Delcath Systems Reports Fourth Quarter and Full Year 2024 Results

March 6, 2025

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

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Mar. 6, 2025-- 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, 2024.

Fourth Quarter and Full Year 2024 Financial Results

- Total fourth quarter and full year revenue of $15.1 million and $37.2 million, respectively
  - HEPZATO KIT™ fourth quarter and full year revenue of $13.7 million and $32.3 million, respectively
  - CHEMOSAT® fourth quarter and full year revenue of $1.4 million and $4.9 million, respectively
- Gross margins of 86% for the fourth quarter and 83% for the full year
- Fourth quarter and full year net loss of $3.4 million and $26.4 million, respectively
- Non-GAAP positive adjusted EBITDA for the fourth quarter of $4.6 million and full year adjusted EBITDA loss of $2.5 million
- During the year, the exercise of warrants generated approximately $41.3 million in funding, resulting in year-end cash and investment balance of $53.2 million. The company's fourth quarter operating cash burn was $1.0 million
- As of December 31, 2024, there are no outstanding debt obligations

Business Highlights and Updates

- Activated 4 U.S. centers in the fourth quarter and 2 more so far in the first quarter of 2025, bringing the current total to 16 active centers, with 8 additional centers currently accepting referrals
- Received FDA Clearance of an IND Application for a Phase 2 Clinical Trial of HEPZATO™ in Liver-Dominant Metastatic Colorectal Cancer
- Appointed Michael Brunner, M.D., as the Senior Vice President of Interventional Oncology to further Delcath’s research and development efforts. Dr. Brunner is the former President of the Society of Interventional Radiology with over 25 years of experience in academia and biotech leadership
- The National Comprehensive Cancer Network (NCCN) updated its Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for metastatic uveal melanoma (mUM) treatment to include HEPZATO KIT as an option for patients with hepatic-dominant uveal melanoma, expanding from the previous guidance that limited its use to those with liver-confined metastases

“In 2024, the successful launch of HEPZATO drove strong financial and operational results, including positive adjusted EBITDA in the fourth quarter,” said Gerard Michel, Delcath’s Chief Executive Officer. “As HEPZATO becomes more established as a leading treatment option for metastatic uveal melanoma, we’re seeing growing adoption across treatment centers and meaningful revenue growth. This momentum enables us to advance R&D programs targeting other liver-dominant cancers, including metastatic colorectal and breast cancer.”

Fourth Quarter and Full Year 2024 Results

Total revenue for the quarter ended December 31, 2024 was $15.1 million compared to $0.5 million for the same period in the prior year. Revenue in the quarter includes sales of $13.7 million of HEPZATO in the U.S. and $1.4 million of CHEMOSAT in Europe.

Total revenue for the year-ended December 31, 2024 was $37.2 million compared to $2.1 million for the same period in the prior year. Revenue in 2024 includes sales of $32.3 million of HEPZATO in the U.S. and $4.9 million of CHEMOSAT in Europe.

Research and development expenses for the quarter and year-ended December 31, 2024, were $2.9 million and $13.9 million,

respectively compared to $4.7 million and $17.5 million for the same periods in the prior year. The decrease is primarily due to lower costs associated with the NDA submission and expanded access program costs offset by an increase in medical affairs and regulatory costs associated with an approved product.

Selling, general and administrative expenses for the quarter and year-ended December 31, 2024, were $7.0 million and $29.6 million, respectively compared to $7.0 million and $22.1 million for the same periods in the prior year. The increase is primarily due to commercial launch activities including marketing-related expenses and additional personnel in the commercial team.

Net loss for the quarter and year-ended December 31, 2024 was $3.4 million and $26.4 million, respectively compared to net loss of $11.1 million and $47.7 million for the same periods in the prior year.

Non-GAAP adjusted EBITDA for the quarter and year-ended December 31, 2024 was $4.6 million and loss of $2.5 million, respectively, compared to adjusted EBITDA loss of $9.3 million and $30.0 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, 2024, the Company had $53.2 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, March 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=1706497&tp_key=9763647546

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)

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 32,412	$ 12,646
Restricted cash	—	50
Short-term investments	20,821	19,808
Accounts receivable	10,890	241
Inventories	6,933	3,322
Prepaid expenses and other current assets	2,704	1,091
Total current assets	73,760	37,158
Property, plant and equipment, net	1,790	1,352
Right-of-use assets	1,039	103
Total assets	$ 76,589	$ 38,613
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 961	$ 1,012
Accrued expenses	5,078	5,249
Lease liabilities, current	105	37
Loan payable, current	—	5,239
Convertible notes payable, current	—	4,911
Total current liabilities	6,144	16,448
Warrant Liability	—	5,548
Lease liabilities, non-current	933	—
Other liabilities, non-current	766	840
Total liabilities	7,843	22,836
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 14,192 and 24,819 shares issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Common stock, $.01 par value; 80,000,000 shares authorized; 33,061,002 shares and 22,761,554 shares issued and outstanding at December 31, 2024 and 2023, respectively	331	228
Additional paid-in capital	599,881	520,576
Accumulated deficit	(531,548)	(505,162)
Accumulated other comprehensive income	82	135
Total stockholders' equity	68,746	15,777

Total liabilities and stockholders' equity	$ 76,589	$ 38,613

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

	Three months ended December 31,		Twelve months ended December 31,	
	2024	**2023**	**2024**	**2023**
Product revenue	15,100	539	37,205	2,065
Cost of goods sold	(2,126)	(171)	(6,188)	(635)
Gross profit	12,974	368	31,017	1,430
Operating expenses:				
Research and development expenses	2,914	4,709	13,874	17,502
Selling, general and administrative expenses	7,021	6,963	29,553	22,110
Total operating expenses	9,935	11,672	43,427	39,612
Operating loss	3,039	(11,304)	(12,410)	(38,182)
Change in fair value of warrant liability	(6,679)	226	(14,071)	(7,998)
Interest income (expense), net	295	15	125	(1,439)
Other expense	(53)	(73)	(30)	(59)
Net loss	(3,398)	(11,136)	(26,386)	(47,678)
Other comprehensive (loss) income:				
Unrealized gain on investments adjustments	125	157	(22)	157
Foreign currency translation adjustments	(54)	37	(31)	61
Total comprehensive loss	$ (3,327)	$ (10,942)	$ (26,439)	$ (47,460)
Common share data:				
Basic and diluted loss per common share	$ (0.11)	$ (0.48)	$ (0.93)	$ (2.94)
Weighted average number of basic and diluted shares outstanding	32,014,365	23,088,685	28,511,393	16,229,931

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

	Three months ended December 31,		Twelve months ended December 31,	
	2024	**2023**	**2024**	**2023**
Net loss	$ (3,398)	$ (11,136)	$ (26,386)	$ (47,678)
Stock-based compensation expense	1,612	1,999	9,767	8,151
Depreciation	38	41	134	128
Net interest (income) expense	(295)	(15)	(125)	1,439
Fair value warrant adjustment	6,679	(226)	14,071	7,998
Adjusted EBITDA (Non-GAAP)	$ 4,636	$ (9,337)	$ (2,539)	$ (29,962)

View source version on businesswire.com: https://www.businesswire.com/news/home/20250306685656/en/

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