UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 26, 2024

Delcath Systems, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-16133**	**06-1245881**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

566 Queensbury Avenue
Queensbury, New York 12804
(Address of Principal Executive Offices)

(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, $0.01 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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 8.01. Other Events.

On August 26, 2024, Delcath Systems, Inc. (the "Company") issued a press release announcing promising results from an independent study on repeated hepatic chemosaturation for liver tumors. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this item 8.01 by reference.

On August 27, 2024, the Company issued a press release announcing positive outcomes from an independent study on hepatic perfusion for uveal melanoma patients. The press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated into this item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 26, 2024.
99.2	Press Release, dated August 27, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: August 28, 2024

By: /s/ Gerard Michel
Name: Gerard Michel
Title: Chief Executive Officer

Delcath Systems, Inc. Announces Promising Results from Independent Study on Repeated Hepatic Chemosaturation for Liver Tumors

NEW YORK, August 26, 2024 — Delcath Systems, Inc. (Nasdaq: DCTH) ("Company" or "Delcath"), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, today announced the publication of an independent study conducted by investigators at the University Hospital of Leipzig, Germany, in the European Society for Medical Oncology journal of Gastrointestinal Oncology. The study, titled "Hepatic chemosaturation with melphalan in patients with primary or secondary liver tumors with or without extrahepatic tumor manifestation," highlights the efficacy and safety of repeated chemosaturation treatments using Delcath's CHEMOSAT® Hepatic Delivery System.

Key Findings from the Independent Study:

- **Patient Population:** This retrospective study evaluated the efficacy of CHEMOSAT in 33 previously treated patients with unresectable intrahepatic metastases from various cancers: uveal melanoma (N=19), cholangiocarcinoma (N=8), hepatocellular carcinoma (N=2), and one patient each with ciliary body melanoma, acinar cell carcinoma, pancreatic cancer, or tonsil cancer (N=4). In addition to hepatic metastases, 7 out of 33 patients also had limited extrahepatic disease, which was found not to significantly impact overall survival.
- **Disease Control Rate:** The study reported a disease control rate (DCR) of 91%, with 30 out of 33 patients experiencing either objective tumor response or stable disease. Notably, 6 patients (18.2%) achieved complete response (CR) in the liver, including 5 patients with uveal melanoma and 1 patient with cholangiocarcinoma, who received a median of 5 treatment cycles.
- **Hepatic Progression-Free Survival:** Median hepatic progression-free survival (hPFS) was 52 weeks across all patients, with particularly strong outcomes for specific cancers:
  - **69 weeks (16 months)** median hPFS in patients with uveal melanoma.
  - **38 weeks (8.5 months)** median hPFS in patients with cholangiocarcinoma.
- **Importance of Repeated Treatments:** The investigators' approach of using CHEMOSAT in the form of regularly repeated treatment cycles as clinically indicated (Figure 1), similar to systemic chemotherapy, resulted in long-term disease control in the majority of patients and was well tolerated.
- **Tolerability and Safety:** The safety profile of CHEMOSAT was consistent with published literature. Most patients experienced transient hematological adverse events, which were routinely managed with supportive care. Importantly, no significant liver damage was reported, even in patients who underwent multiple treatment cycles. Treatment was discontinued in 2 patients due to adverse events, and 2 patients withdrew consent during the treatment period.

