Delcath Systems Announces Preliminary Third Quarter 2025 Financial Results

October 18, 2025

Conference Call October 20, 8:45am EST

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Oct. 18, 2025-- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today provided preliminary revenue and financial results for the quarter ended September 30, 2025, and updated 2025 full-year revenue guidance.

Preliminary Third Quarter Financial Results (unaudited)

- Total CHEMOSAT and HEPZATO KIT revenue of approximately $20.5 million
  - HEPZATO KIT revenue of $19.2 million
  - CHEMOSAT revenue of $1.3 million
- Gross margins expected to be 87%

Net income of $0.8 million

- Positive adjusted EBITDA of $5.3 million

Positive operating cashflow of approximately $4.8 million

As of September 30, 2025, the Company had approximately $88.9 million of cash, cash equivalents and short-term investments and no debt.

2025 Full Year Financial Guidance

- Total CHEMOSAT and HEPZATO KIT revenue of $83 million to $85 million, reflecting an approximate 150% increase in treatment volume over 2024
- Quarterly gross margins between 85% to 87%
- Positive adjusted EBITDA and operating cashflow in each quarter of 2025

“Although our third quarter revenue was modestly lower than the second quarter, this decline was primarily due to the NDRA discounts and unexpected summer seasonality which impacted the scheduling of new patient starts,” said Gerard Michel, Chief Executive Officer of Delcath Systems. “We are confident that we will achieve strong growth in 2026 and beyond. This expectation is based on our ongoing expansion of active treatment centers and the positive influence of the CHOPIN trial results, which have demonstrated impressive efficacy and offer practical advantages for initiating patients on systemic therapy, while preparing for PHP therapy.”

Conference Call Information

Delcath Systems, Inc. will host a conference call and webcast on October 20, 2025, at 8:45 a.m. Eastern Time to discuss the Phase 2 CHOPIN Trial results and provide a brief overview of the financial results announced in this release.
Joining Delcath management on the call with pre-recorded remarks will be Dr. Vincent T. Ma, Assistant Professor and Medical Oncologist at the University of Wisconsin Department of Medicine, a current user of HEPZATO KIT for the treatment of metastatic uveal melanoma patients, an expert in treating cutaneous melanoma, and a co-author on the seminal Nature Medicine paper exploring liver immune tolerance mechanisms in cancer.

To participate in this event, dial in approximately 5 to 10 minutes before the beginning of the call.

Event Date: Monday, October 20
Time: 8:45 AM Eastern Time

Participant Numbers:
Toll Free: 1-877-407-3982
International: 1-201-493-6780
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1738867&tp_key=6f3953dd75

A replay of the webinar will be available shortly after the conclusion of the call and will be archived on the company's website https://investors.delcath.com/news-events/events-and-presentations.

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.

Preliminary Nature of Third Quarter Financial Results

The preliminary estimated financial results for the quarter ended September 30, 2025 included in this press release are preliminary, unaudited and have not been reviewed by Delcath's independent auditors and are subject to completion of quarter-end financial and accounting procedures and may change as a result of management's continued review. The preliminary financial results represent management estimates that constitute forward-looking statements subject to risks and uncertainties. The preliminary financial results are not a comprehensive statement of all financial results for the quarter ended September 30, 2025. Subsequent information or events may lead to material differences between the foregoing preliminary financial results and those reported in Delcath's subsequent SEC filings. Accordingly, investors should not place undue reliance on these preliminary financial results.

GAAP v. Non-GAAP Measures

In addition to the financial information presented in this release in accordance with accounting principles generally accepted in the United States of America (GAAP), Delcath also presents adjusted non-GAAP financial measures. Delcath's management believes that the non-GAAP adjusted EBITDA described in this release, which includes adjustments for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding Delcath's underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in Delcath's industry. However, the non-GAAP financial measures that Delcath uses may differ from measures that other companies may use. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

Delcath does not provide guidance for net loss, the most directly comparable GAAP measure to Adjusted EBITDA, and similarly cannot provide a reconciliation between its forecasted Adjusted EBITDA and net loss without unreasonable effort due to the unavailability of reliable estimates for certain components of net income and the respective reconciliations. These forecasted items are not within Delcath's control, may vary greatly between periods, and could significantly impact future financial results.

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; statements regarding the potential of CHEMOSAT Hepatic Delivery System and HEPZATO KIT to improve outcomes for patients with metastatic uveal melanoma; statements regarding the potential to drive increased adoption of HEPZATO KIT; statements regarding the CHOPIN Phase 2 Trial results supporting the opening of new treatment sites, and accelerating the referral of mUM patients to treatment sites; statements regarding Delcath's continued growth and leadership in liver-directed oncology; and statements regarding Delcath's 2025 full-year revenue guidance, , 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.

This release contains forward-looking statements, including statements regarding the expected release of clinical trial results, which are subject to risks and uncertainties. Factors that could affect these forward-looking statements include, but are not limited to, delays in the presentation of the data, or other unforeseen issues relating to the release of the clinical trial results. For a detailed discussion of these and other risks, please refer to Delcath's filings with the SEC.

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