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): May 12, 2023

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.)**

1633 Broadway, Suite 22C,
New York, New York 10019
(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 (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 May 12, 2023, Delcath Systems, Inc. ("Delcath") issued a press release announcing business updates and preliminary financial results for the quarter ended March 31, 2023 (the "Press Release").

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 May 12, 2023
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: May 12, 2023

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

Exhibit 99.1

Delcath Systems Provides Business Update and Reports Preliminary First Quarter 2023 Financial Results

NEW YORK – May 12, 2023, 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 business highlights and certain preliminary financial results for the first quarter ended March 31, 2023.

Recent Business Highlights

During and since the first quarter, Delcath:

- Received an acknowledgement of Class 2 NDA resubmission from the U.S. Food and Drug Administration (FDA) for Hepzato Kit® (melphalan hydrochloride for Injection/Hepatic Delivery System) with a Prescription Drug User Fee Act (PDUFA) goal date of August 14, 2023,
- Completed a private placement of up to $85 million in gross proceeds, including the closing of initial upfront funding of $25 million. The financing was led by Vivo Capital with participation from Logos Capital, BVF Partners LP, Stonepine Capital Management LLC, and Serrado Capital LLC as well as existing investors including Rosalind Advisors,
- Amended an existing loan agreement with Avenue Venture Opportunities Fund, L.P. to provide an interest only period spanning March 31, 2023, to September 30, 2023 thereby deferring $4.3 million in principal payments,
- Appointed John R. Sylvester as Chairman of the Board, and
- Announced that updated results from the CHOPIN phase 1B trial were published in the Journal Cardiovascular and Interventional Radiology. The article reported seven patients with advanced uveal melanoma treated with CHEMOSAT and ipilimumab plus nivolumab showed a median PFS of 29.1 months at a median follow-up of 29.1 months.

"With a critical financing behind us, the Company is focused on preparing to commercialize Hepzato if approved," said Gerard Michel, Chief Executive Officer of Delcath. Mr. Michel added, "Importantly, as we approach the August 14 PDUFA date, we continue to expand the list of institutions that have indicated their interest in becoming a treating center upon approval."

Preliminary First Quarter 2023 Financial Results

Delcath is in the process of completing its customary quarter-end close and review procedures, including certain valuation work associated with the issuance of warrants and preferred stock in Delcath's previously announced private placement that closed on March 29, 2023, as of and for the quarter ended March 31, 2023, and the final results for this period could materially differ from the preliminary expected results disclosed in this press release. Delcath's full first quarter 2023 financial results will be reflected in a Quarterly Report on Form 10-Q, which pursuant to Rule 12b-25, is expected to be filed no later than May 22, 2023. The financial performance measures presented in this press release for the first quarter of 2023 are forward-looking statements, preliminary estimates and unaudited, based on management's initial review of the information presented, and are thus inherently uncertain and subject to change as Delcath completes its end-of-period reporting process and related activities for the first quarter of 2023. During the course of the review of Delcath's condensed consolidated financial statements and related notes as of and for the quarter ended March 31, 2023, Delcath's independent registered public accountants may identify items that could cause final reported results to be materially different from the preliminary estimates presented herein. Additional information and disclosures would be required for a more complete understanding of Delcath's financial position and results of operations as of and for the quarter ended March 31, 2023. Accordingly, undue reliance should not be placed on this preliminary information.

Financial Highlights.

Revenue is expected to be approximately $0.6 million in revenue for the three months ended March 31, 2023, compared to $0.4 million for the three months ended March 31, 2022. The estimated increase in product revenue was due to the transition to direct sales in Europe which occurred in March 2022 as well as an approximately 37% increase in unit volume.

For the three months ended March 31, 2023, research and development expenses is expected to be relatively flat at approximately $4.5 million for both periods compared to the three months ended March 31, 2022.

As of March 31, 2023, the Company had cash, cash equivalents and restricted cash totaling $24.3 million, as compared to cash, cash equivalents and restricted cash totaling $11.8 million as of March 31, 2022. The increase in cash of $12.5 million was due to the proceeds from the private placement which closed on March 29, 2023, offset by the use of $4.3 million of cash in our operating activities and $6.3 million of principal payments toward the Company's existing loan with Avenue.

Conference Call Information

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

Event Date: Friday May 12, 2023

Time: 8:30 AM Eastern Time

Participant Numbers: Toll Free: 1-833-630-1960

International: 1-412-317-1841

Webcast: https://app.webinar.net/EwPL2ydl3ra

CONFERENCE REPLAY

US Toll Free:	1-877-344-7529
Canada Toll Free:	855-669-9658
Replay Access Code:	2940240
End Date:	May 19, 2023

About Delcath Systems, Inc.

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 (melphalan hydrochloride 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 an investigational drug/device combination product regulated as a drug by the United States Food and Drug Administration (FDA). HEPZATO Kit is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System (HDS). The HDS is used to surgically isolate the liver 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. In the US, HEPZATO Kit was the subject of a February 14, 2023 new drug application resubmission to FDA for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM). FDA has established an August 14, 2023 PDUFA date for the resubmission. 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements relating to: Delcath's preliminary estimated financial results for the quarter ended March 31,2023; the timing of the filing of Delcath's Form 10-Q for the quarter ended March 31, 2023; the therapeutic and commercial potential of Delcath's product candidates, including the Hepzato Kit and CHEMOSTAT; and other statements that are not historical fact. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that can cause actual results to differ materially from those described herein. Factors that could cause actual results to differ include, but are not limited to, uncertainties relating to: adjustments to Delcath's preliminary measures of financial performance resulting from, among other things, the completion of Delcath's financial close procedures, including valuation work associated with the issuance of warrants and preferred stock in the private placement; achievement of milestones; the likelihood and timing of the potential approval of HEPZATO by the FDA by the PDUFA date of August 14, 2023; the Company's ability to commercialize HEPZATO;; the sufficiency of Delcath's upfront and milestone financing payments to fund commercialization of HEPZATO in the U.S.; Delcath's ability to generate revenue from HEPZATO; clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in; the Company's ability to successfully commercialize the HEPZATO KIT/CHEMOSAT system and the potential of the HEPZATO KIT/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver; approval of the current or future HEPZATO KIT/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. and/or in foreign markets; actions by the FDA or foreign regulatory agencies; uncertainties relating to the timing and results of research and development projects; uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These risks and uncertainties are described more fully in our Securities and Exchange Commission ("SEC") filings and reports, including our Annual Report on Form 10-K for the year ended December 31, 2022, and other filings and reports made from time to time with the SEC. 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.

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