Delcath Systems Announces Preliminary Fourth Quarter and Full Year 2025 Financial Results

January 9, 2026

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Jan. 9, 2026-- 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 financial results and business updates for the fourth quarter and year-ended December 31, 2025.

Preliminary Fourth Quarter and Full-Year 2025 Financial Results (unaudited)

- Total fourth quarter and full year revenue expected to be approximately $20.7 million and $85.2 million, respectively
  - HEPZATO KIT™ fourth quarter and full year revenue expected to be approximately $19.0 million and $78.8 million, respectively
  - CHEMOSAT® fourth quarter and full year revenue expected to be approximately $1.7 million and $6.4 million, respectively
- 628,572 common shares repurchased for $6.0 million through December 31, 2025 under the approved $25.0 million Share Buyback Program
- As of December 31, 2025, the Company had approximately $91.0 million of cash and short-term investments and no debt compared to cash and short-term investments of $88.9 million as of September 30, 2025

Final financial results for the fourth quarter and full year 2025 and a detailed business update will be provided during Delcath's annual financial results release and business update call.

Recent Business Highlights

- Currently 25 active centers
- Approximately 140% growth in HEPZATO procedure volume in 2025 versus 2024
- Independent investigators presented results from the Phase 2 CHOPIN trial sponsored by Leiden University Medical Center evaluating CHEMOSAT with ipilimumab and nivolumab in metastatic uveal melanoma at the 2025 European Society of Medical Oncology Annual Congress showing a significant improvement in one-year progression-free survival versus CHEMOSAT alone
- Recent publications have highlighted the application, enhanced outcomes, and associated efficacy of percutaneous hepatic perfusion (PHP) in the management of metastatic uveal melanoma (mUM):
  - "Characterization of long-term survivors with liver metastases from uveal melanoma diagnosed between 2005 and 2021" in *International Journal of Cancer*
  - "Survival Outcome After Percutaneous Hepatic Perfusion with High-Dose Melphalan for Liver-Dominant Metastatic Uveal Melanoma: A 10-Year Single-Center Experience" in *Cancers*
  - "Subgroup Analyses of the Phase 3 FOCUS Study of Melphalan/Hepatic Delivery System in Patients with Unresectable Metastatic Uveal Melanoma" in *Journal of Cancer Research and Clinical Oncology*

"In 2026 we will continue to drive increased adoption and utilization of HEPZATO by raising awareness among treating physicians of the CHOPIN study findings," said Gerard Michel, Chief Executive Officer of Delcath. "Our strong financial position enables us to invest in both commercial expansion and the initiation of additional clinical programs in 2026."

Preliminary and Unaudited Nature of Reported Results

The Company has not yet completed its financial close process for the fourth quarter and full year 2025 and, as a result, actual results may vary from the estimated preliminary results set forth in this press release due to a number of factors, including audit adjustments and other developments that may arise between now and the time the financial results for the fourth quarter and fiscal year ended December 31, 2025, are finalized. The estimated preliminary financial results have not been audited or reviewed by the Company's independent registered public accounting firm. These estimates should not be viewed as a substitute for the

Company's full, interim or annual audited financial statements.

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 (HDS) 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 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.

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, including the Company's statements regarding the possible synergy seen in the successful Phase 2 CHOPIN Trial being transferable to clinical practice; Company's 2025 financial outlook, 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, uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; contributions to adjusted EBITDA; 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.

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