UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 5, 2024

DELCATH SYSTEMS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	001-16133	06-1245881
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

566 Queensbury Avenue
Queensbury, NY 12804
(Address of principal executive offices) (Zip Code)
(212) 489-2100
(Registrant's telephone number, including area code)
Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $.01 par value	**DCTH**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02
Results of Operations and Financial Condition.

On August 5, 2024, Delcath Systems, Inc. ("Delcath") issued a press release announcing financial results and business highlights for the quarter ended June 30, 2024 (the "Press Release"). A copy of the press release is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

The information contained in this Current Report on Form 8-K, including the Press Release, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the Press Release shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission by Delcath whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01
Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 5, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: August 5, 2024

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Executive Officer

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, NY – August 5, 2024, 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.

Investor Relations Contact:

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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 (loss) 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