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 28, 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 7.01. Regulation FD Disclosure

On August 28, 2024, Delcath Systems, Inc. issued a press release announcing positive results from an independent study on liver-directed therapy for uveal melanoma patients, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 28, 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 29, 2024

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

Delcath Systems, Inc. Announces Positive Results from Independent Study on Liver-Directed Therapy for Uveal Melanoma Patients

NEW YORK - August 28, 2024 Delcath Systems, Inc. (Nasdaq: DCTH) (the "Company" or "Delcath"), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today announced the publication of a clinical study in the journal Therapeutic Advances in Medical Oncology. The publication, entitled "Melanoma-specific survival of patients with uveal melanoma and liver metastases diagnosed between 2005 and 2021", was based on an independent retrospective clinical study conducted by investigators from the University of Tübingen, Germany. The study demonstrates that first-line liver-directed therapies, including Delcath's CHEMOSAT® Hepatic Delivery System, significantly improve melanoma-specific survival (MSS) in patients with liver metastases from uveal melanoma, compared to first-line systemic therapies.

Key Findings from the Study:

- **Positive Trends in Survival With First-Line Liver-Directed Therapies:** The study analyzed 167 patients diagnosed with metastatic uveal melanoma between 2005 and 2021. Among those receiving first-line liver-directed therapy (N=89), the median MSS was 28 months, compared to 10 months for patients who received first-line systemic therapy (N=45).
- **Comparison of Outcomes Over Time with First-Line Liver-Directed Therapies:** The study found that patients diagnosed with liver metastases between 2016 and 2021 (N=56) and treated with first-line liver-directed therapy, including CHEMOSAT, had a median MSS of 30 months. In comparison, patients diagnosed between 2005 and 2015 (N=33) who received first-line liver-directed therapy had a median MSS of 20 months.

  During the 2005-2015 period, 33 patients received liver-directed therapy, with 8 of those receiving CHEMOSAT. In the 2016-2021 period, 56 patients received liver-directed therapy, with 30 of those receiving CHEMOSAT.

Dr. Vojislav Vukovic, Chief Medical Officer of Delcath Systems, commented, "We are encouraged by the findings from this independent study, which reinforce the critical role of liver-directed therapies in the first-line setting, including our CHEMOSAT system, in treating patients with liver metastases from uveal melanoma."

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.

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