# Delcath Systems Reports Second Quarter 2024 Results and Business Highlights

## Company Reports $7.8 million in Quarterly Revenue

*Conference Call Today at 4:30pm Eastern Time*

QUEENSBURY, N.Y. – 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 second quarter ended June 30, 2024.

### Recent Business Highlights

- Recognized second quarter 2024 revenues of $6.6 million from sales of HEPZATO KIT™ (melphalan/Hepatic Delivery System) and $1.2 million in CHEMOSAT sales;

- Activated three HEPZATO KIT treating centers in the US during the second quarter with an additional center in July for a total of eight active treating centers. Two additional centers have completed the necessary steps and have scheduled their first treatments in August. An additional four centers are ready to conduct their first commercial treatment and are currently in the process of scheduling patients for treatment;

- Received New Technology Add-on Payment status (NTAP) on August 1, 2024 for HEPZATO from the Centers for Medicare & Medicaid Services (CMS) which provides hospitals additional payments to cover the costs associated with the treatment for cases in the inpatient setting. While HEPZATO KIT is used primarily in the outpatient setting, there are instances where it is used in the inpatient setting;

- Published key results from the pivotal Phase 3 FOCUS study of HEPZATO KIT in patients with unresectable metastatic Uveal Melanoma in the journal Annals of Surgical Oncology;

- Announced the acceptance of the FOCUS study efficacy analysis as a poster presentation at the upcoming ESMO conference to be held September 2024;

- Reported that independent investigators at the Leiden University have enrolled 70 of the total 76 patients planned in the Phase 2 part of the CHOPIN trial which is evaluating

the effect of sequencing Immunotherapy with CHEMOSAT liver directed therapy;

- Executed an amendment with Synerx Pharma, LLC and Mylan Teoranta for Delcath's supply of melphalan hydrochloride which extends the term of the original agreement to December 31, 2028;

- Appointed Dr. Bridget Martell to the Company's Board of Directors effective May 23, 2024;

- Submitted the final principal payment due to Avenue Venture Opportunities Fund, L.P. (Avenue) on August 1, 2024 for the Loan and Security Agreement entered into in August 2021; and

- Ended the quarter with cash and investments of $19.9 million

"We are excited about the continued adoption of the HEPZATO KIT and the positive feedback from physicians," said Gerard Michel, Delcath's Chief Executive Officer. "We are optimistic that HEPZATO KIT will become a key part of the therapeutic approach for metastatic uveal melanoma patients."

**Second Quarter 2024 Results**

Total revenue for the quarter ended June 30, 2024 was $7.8 million compared to $0.5 million for the same period in the prior year. Revenues include sales of $6.6 million of HEPZATO in the U.S. and $1.2 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ended June 30, 2024, were $3.4 million compared to $3.6 million for the same period in the prior year. The change in research and development expenses is primarily due to lower costs associated with NDA submission incurred in previous periods offset by an increase in medical affairs and regulatory costs associated with an approved product.

Selling, general and administrative expenses for the quarter ended June 30, 2024, were $6.8 million compared to $4.8 million for the same period in the prior year. The increase primarily relates to commercial launch activities including marketing-related expenses and additional personnel in the commercial team.

Cash, cash equivalents and investment totaled $19.9 million as of June 30, 2024.

**Conference Call Information**

To participate in this event, dial in approximately 5 to 10 minutes before the beginning of the call.

| | |
|---|---|
| Event Date: | Monday, August 5, 2024 |
| Time: | 4:30 PM Eastern Time |
| Participant Numbers | |
| Toll Free: | 1-877-407-3982 |
| International: | 1-201-493-6780 |
| Webcast: | https://viavid.webcasts.com/starthere.jsp?ei=1679582&tp_key=87da4fb106 |

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://delcath.com/investors/events-presentations/

**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 the 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; 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, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 14,782 | $ 12,646 |
| Restricted cash | – | 50 |
| Short-term investments | 5,124 | 19,808 |
| Accounts receivable, net | 3,726 | 241 |
| Inventory | 6,316 | 3,322 |
| Prepaid expenses and other current assets | 1,451 | 1,091 |

| | | |
|---|---|---|
| Total current assets | 31,399 | 37,158 |
| Property, plant and equipment, net | 1,422 | 1,352 |
| Right-of-use assets | 1,092 | 103 |
| Total assets | $ 33,913 | $ 38,613 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 3,279 | $ 1,012 |
| Accrued expenses | 4,418 | 5,249 |
| Lease liabilities, current | 103 | 37 |
| Loan payable | – | 5,239 |
| Convertible notes payable | 4,491 | 4,911 |
| Total current liabilities | 12,291 | 16,448 |
| Warrant liability | 15,809 | 5,548 |
| Lease Liabilities, non-current | 989 | – |
| Other liabilities, non-current | 632 | 840 |
| Total liabilities | 29,721 | 22,836 |
| Commitments and contingencies | | |
| Stockholders' equity | | |
| Preferred stock, $0.01 par value; 10,000,000 shares authorized; 12,342 and 24,819 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | – | – |
| Common stock, $0.01 par value; 80,000,000 shares authorized; 27,931,393 shares and 22,761,554 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 279 | 228 |
| Additional paid-in capital | 533,919 | 520,576 |
| Accumulated deficit | (530,014) | (505,162) |
| Accumulated other comprehensive loss | 8 | 135 |
| Total stockholders' equity | 4,192 | 15,777 |
| Total liabilities and stockholders' equity | $ 33,913 | $ 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 June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| Product revenue | $ 7,766 | $ 495 | $ 10,905 | $ 1,092 |
| Cost of goods sold | (1,519) | (150) | (2,422) | (331) |
| Gross profit | 6,247 | 345 | 8,483 | 761 |
| Operating expenses: | | | | |
| Research and development expenses | 3,394 | 3,555 | 7,094 | 8,131 |
| Selling, general and administrative expenses | 6,765 | 4,787 | 15,579 | 8,952 |
| Total operating expenses | 10,159 | 8,342 | 22,673 | 17,083 |

| | | | | |
|---|---|---|---|---|
| Operating loss | (3,912) | (7,997) | (14,190) | (16,322) |
| Change in fair value of warrant liability | (9,755) | 1,160 | (10,367) | 1,160 |
| Interest expense, net | (84) | (371) | (283) | (1,059) |
| Other (expense) income | 10 | 6 | (12) | 19 |
| Net loss | (13,741) | (7,202) | (24,852) | (16,202) |
| Other comprehensive (loss) income: | | | | |
| Unrealized gain on investments | (141) | – | (133) | – |
| Foreign currency translation adjustments | (8) | – | 6 | 19 |
| Total comprehensive loss | $ (13,890) | $ (7,202) | $ (24,979) | $ (16,183) |
| Common share data: | | | | |
| Basic and diluted loss per common share | $ (0.48) | $ (0.58) | $ (0.93) | $ (1.35) |
| Weighted average number of basic and diluted shares outstanding | 28,364,731 | 12,463,665 | 26,625,955 | 12,035,738 |

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