Delcath Systems Reports First Quarter 2026 Results and Business Highlights

May 7, 2026

2026 Revenue Guidance of at least $100M

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

QUEENSBURY, N.Y.--(BUSINESS WIRE)--May 7, 2026-- Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced financial results and business highlights for the first quarter ended March 31, 2026.

First Quarter 2026 Financial Results

- Total revenue of $25.0 million, compared with $19.8 million in the first quarter of 2025
  - HEPZATO KIT™ revenue of $23.3 million, compared to $18.0 million in the first quarter of 2025
  - CHEMOSAT® revenue of $1.7 million, compared to $1.8 million in the first quarter of 2025
- Gross margins of 85%, compared to 86% in the first quarter of 2025
- Net loss of $1.1 million, compared to a net income of $1.1 million in the first quarter of 2025
- Non-GAAP adjusted EBITDA of $3.4 million, compared to $7.6 million in the first quarter of 2025
- Cash provided by operations of $0.9 million in the quarter; compared to $2.2 million provided by operations in the first quarter of 2025
- Repurchased 316,023 common shares for proceeds of approximately $3.0 million in the first quarter of 2026 under the approved $25 million Share Buyback Program
- Cash and investments of $89.3 million as of March 31, 2026

Business Highlights

- Currently 29 active centers
- Approximately 36% growth in HEPZATO volume in the first quarter 2026 compared to the first quarter 2025
- Announced the publication of full results from the investigator-initiated CHOPIN randomized Phase 2 trial in The Lancet Oncology, demonstrating that adding ipilimumab and nivolumab to percutaneous hepatic perfusion significantly improved progression-free survival in metastatic uveal melanoma.
- Announced that CHEMOSAT Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (M-PHP) has been included as a recommended liver-directed regional therapy option in the newly published *Uveal Melanoma: ESMO–EURACAN Clinical Practice Guideline for diagnosis, treatment and follow-up* (April 2026)

“We delivered a strong first quarter, marked by 20% volume growth over the prior quarter and a strong increase in new patient starts,” said Gerard Michel, Chief Executive Officer. “The recent publication of the full CHOPIN results in The Lancet Oncology is already having a meaningful impact on prescribing patterns, further validating HEPZATO KIT and positioning us for continued momentum and 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
- Gross margins in the range of 84% to 87%
- Positive adjusted EBITDA

First Quarter 2026 Results
Total revenue for the quarter ending March 31, 2026, was $25.0 million compared to $19.8 million for the same period in the prior year. Revenue in the quarter includes sales of $23.3 million of HEPZATO in the U.S. and $1.7 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ending March 31, 2026, were $9.8 million compared to $5.0 million for the same period in the prior year. The increase is primarily due to the continued costs associated with expanding the clinical team, including the share-based compensation expense related to an increase in headcount, and continuation of the Phase 2 clinical trials evaluating HEPZATO.

Selling, general and administrative expenses for the quarter ended March 31, 2026, were $13.1 million compared to $11.3 million for the same period in the prior year. The increase is primarily due to continued commercial expansion activities including marketing-related expenses, additional personnel in the commercial team and share-based compensation expenses.

Net loss for the quarter ended March 31, 2026, was $1.1 million compared to net income of $1.1 million for the same period in the prior year.

Non-GAAP adjusted EBITDA for the quarter ended March 31, 2026 was $3.4 million compared to adjusted EBITDA of $7.6 million for the same period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

As of March 31, 2026, the Company had $89.3 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, May 7, 2026
Time: 8:30 AM Eastern Time

Participant Numbers:
Toll Free: 1-800-717-1738
International: 1-646-307-1865
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1757946&tp_key=463dd4d428

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)

	March 31, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 41,313	$ 43,454
Short-term investments	47,986	47,582
Accounts receivable	14,159	11,744
Inventories	9,808	10,252
Prepaid expenses and other current assets	7,003	6,498
Total current assets	120,269	119,530
Property, plant and equipment, net	3,662	3,166
Right-of-use assets	907	936
Total assets	$ 124,838	$ 123,632
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,463	$ 2,658
Accrued expenses	7,143	8,191
Lease liabilities, current	92	101
Total current liabilities	10,698	10,950
Lease liabilities, non-current	815	835
Other liabilities, non-current	615	628
Total liabilities	$ 12,128	$ 12,413
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 14,192 and 14,192 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 34,465,087 shares and 34,691,671 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	344	347
Additional paid-in capital	641,713	639,145
Accumulated deficit	(529,918)	(528,848)
Accumulated other comprehensive income	571	575
Total stockholders' equity	112,710	111,219
Total liabilities and stockholders' equity	$ 124,838	$ 123,632

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three months ended March 31,	
	2026	**2025**
Product revenue	$ 24,994	$ 19,784
Cost of goods sold	(3,736)	(2,845)
Gross profit	21,258	16,939
Operating expenses:		
Research and development expenses	9,824	5,007
Selling, general and administrative expenses	13,071	11,290
Total operating expenses	22,895	16,297
Operating (loss) income	(1,637)	642
Interest income	787	618
Other (expense) income	(58)	4
(Loss) income before income taxes	(908)	1,264
Income tax expense	162	195
Net (loss) income	(1,070)	1,069
Other comprehensive income (loss):		
Unrealized gain on investments adjustments	45	239
Foreign currency translation adjustments	(49)	60
Total comprehensive (loss) income	$ (1,074)	$ 1,368
Common share data:		
Basic (loss) income per common share	$ (0.03)	$ 0.03
Weighted average number of basic shares outstanding	36,021,210	34,642,641
Diluted (loss) income per common share	$ (0.03)	$ 0.03
Weighted average number of dilutive shares outstanding	36,021,210	39,511,120

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

	Three months ended March 31,	
	2026	**2025**
Net (loss) income	$ (1,070)	$ 1,069
Stock-based compensation expense	4,946	6,863
Depreciation	102	43
Interest income	(787)	(618)
Income tax expense	162	195
Adjusted EBITDA (Non-GAAP)	$ 3,353	$ 7,552

View source version on businesswire.com: https://www.businesswire.com/news/home/20260507125922/en/

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