to resolve the partial clinical hold of FHD-286 in AML and MDS. In addition, we are pleased with the continued progress with our Merck collaboration, and in particular, the achievement of the first research milestone."

Key Recent Updates

- **FHD-286 AML/MDS Update.** In May, the Food and Drug Administration (FDA) placed the Phase 1 dose escalation study of FHD-286 in relapsed and/or refractory acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) on a partial clinical hold. The partial clinical hold was initiated by the FDA following the report of a recent death that occurred in a subject with potential differentiation syndrome. Differentiation syndrome is associated with AML/MDS therapeutics that induce differentiation, an effect that is believed to be on-target for the proposed mechanism of action for FHD-286. The Company continues to work to resolve the partial clinical hold with the FDA.

- **FHD-286 mUM Update.** The dose escalation Phase 1 study in metastatic uveal melanoma (mUM) continues to enroll patients per protocol. The partial clinical hold does not apply to this study of FHD-286.

- **FHD-609 Update.** Patient enrollment is continuing in the Phase 1 dose escalation clinical study of FHD-609, a potent and selective heterobifunctional protein degrader of BRD9, initially being developed for the treatment of synovial sarcoma with initial data expected in 2023.

- **Merck Collaboration Update.** In July 2022, a research milestone was achieved under the Merck collaboration triggering a $5 million milestone payment to Foghorn which will be reflected in the quarter ended September 30, 2022 financials.

- **BRM-selective Progress.** Foghorn is advancing its BRM-selective programs in collaboration with Loxo@Lilly, with the BRM-selective inhibitor program in lead optimization and the protein degrader program in hit-to-lead stage. Foghorn is leading discovery and early research activities, and Lilly is leading development and commercialization activities with participation from Foghorn. U.S. economics will be shared equally, and Foghorn is eligible to receive royalties on ex-U.S. sales in the low double-digit to twenties range based on revenue levels.

- **Pipeline Advancement.** Foghorn continued to advance its broad therapeutic pipeline of which the majority are wholly owned, including protein degraders, enzymatic inhibitors and transcription factor disruptors targeting cancers impacted by breakdowns in the chromatin regulatory system. We continue to invest in our protein degradation capabilities with approximately half of our pipeline programs utilizing this modality. This investment includes our protein degrader asset, ARID1B, for which we have identified several different biophysically validated chemical scaffolds.

Second Quarter 2022 Financial Highlights

- **Strong Balance Sheet and Cash Runway**. As of June 30, 2022, the Company had $394.7 million in cash, cash equivalents and marketable securities.
- **Collaboration Revenues.** Collaboration revenues were $4.5 million for the second quarter of 2022 compared to $0.3 million the second quarter of 2021. The increase was driven by revenue recognized under the Lilly Collaboration Agreement which was entered into in December 2021.
- **Research and Development Expenses**. Research and development expenses were $26.0 million for the second quarter of 2022 compared to $18.6 million for the second quarter of 2021. This increase was primarily due to costs associated with the Phase 1 studies for both FHD-286 and FHD-609, which were initiated in 2021, and continued investment in R&D personnel, the platform and other early-stage research.
- **General and Administrative Expenses**. General and administrative expenses were $7.7 million for the second quarter of 2022, compared to $4.9 million for the second quarter of 2021. This increase was primarily due to an increase in headcount to support the growing business.
- **Net Loss**. Net loss was $27.3 million for the second quarter of 2022 compared to a net loss of $23.1 million for the second quarter of 2021.

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 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 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 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, a cancer genetically dependent on BRD9. To learn more about the first-in-human clinical trial of FHD-609 in synovial sarcoma, 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 partial clinical hold relating to FHD-286 in AML and MDS, the anticipated timing of receipt of initial clinical data, its collaboration with Lilly and its research pipeline, including its 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)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 394,729	$ 154,289
Collaboration receivable	—	300,000
All other assets	62,171	65,485
Total assets	**$ 456,900**	**$ 519,774**
Deferred revenue, total	$ 342,637	$ 351,047
All other liabilities	66,631	71,856
Total liabilities	**409,268**	**422,903**
Total stockholders' equity	**47,632**	**96,871**
Total liabilities and stockholders' equity	**$ 456,900**	**$ 519,774**

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

	Three Months Ended June 30,	
	2022	2021
Collaboration revenue	$ 4,490	$ 279
Operating expenses:		
Research and development	25,974	18,642
General and administrative	7,704	4,898
Total operating expenses	**33,678**	**23,540**
Loss from operations	**(29,188)**	**(23,261)**
Total other income, net	**1,875**	**150**
Net loss	**$ (27,313)**	**$ (23,111)**
Net loss per share attributable to common stockholders—basic and diluted	$ (0.66)	$ (0.63)
Weighted average common shares outstanding—basic and diluted	**41,515,305**	**36,847,435**

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