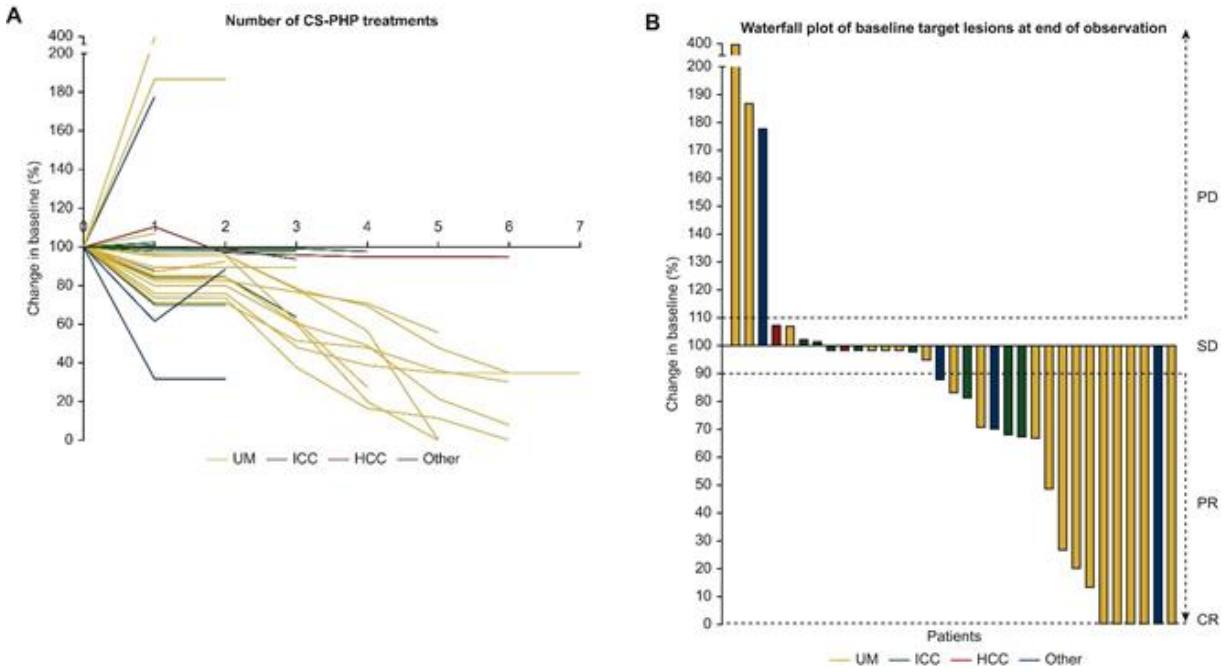

Figure 1: Individual changes in tumor sizes during CHEMOSAT treatment. (A) Individual changes in tumor sizes during CHEMOSAT treatment. On the y-axis the change in tumor size is indicated according to the baseline lesions. (B) Waterfall plot of changes in the size of target lesions at the end of observation. Dashed lines are thresholds for hepatic PD, hepatic SD, hepatic PR and hepatic CR. CR, complete response; HCC, hepatocellular carcinoma; ICC, intrahepatic cholangiocellular carcinoma; other, ciliary body melanoma, angiosarcoma, tonsil and pancreatic carcinoma; PD, progressive disease; PR, partial response; SD, stable disease; UM, uveal melanoma.

Dr. Vojislav Vukovic, Chief Medical Officer of Delcath Systems, commented, "The results of this independent study reinforce the potential of our CHEMOSAT Hepatic Delivery System as an essential tool in the management of primary and secondary liver tumors, particularly for patients with limited treatment options. The high rate of disease control observed, even in patients with extrahepatic tumor spread, underscores the importance of continuing to explore and refine this treatment approach in larger, prospective trials."

The publication is available here.

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.

Investor Relations Contact:

ICR Westwicke

investorrelations@delcath.com

Delcath Systems, Inc. Announces Positive Outcomes from Independent Study on Hepatic Perfusion for Uveal Melanoma Patients

NEW YORK, August 27, 2024—Delcath Systems, Inc. (Nasdaq: DCTH) (the "Company" or "Delcath"), an interventional oncology company specializing in the treatment of primary and metastatic liver cancers, today announced the publication of a retrospective study by independent investigators in the *Annals of Surgical Oncology*. The study, titled "Hepatic and Overall Progression-Free Survival After Percutaneous Hepatic Perfusion (PHP) as First-Line or Second-Line Therapy for Metastatic Uveal Melanoma," was conducted by researchers at Moffitt Cancer Center in Tampa, Florida. The 30-patient study reported that Delcath's HEPZATO KIT™ (melphalan/Hepatic Delivery System (HDS)) provided better disease control in the liver and improved progression-free survival in patients with hepatic metastases from uveal melanoma, compared to both immunotherapy and other liver-directed therapies.

Key Findings from the Study:

- **Overall Survival (OS):** The study reported median OS of 22.4 months for patients treated with HEPZATO KIT as a first-line therapy (N=17) and 18.4 months as a second-line therapy (N=6).
- **Hepatic Progression-Free Survival (hPFS):** Patients receiving HEPZATO KIT as first-line therapy had a median hPFS of 17.6 months (N=17), compared to 8.8 months (N=6) for immunotherapy and 9.2 months (N=7) for other liver-directed therapies. When used as a second-line therapy, HEPZATO KIT resulted in a median hPFS that was not reached (N=6), showing better outcomes than immunotherapy (14.7 months, N=5) and other liver-directed therapies (7.5 months, N=3) in this patient cohort.
- **Progression-Free Survival (PFS):** The median overall PFS was 15.4 months (N=17) for patients receiving HEPZATO KIT as first-line therapy, compared to 8.8 months (N=6) for immunotherapy and 9.2 months (N=7) for other liver-directed therapies. In the second-line setting, HEPZATO KIT resulted in a median PFS of 22.2 months (N=6), compared to 14.7 months (N=5) for immunotherapy and 7.5 months (N=3) for other liver-directed therapies, reflecting longer disease control in this group.

Jonathan Zager, MD Chief Academic Officer and Director of Regional Therapies at Moffitt Cancer Center, remarked, "The findings from this study reaffirm the critical role of melphalan/HDS in managing liver-dominant metastatic uveal melanoma. These results highlight the potential benefits melphalan/HDS offers to patients, particularly in the context of first- and second-line treatments. My team is committed to further exploring the potential of combining melphalan/HDS with systemic therapies to continue improving patient outcomes."

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