Delcath Systems Reports Third Quarter 2025 Results and Business Highlights

November 4, 2025

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

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Nov. 4, 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 financial results and business highlights for the third quarter ended September 30, 2025.

Third Quarter 2025 Financial Results

- Total revenue of $20.6 million, compared with $11.2 million in the third quarter of 2024
  - HEPZATO KIT™ revenue of $19.3 million, compared to $10.0 million in the third quarter of 2024
  - CHEMOSAT® revenue of $1.3 million, compared to $1.2 million in the third quarter of 2024
- Gross margins of 87%, compared to 85% in the third quarter of 2024
- Net income of $0.8 million, compared to a net income of $1.9 million in the third quarter of 2024
- Non-GAAP positive adjusted EBITDA in the third quarter of $5.3 million, compared to a positive adjusted EBITDA of $1.0 million in the third quarter of 2024
- Cash provided by operations of $4.8 million in the quarter; compared to $3.6 million used by operations in the third quarter of 2024
- Cash and investments of $88.9 million as of September 30, 2025

Business Highlights

- There are currently 25 active centers across the U.S.
- In August, the first patient was dosed at City of Hope National Medical Center in the global Phase 2 trial of HEPZATO in combination with trifluridine-tipiracil and bevacizumab for liver-dominant metastatic colorectal cancer. The study will enroll approximately 90 patients across 20+ sites in the U.S. and Europe, with topline data expected in 2028
- Announced that results from the investigator-initiated Phase 2 CHOPIN trial at Leiden University Medical Center evaluating CHEMOSAT with ipilimumab and nivolumab in metastatic uveal melanoma were presented at the October 2025 European Society of Medical Oncology Annual Congress by Principal Investigator Ellen Kapiteijn, MD, showing a significant improvement in one-year progression-free survival versus CHEMOSAT alone

“In the third quarter, we made strong progress with our clinical programs, reporting compelling positive CHOPIN results and first-patient dosing in our global Phase 2 trial in liver-dominant metastatic colorectal cancer,” said Gerard Michel, Chief Executive Officer of Delcath Systems. “While revenue results in the quarter reflected the impact of NDRA discounts and seasonal factors, our fundamentals remain strong. We are confident that the growing clinical validation of HEPZATO positions us well to drive continued progress and long-term value for patients and shareholders.”

2025 Full Year Financial Guidance

The Company’s financial outlook for fiscal year 2025:

- Total CHEMOSAT and HEPZATO KIT revenue to be in the range of $83 to $85 million, an increase in volume of approximately 150% over 2024
- Gross margins in the range of 85% to 87%
- Positive adjusted EBITDA and cashflow in each quarter of 2025

Third Quarter 2025 Results

Total revenue for the quarter ending September 30, 2025 was $20.6 million compared to $11.2 million for the same period in the prior year. Revenue in the quarter includes sales of $19.3 million of HEPZATO in the U.S. and $1.3 million of CHEMOSAT

in Europe.

Research and development expenses for the quarter ending September 30, 2025, were $8.0 million compared to $3.9 million for the same period in the prior year. The increase is primarily due to costs associated with expanding the clinical team including the 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 metastatic colorectal cancer and Phase 2 clinical trial in metastatic breast cancer. In 2024, these costs primarily related to medical affairs and regulatory costs associated with the approved products.

Selling, general and administrative expenses for the quarter ended September 30, 2025, were $10.3 million compared to $7.0 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 income for the quarter ended September 30, 2025 was $0.8 million compared to net income of $1.9 million for the same period in the prior year.

Non-GAAP adjusted EBITDA for the quarter ended September 30, 2025 was $5.3 million compared to adjusted EBITDA of $1.0 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 September 30, 2025, the Company had $88.9 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, November 6, 2025
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=1735083&tp_key=a3bb91787b

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 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.

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

	September 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 41,813	$ 32,412
Short-term investments	47,099	20,821
Accounts receivable	13,751	10,890
Inventories	10,745	6,933
Prepaid expenses and other current assets	7,207	2,704
Total current assets	120,615	73,760
Property, plant and equipment, net	2,715	1,790
Right-of-use assets	965	1,039
Total assets	$ 124,295	$ 76,589
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,133	$ 961
Accrued expenses	5,768	5,078
Lease liabilities, current	110	105
Total current liabilities	8,011	6,144
Lease liabilities, non-current	855	933
Other liabilities, non-current	582	766
Total liabilities	$ 9,448	$ 7,843
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 September 30, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 35,308,939 shares and 33,061,002 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	353	331

Additional paid-in capital	640,571	599,881
Accumulated deficit	(526,952)	(531,548)
Accumulated other comprehensive income	875	82
Total stockholders' equity	114,847	68,746
Total liabilities and stockholders' equity	$ 124,295	$ 76,589

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

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Product revenue	$ 20,563	$ 11,200	$ 64,503	$ 22,105
Cost of goods sold	(2,624)	(1,640)	(8,787)	(4,062)
Gross profit	17,939	9,560	55,716	18,043
Operating expenses:				
Research and development expenses	7,986	3,866	19,875	10,960
Selling, general and administrative expenses	10,341	6,953	32,997	22,532
Total operating expenses	18,327	10,819	52,872	33,492
Operating income (loss)	(388)	(1,259)	2,844	(15,449)
Change in fair value of warrant liability	—	2,975	—	(7,392)
Interest income (expense), net	796	113	2,063	(170)
Other income (expense)	(33)	35	(63)	$ 23
Income (loss) before income taxes	375	1,864	4,844	(22,988)
Income tax (benefit) expense	(455)	—	248	—
Net income (loss)	830	1,864	4,596	(22,988)
Other comprehensive income (loss):				
Unrealized gain on investments adjustments	296	(14)	592	(147)
Foreign currency translation adjustments	(13)	17	201	23
Total comprehensive income (loss)	$ 1,113	$ 1,867	$ 5,389	$ (23,112)
Common share data:				
Basic income (loss) per common share	$ 0.02	$ 0.06	$ 0.13	$ (0.84)
Weighted average number of basic shares outstanding	36,383,277	28,738,307	35,610,619	27,335,212
Diluted income (loss) per common share	$ 0.02	$ 0.06	$ 0.12	$ (0.84)
Weighted average number of dilutive shares outstanding	40,056,814	32,345,672	39,949,941	27,335,212

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

	Three months ended September 30,		Six months ended September 30,	
	2025	2024	2025	2024
Net income (loss)	$ 830	$ 1,864	$ 4,596	$ (22,988)
Stock-based compensation expense	5,648	2,141	19,720	8,155
Depreciation	64	34	158	96
Net interest (income) expense	(796)	(113)	(2,063)	170
Fair value warrant adjustment	—	(2,975)	—	7,392
Income tax expense	(455)	—	248	—
Adjusted EBITDA (Non-GAAP)	$ 5,291	$ 951	$ 22,659	$ (7,175)

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