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): March 27, 2023

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.)**

1633 Broadway, Suite 22C, New York, New York 10019
(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 March 27, 2023, Delcath Systems, Inc. (the "Company") issued a press release, furnished as Exhibit 99.1 and incorporated in this Item 2.02 by reference, announcing its financial results for the fiscal quarter and year ended December 31, 2022.

The information contained in this Item 2.02, including Exhibit 99.1, is being furnished, and 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 Section 18. Furthermore, the information contained in this Item 2.02, including Exhibit 99.1, shall not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1	Press Release of the Company, Dated March 27, 2023, Reporting Fourth Quarter and Full year 2022 Results and Provides Business Update.
104	Cover Page Interactive File (the cover page tags 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 thereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: March 27, 2023

By: /s/ David Hoffman
Name: David Hoffman
Title: Chief Executive Officer

Exhibit 99.1

Delcath Systems Announces up to $85 Million Financing

Led by Vivo Capital with participation from Logos Capital, BVF Partners LP, Stonepine Capital Management, LLC, Serrado Capital LLC and supported by existing investor, Rosalind Advisors

$25 million financing upfront with up to an additional $60 million tied to satisfaction of milestones

Aggregate financing expected to be sufficient to fund Company through potential approval of HEPZATO and commercialization

NEW YORK, Mar. 27, 2023 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 that the Company has signed securities purchase agreements with certain healthcare-focused institutional investors that will provide up to $85 million in gross proceeds to Delcath through a private placement that includes initial upfront funding of $25 million.

The financing is being led by Vivo Capital with participation from Logos Capital, BVF Partners LP, Stonepine Capital Management, LLC, Serrado Capital LLC and supported by existing investor, Rosalind Advisors.

This financing is expected to enable the Company to have sufficient cash past its anticipated PDUFA date of August 14, 2023, and fund the commercialization of HEPZATO, if approved.

About the Private Placement

Pursuant to the securities purchase agreements, the Company will issue to purchasers (i) an aggregate $24.9 million in shares of the Company's Series F Convertible Preferred Stock and (ii) two tranches of warrants that are exercisable for shares of the Company's Series F Convertible Preferred Stock as follows:

- Tranche A warrants for an aggregate exercise price of approximately $34.9 million are exercisable until the earlier of 3/31/2026 or 21 days following the Company's announcement of receipt of FDA approval for HEPZATO; and
- Tranche B warrants for an aggregate exercise price of approximately $24.9 million are exercisable until the earlier of 3/31/2026 or 21 days following disclosure of the Company's public announcement of recording at least $10 million in quarterly U.S. revenue from the commercialization of HEPZATO.

Shares of Series F Convertible Preferred Stock will be issued at a price of $1,000.00 per share. Conversion of the Series F Convertible Preferred Stock into shares of common stock of the Company, and the exercisability of the warrants, is subject to approval by the Company's stockholders. Pursuant to a separate securities purchase agreement, the Company will issue to a certain purchaser (i) an aggregate of $0.1 million in shares of the Company's common stock and (ii) the Tranche A and Tranche B warrants to purchase shares of common stock. All of the securities in this private placement are being offered by Delcath.

Canaccord Genuity acted as the placement agent for the private placement.

The securities to be issued in connection with the private placement described above are being offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder and have not been registered under the Act or applicable state securities laws. Accordingly, such securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws. The Company has agreed to file a resale registration statement with the U.S. Securities and Exchange Commission (SEC), for purposes of registering the resale of the common stock issued or issuable in connection with the private placement.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

For further information, please see the Company's current report on Form 8-K to be filed with the SEC.

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.

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 news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described in particular, the statements regarding our private placement and expected gross proceeds and the expected uses of the proceeds from the private placement. Factors that may cause such differences include, but are not limited to, uncertainties relating to: anticipated use of proceeds from 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 receipt of stockholder approval to allow for the conversion of the Series F Preferred Stock into shares of the Company's common stock and the exercisability of the warrants; the sufficiency of the aggregate proceeds from the financing to fund commercialization of HEPZATO in the U.S., the Company'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; and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings 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.