Delcath Systems Announces Preliminary Third Quarter 2024 Revenue Results

October 17, 2024

$10 Million Quarterly U.S. Revenue Triggers $25 Million Financing Tranche

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Oct. 17, 2024-- Delcath Systems, Inc. (Nasdaq: DCTH) ("Delcath" or the "Company"), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced preliminary revenue results for the third quarter of 2024, achieving $11.2 million, which included the recording of $10.0 million in U.S. revenue from the commercialization of HEPZATO KIT.

The announcement of the recording of $10.0 million in U.S. quarterly revenue from the commercialization of HEPZATO KIT effectively triggers the exercise of Tranche B warrants issued in the previously announced March 29, 2023 Private Investment in Public Equity (the "PIPE"). Holders of the Tranche B warrants from the PIPE have 21 days from the date of this announcement to exercise their Tranche B warrants to purchase shares of common stock at an effective price of $6.00 per share of common stock for an aggregate exercise price of up to approximately $25 million.

"This revenue milestone is an important indicator of the strong demand for HEPZATO KIT, highlighting the unmet medical need it addresses in uveal melanoma patients with liver metastases and the rapid uptake by physicians," said Gerard Michel, Chief Executive Officer of Delcath. "The Company will utilize the additional $25 million of financing to support the ongoing commercial launch and invest in new clinical trials to expand indications which we plan to initiate in 2025."

Final financial results for the third quarter and a detailed business update will be provided during Delcath's quarterly financial results release and investor call scheduled for November 8, 2024.

About Delcath Systems, Inc., HEPZATO KIT and CHEMOSAT

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company's proprietary products, HEPZATO KIT™ (HEPZATO (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP), are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated and approved for sale as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System (HDS). The HDS is used to isolate the hepatic venous blood from the systemic circulation while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used in the conduct of percutaneous hepatic perfusion procedures at major medical centers to treat a wide range of cancers of the liver.

Financial Disclaimer

Delcath has not completed preparation of its financial statements for the third quarter of 2024. Delcath is in the process of completing its customary quarter-end close and review procedures as of and for the quarterly period ended September 30, 2024, and there can be no assurance that final results for this period will not differ from these estimates.

Safe Harbor / Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This press release contains forward-looking statements, which are subject to certain risks and uncertainties, that can cause actual results to differ materially from those described. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Factors that may cause such differences include, but are not limited to, potential proceeds from exercise of the Tranche B warrants; uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; the Company's successful management of the HEPZATO KIT supply chain, including securing adequate supply of critical components necessary to manufacture and assemble the HEPZATO KIT; successful FDA inspections of the facilities of the Company and those of its third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential benefits of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; the Company's ability to obtain reimbursement for the HEPZATO KIT; and the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT. For additional information about these factors, and others that may impact the Company, please see the Company's filings with the Securities and Exchange Commission, including those on Forms 10-K, 10-Q, and 8-K. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, you should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

View source version on businesswire.com: https://www.businesswire.com/news/home/20241017610926/en/

Investor Relations:
ICR Healthcare
investorrelations@delcath.com

Source: Delcath Systems, Inc.