Delcath Systems Reports Second Quarter 2025 Results and Business Highlights

August 6, 2025

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

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Aug. 6, 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 second quarter ended June 30, 2025.

Second Quarter 2025 Financial Results

- Total revenue of $24.2 million, compared with $7.8 million in the second quarter of 2024
  - HEPZATO KIT ™ revenue of $22.5 million, compared to $6.6 million in the second quarter of 2024
  - CHEMOSAT® revenue of $1.7 million, compared to $1.2 million in the second quarter of 2024
- Gross margins of 86%, compared to 80% in the second quarter of 2024
- Net income of $2.7 million, compared to a net loss of $13.7 million in the second quarter of 2024
- Non-GAAP positive adjusted EBITDA in the second quarter of $9.8 million, compared to a loss of $0.8 million in the second quarter of 2024
- Cash provided by operations of $7.3 million in the quarter
- Cash and investments of $81.0 million as of June 30, 2025

Business Highlights

- Activated three new U.S. centers in the second quarter, which brings the current total to 20 active centers, with an additional 10 centers accepting referrals
- Announced its intention to enter into a Medicaid National Drug Rebate Agreement (NDRA) to expand patient access beginning July 1, 2025
- Received authorization from the European Union and United Kingdom regulatory authorities for the clinical study of Melphalan for Injection/Hepatic Delivery System in patients with refractory metastatic colorectal cancer with liver dominant disease

“The consistent utilization of HEPZATO at treating sites and continued positive feedback from treating physicians has increased our confidence in HEPZATO’s long term growth prospects," said Gerard Michel, Chief Executive Officer of Delcath. “Physicians are sharing positive results, which is expanding interest at sites not yet activated as well as interest in participating in the future development of HEPZATO. With growing physician engagement and a strong financial outlook, the company is well prepared to pursue additional indications for HEPZATO.”

2025 Full Year Financial Guidance
The Company updates its financial outlook for fiscal year 2025:

- Total CHEMOSAT and HEPZATO KIT revenue to be in the range of $93 to $96 million, an increase of more than 150% over 2024
- Gross margins in the range of 83% to 85%
- Positive adjusted EBITDA and cashflow in each quarter of 2025

Second Quarter 2025 Results
Total revenue for the quarter ending June 30, 2025 was $24.2 million compared to $7.8 million for the same period in the prior year. Revenue in the quarter includes sales of $22.5 million of HEPZATO in the U.S. and $1.7 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ending June 30, 2025, were $6.9 million compared to $3.4 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 June 30, 2025, were $11.4 million compared to $6.8 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 June 30, 2025 was $2.7 million compared to net loss of $13.7 million for the same period in the prior year.

Non-GAAP adjusted EBITDA for the quarter ended June 30, 2025 was $9.8 million compared to adjusted EBITDA loss of $0.8 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 June 30, 2025, the Company had $81.0 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: Wednesday, August 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=1723203&tp_key=fbe0333159

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 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)

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 34,421	$ 32,412
Short-term investments	46,584	20,821
Accounts receivable	15,836	10,890
Inventories	10,523	6,933
Prepaid expenses and other current assets	6,118	2,704
Total current assets	113,482	73,760
Property, plant and equipment, net	2,401	1,790
Right-of-use assets	993	1,039
Total assets	$ 116,876	$ 76,589
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,716	$ 961
Accrued expenses	5,603	5,078
Lease liabilities, current	116	105
Total current liabilities	10,435	6,144
Lease Liabilities, non-current	877	933
Other liabilities, non-current	578	766
Total liabilities	$ 11,890	$ 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 June 30, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 34,955,974 shares and 33,061,002 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	350	331
Additional paid-in capital	631,826	599,881
Accumulated deficit	(527,782)	(531,548)
Accumulated other comprehensive income	592	82
Total stockholders' equity	104,986	68,746
Total liabilities and stockholders' equity	$ 116,876	$ 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 June 30,		Six months ended June 30,	
	2025	**2024**	**2025**	**2024**
Product revenue	$ 24,156	$ 7,766	$ 43,940	$ 10,905
Cost of goods sold	(3,318)	(1,519)	(6,163)	(2,422)
Gross profit	20,838	6,247	37,777	8,483
Operating expenses:				
Research and development expenses	6,882	3,394	11,889	7,094
Selling, general and administrative expenses	11,366	6,765	22,656	15,579
Total operating expenses	18,248	10,159	34,545	22,673
Operating income (loss)	2,590	(3,912)	3,232	(14,190)
Change in fair value of warrant liability	—	(9,755)	—	(10,367)
Interest income (expense), net	649	(84)	1,267	(283)
Other income (expense)	(34)	10	(30)	$ (12)
Income (loss) before income taxes	3,205	(13,741)	4,469	(24,852)
Income tax expense	508	—	703	—
Net income (loss)	2,697	(13,741)	3,766	(24,852)
Other comprehensive income (loss):				
Unrealized gain on investments adjustments	57	(141)	296	(133)
Foreign currency translation adjustments	154	(8)	214	6
Total comprehensive income (loss)	$ 2,908	$ (13,890)	$ 4,276	$ (24,979)
Common share data:				
Basic income (loss) per common share	$ 0.08	$ (0.48)	$ 0.11	$ (0.93)
Weighted average number of basic shares outstanding	35,786,813	28,364,731	35,217,887	26,625,955
Diluted income (loss) per common share	$ 0.07	$ (0.48)	$ 0.09	$ (0.93)
Weighted average number of dilutive shares outstanding	40,262,764	28,364,731	39,890,102	26,625,955

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

	Three months ended June 30,		Six months ended June 30,	
	2025	**2024**	**2025**	**2024**
Net income (loss)	$ 2,697	$ (13,741)	$ 3,766	$ (24,852)
Stock-based compensation expense	7,209	3,069	14,072	6,014
Depreciation	51	33	94	62
Net interest (income) expense	(649)	84	(1,267)	283
Fair value warrant adjustment	—	9,755	—	10,367
Income tax expense	508	—	703	—
Adjusted EBITDA (Non-GAAP)	$ 9,816	$ (800)	$ 17,368	$ (8,126)

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