Delcath Systems Reports First Quarter 2025 Results and Business Highlights

May 8, 2025

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

QUEENSBURY, N.Y.--(BUSINESS WIRE)--May 8, 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 first quarter ended March 31, 2025.

First Quarter 2025 Financial Results

- Total revenue of $19.8 million, compared with $3.1 million in the first quarter of 2024
  - HEPZATO KIT™ revenue of $18.0 million, compared to $2.0 million in the first quarter of 2024
  - CHEMOSAT® revenue of $1.8 million, compared to $1.1 million in the first quarter of 2024
- Gross margins of 86%, compared to 71% in the first quarter of 2024
- Net income of $1.1 million, compared to a net loss of $11.1 million in the same quarter of 2024
- Non-GAAP positive adjusted EBITDA in the first quarter of $7.6 million, compared to a loss of $7.3 million in the first quarter of 2024
- Cash and investments of $58.9 million as of March 31, 2025
- Cash provided by operations of $2.2 million in the quarter

Business Highlights and Updates

- Activated three new U.S. centers in the first quarter and two more so far in the second quarter of 2025, bringing the current total to 19 active centers, with 10 additional centers accepting referrals
- Received FDA clearance of an IND application for a phase 2 clinical trial of HEPZATO™ in liver-dominant metastatic breast cancer
- Announced publication of comparative analysis from randomized portion of FOCUS Study in metastatic uveal melanoma
- The exercise of 1.62 million Series F warrants resulted in $16.2 million of funding in 2025. The warrants were issued in 2020 as a component of a private placement and had an exercise price of $10.00 per share and expired on May 5, 2025

"Consistent revenue growth and the continued expansion of active treatment centers represent a strong start to 2025," said Gerard Michel, Chief Executive Officer of Delcath. "We achieved our first quarter of net income and positive operating cash flow, underscoring the accelerating clinical adoption of HEPZATO for patients with metastatic uveal melanoma. Ongoing dialogue with oncologists and interventional radiologists reinforces the importance of whole-liver treatment for patients with liver-dominant disease. These insights continue to shape our development strategy as we pursue additional indications for HEPZATO."

First Quarter 2025 Results

Total revenue for the quarter ending March 31, 2025 was $19.8 million compared to $3.1 million for the same period in the prior year. Revenue in the quarter includes sales of $18.0 million of HEPZATO in the U.S. and $1.8 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ended March 31, 2025, were $5.0 million compared to $3.7 million for the same period in the prior year. The increase is primarily due to costs associated with expanding the clinical team and initiation of the Phase 2 clinical trial evaluating HEPZATO in combination with standard of care for mCRC. 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 ending March 31, 2025, were $11.3 million compared to $8.8 million for the same period in the prior year. The increase is primarily due to continued commercial expansion activities including marketing-related expenses and additional personnel in the commercial team.

Net income for the quarter ended March 31, 2025 was $1.1 million compared to net loss of $11.1 million for the same period in

the prior year.

Non-GAAP adjusted EBITDA for the quarter ended March 31, 2025 was $7.6 million compared to adjusted EBITDA loss of $7.3 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, 2025, the Company had $58.9 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, May 8, 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=1713022&tp_key=6de250d858
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 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 Hepatic Delivery System (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, 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, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 12,776	$ 32,412
Short-term investments	46,120	20,821
Accounts receivable	13,942	10,890
Inventories	7,132	6,933
Prepaid expenses and other current assets	4,379	2,704
Total current assets	84,349	73,760
Property, plant and equipment, net	1,954	1,790
Right-of-use assets	1,016	1,039
Total assets	$ 87,319	$ 76,589
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,619	$ 961
Accrued expenses	3,558	5,078
Lease liabilities, current	110	105
Total current liabilities	5,287	6,144
Lease Liabilities, non-current	906	933
Other liabilities, non-current	896	766
Total liabilities	$ 7,089	$ 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 March 31, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 33,436,612 shares and 33,061,002 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	334	331
Additional paid-in capital	609,994	599,881
Accumulated deficit	(530,479)	(531,548)
Accumulated other comprehensive income	381	82
Total stockholders' equity	80,230	68,746
Total liabilities and stockholders' equity	$ 87,319	$ 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 March 31,	
	2025	2024
Product revenue	$ 19,784	$ 3,139
Cost of goods sold	(2,845)	(903)
Gross profit	16,939	2,236
Operating expenses:		
Research and development expenses	5,007	3,700
Selling, general and administrative expenses	11,290	8,814
Total operating expenses	16,297	12,514

Operating gain (loss)	642	(10,278)
Change in fair value of warrant liability	—	(612)
Interest income (expense), net	618	(199)
Other income (expense)	4	(22)
Income (loss) before income taxes	1,264	(11,111)
Income tax expense	195	—
Net income (loss)	1,069	(11,111)
Other comprehensive income (loss):		
Unrealized gain on investments adjustments	239	8
Foreign currency translation adjustments	60	14
Total comprehensive income (loss)	$ 1,368	$ (11,089)
Common share data:		
Basic income (loss) per common share	$ 0.03	$ (0.45)
Weighted average number of basic shares outstanding	34,642,641	24,887,180
Diluted income (loss) per common share	$ 0.03	$ (0.45)
Weighted average number of dilutive shares outstanding	39,511,120	24,887,180

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

(in thousands)	**Three months ended December 31,**	
	2025	**2024**
Net income (loss)	$ 1,069	$ (11,111)
Stock-based compensation expense	6,863	2,945
Depreciation	43	29
Net interest (income) expense	(618)	199
Fair value warrant adjustment	—	612
Income tax expense	195	—
Adjusted EBITDA (Non-GAAP)	$ 7,552	$ (7,326)

View source version on businesswire.com: https://www.businesswire.com/news/home/20250508705446/en/

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