Delcath Systems Reports Fourth Quarter and Full Year 2025 Results

February 26, 2026

Conference Call Today at 8:30 a.m. Eastern Time

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Feb. 26, 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 reported financial results and business highlights for the fourth quarter and full year-ended December 31, 2025.

Fourth Quarter and Full Year 2025 Financial Results

- Total fourth quarter and full year revenue of $20.7 million and $85.2 million, respectively
  - HEPZATO KIT ™ fourth quarter and full year revenue of $19.0 million and $78.8 million, respectively
  - CHEMOSAT® fourth quarter and full year revenue of $1.7 million and $6.4 million, respectively
- Gross margins of 85% for the fourth quarter and 86% for the full year
- Fourth quarter net loss of $1.9 million and full year net income of $2.7 million
- Non-GAAP positive adjusted EBITDA for the fourth quarter and full year of $2.4 million and $25.1 million, respectively
- Repurchased 628,572 common shares for $6.0 million through December 31, 2025 under the approved $25 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

Business Highlights

- Currently 28 active centers
- Approximately 140% growth in HEPZATO procedure volume in 2025 compared to 2024
- Announced the publication of additional results from the FOCUS study, "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
- Announced the publication of results from multiple studies by independent investigators, including:
  - 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
  - A long-term retrospective study conducted by researchers at the University Hospital Tübingen, Germany, "Characterization of long-term survivors with liver metastases from uveal melanoma diagnosed between 2005 and 2021", in International Journal of Cancer
  - A long-term retrospective study conducted by researchers at the Asklepios Hospital Barmbek, Germany, "Survival Outcome After Percutaneous Hepatic Perfusion with High-Dose Melphalan for Liver-Dominant Metastatic Uveal Melanoma: A 10-Year Single-Center Experience" in Cancers

"2025 was a pivotal year in which we delivered robust procedure-volume growth, positive operating cashflow and successfully navigated temporary headwinds to stabilize the HEPZATO revenue base in the fourth quarter," said Gerard Michel, President and Chief Executive Officer of Delcath "With 28 active treatment centers now delivering therapy and compelling CHOPIN data demonstrating clear clinical benefit when PHP is sequenced with checkpoint inhibitors, we enter 2026 with strong momentum. Through continued site activations, commercial expansion, and heightened physician awareness of the CHOPIN results, we expect accelerated adoption and utilization that will drive long-term value for patients and shareholders alike."

2026 Full Year Financial Guidance

The Company's financial outlook for fiscal year 2026:

- Total CHEMOSAT and HEPZATO KIT revenue to be at least $100 million, reflecting an increase in HEPZATO KIT volume of at least 20% over 2025, and
- Gross margins in the range of 84% to 87%.

Fourth Quarter and Full Year 2025 Results

Total revenue for the quarter ended December 31, 2025 was $20.7 million compared to $15.1 million for the same period in the prior year. Revenue in the quarter includes sales of $19.0 million of HEPZATO in the U.S. and $1.7 million of CHEMOSAT in Europe.

Total revenue for the year-ended December 31, 2025 was $85.2 million compared to $37.2 million for the same period in the prior year. Revenue in 2025 includes sales of $78.8 million of HEPZATO in the U.S. and $6.4 million of CHEMOSAT in Europe.

Research and development expenses for the quarter and year-ended December 31, 2025, were $9.4 million and $29.2 million, respectively compared to $2.9 million and $13.9 million for the same periods in the prior year. The increase is primarily due to costs associated with expanding the clinical team including share-based compensation expense related to an increase in headcount and initiation of the Phase 2 clinical trial evaluating HEPZATO in combination with standard of care for mCRC and mBC. In 2024, these costs are primarily related to medical affairs and regulatory costs associated with the approved products.

Selling, general and administrative expenses for the quarter and year-ended December 31, 2025, were $10.5 million and $43.5 million, respectively compared to $7.0 million and $29.6 million for the same periods in the prior year. The increase is primarily due to continued commercial expansion activities including marketing-related expenses and additional personnel on the commercial team. In addition, the increase in personnel along with higher grant date exercise prices has increased the share-based compensation expense.

Net loss for the quarter ended December 31, 2025 was $1.9 million and net income for the full year was $2.7 million, compared to net loss of $3.4 million and $26.4 million for the same periods in the prior year.

