



Delcath Systems Issues Full Year 2025 Guidance

May 22, 2025

2025 Full Year Total Revenue Guidance of \$94 to \$98 million Delcath Announces Plan to Enter into National Medicaid Drug Rebate Agreement

QUEENSBURY, N.Y.--(BUSINESS WIRE)--May 22, 2025-- Delcath Systems, Inc. (Nasdaq: DCTH) ("Delcath" or the "Company"), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced full year 2025 financial guidance and its intention to enter into a Medicaid National Drug Rebate Agreement (NDRA) to expand patient access.

2025 Full Year Financial Guidance

The Company's financial outlook for fiscal year 2025 is as follows:

- Total CHEMOSAT and HEPZATO KIT revenue of \$94 to \$98 million, an increase of more than 150% over 2024
- Gross margins between 83% to 85%
- Positive adjusted EBITDA and cashflow in each quarter of 2025

National Medicaid Drug Rebate Agreement

Delcath will participate in the Medicaid Drug Rebate Program, which entails providing Medicaid rebates and 340B discounts to eligible entities. The Company has initiated the process of entering into the NDRA with the Centers for Medicare and Medicaid Services and expects it to take effect at the beginning of the third quarter of 2025.

"Our decision to enter into the NDRA simplifies Medicaid access and enables eligible hospitals to access 340B drug pricing. We believe this will expand treatment availability and accelerate adoption of HEPZATO in the United States," said Gerard Michel, Chief Executive Officer of Delcath. "Based on current center activation rates and rising utilization, we expect total HEPZATO treatment volume in 2025 to increase at least 200% versus 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 filtering 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 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 ability to successfully enter into the NDRA and its potential impact on the Company's business and operation; 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.

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