Non-GAAP positive adjusted EBITDA for the quarter and year-ended December 31, 2025 was $2.4 million and $25.1 million compared to adjusted EBITDA gain of $4.6 million and loss of $2.5 million for the same periods in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

As of December 31, 2025, the Company had $91.0 million in cash and investments, and no debt.

Conference Call Information

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

Event Date: Thursday, February 26, 2026
Time: 8:30 AM Eastern Time

Participant Numbers:
Toll Free: 1-877-407-3982
International: 1-201-493-6780
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1747469&tp_key=15ec7bd15c

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.

GAAP v. Non-GAAP Measures

Delcath's reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission. Delcath has provided in this release certain financial information that has not been prepared in accordance with GAAP. 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.

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 2026 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.

DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 43,454	$ 32,412
Short-term investments	47,582	20,821
Accounts receivable	11,744	10,890
Inventories	10,252	6,933
Prepaid expenses and other current assets	6,498	2,704
Total current assets	119,530	73,760
Property, plant and equipment, net	3,166	1,790
Right-of-use assets	936	1,039
Total assets	$ 123,632	$ 76,589
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,658	$ 961
Accrued expenses	8,191	5,078
Lease liabilities, current	101	105
Total current liabilities	10,950	6,144

Lease liabilities, non-current	835	933
Other liabilities, non-current	628	766
Total liabilities	12,413	7,843
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 24,819 and 11,357 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, $.01 par value; 80,000,000 shares authorized; 22,761,554 shares and 10,046,571 shares issued and outstanding at December 31, 2023 and 2022, respectively	347	331
Additional paid-in capital	639,145	599,881
Accumulated deficit	(528,848)	(531,548)
Accumulated other comprehensive income	575	82
Total stockholders' equity	111,219	68,746
Total liabilities and stockholders' equity	$ 123,632	$ 76,589

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(Unaudited)
(in thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2025	**2024**	**2025**	**2024**
Product revenue	20,728	15,100	$ 85,231	$ 37,205
Cost of goods sold	(3,010)	(2,126)	(11,797)	(6,188)
Gross profit	17,718	12,974	73,434	31,017
Operating expenses:				
Research and development expenses	9,371	2,914	29,246	13,874
Selling, general and administrative expenses	10,531	7,021	43,528	29,553
Total operating expenses	19,902	9,935	72,774	43,427
Operating income (loss)	(2,184)	3,039	660	(12,410)
Change in fair value of warrant liability	—	(6,679)	—	(14,071)
Interest income, net	857	295	2,920	125
Other expense	(7)	(53)	(70)	(30)
Income (loss) before income taxes	(1,334)	(3,398)	3,510	(26,386)
Income tax expense	562	—	810	—
Net income (loss)	(1,896)	(3,398)	2,700	(26,386)
Other comprehensive income (loss):				
Unrealized gain on investments adjustments	(198)	125	394	(22)
Foreign currency translation adjustments	(102)	(54)	99	(31)
Total comprehensive income (loss)	$ (2,196)	$ (3,327)	$ 3,193	$ (26,439)
Common share data:				
Basic income (loss) per common share	$ (0.05)	$ (0.11)	$ 0.08	$ (0.93)
Weighted average number of basic shares outstanding	36,445,905	32,014,365	35,821,157	28,511,393
Diluted income (loss) per common share	$ (0.05)	$ (0.11)	$ 0.07	$ (0.93)
Weighted average number of diluted shares outstanding	36,445,905	32,014,365	39,919,557	28,511,393

DELCATH SYSTEMS, INC.
Reconciliation of Reported Net Income (Loss) (GAAP) to Adjusted EBITDA (NON-GAAP Measure)
(Unaudited)

(in thousands)	Three months ended December 31,		Twelve months ended December 31,	
	2025	**2024**	**2025**	**2024**
Net income (loss)	$ (1,896)	$ (3,398)	$ 2,700	$ (26,386)
Stock-based compensation expense	4,512	1,612	24,232	9,767
Depreciation	80	38	238	134
Net interest (income) expense	(857)	(295)	(2,920)	(125)
Fair value warrant adjustment	—	6,679	—	14,071
Income tax expense	562	—	810	—
Adjusted EBITDA (Non-GAAP)	$ 2,401	$ 4,636	$ 25,060	$ (2,539)

View source version on businesswire.com: https://www.businesswire.com/news/home/20260226305802/en/

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