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 9, 2022

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 May 9, 2022, 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 ended March 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 May 9, 2022, announcing financial results for the fiscal quarter ended March 31, 2022.
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: May 11, 2022

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

Exhibit 99.1

Delcath Systems Reports First Quarter 2022 Results and Provides Business Update

NEW YORK — Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today reported business highlights and financial results for the first quarter ended March 31, 2022.

Recent Business Highlights

During and since the first quarter, Delcath:

- Held a pre-NDA meeting with FDA and announced plans to file an NDA in the third quarter of 2022,
- Announced the acceptance of a poster presentation updating results from the FOCUS Phase 3 Trial at the upcoming American Society of Clinical Oncology (ASCO) 2022 Annual Meeting,
- Resumed direct responsibility for sales, marketing, and distribution activities for the CHEMOSAT® Hepatic Delivery System in all of Europe,
- Achieved medical device regulation (MDR) certification for CHEMOSAT in Europe, which is now regulated as a Class lll device,
- Announced that investigators from the University Hospital Southampton published in Melanoma Research results of a single center study on Delcath's CHEMOSAT Hepatic Delivery System in 81 metastatic uveal melanoma patients with liver dominant disease receiving 250 treatments showing hepatic disease control rate of 88.9%, hepatic response rate of 66.7% and overall response rate of 60.5%, and
- Appointed David Hoffman as General Counsel and Chief Compliance Officer and Anthony Dias as Vice President of Finance.

"During and since the first quarter, we held a pre-NDA meeting with FDA and, while we wait for the final meeting minutes from FDA, we do not believe any additional pre-clinical or clinical studies will be required in order to file the NDA. We expect to file the NDA in the third quarter of 2022," said Gerard Michel, CEO of Delcath. "Additionally, the body of published research on the efficacy of our CHEMOSAT system in the European commercial setting continued to grow, we resumed direct sales of CHEMOSAT in Europe, and we strengthened our leadership team. These accomplishments move

us much closer to achieving our strategic priorities – filing of the HEPZATO NDA, preparing for the subsequent US launch when approved, and expanding the clinical development of HEPZATO and CHEMOSAT into additional indications of high unmet medical need."

First Quarter 2022 Results

Income Statement Highlights.

Total revenue for the three months ended March 31, 2022 and 2021, was approximately $0.3 million, from primarily sales of CHEMOSAT in Europe. Research and development expenses for the quarter were $4.2 million compared to $3.7 million in the prior year quarter. Selling, general and administrative expenses for the quarter were approximately $3.6 million compared to $3.3 million in the prior year quarter. Total operating expenses for the quarter were $7.9 million compared with $7.0 million in the prior year quarter.

The Company recorded a net loss for the three months ended March 31, 2022, of $8.2 million, compared to a net loss of $6.7 million for the same period in 2021.

Balance Sheet Highlights

On March 31, 2022, the Company had cash, cash equivalents and restricted cash totaling $20.5 million, as compared to cash, cash equivalents and restricted cash totaling $27.0 million on December 31, 2021. During the three months ended March 31, 2022, and March 31, 2021, we used $6.4 million and $4.6 million, respectively, of cash in our operating activities.

Conference Call Information

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

Event Date: Tuesday, May 10, 2022
Time: 8:30 AM Eastern Time
Participant Numbers: Toll Free: 877-545-0523; Participant Access Code: 633971
International: 973-528-0016 Participant Access Code: 633971
Webcast: https://www.webcaster4.com/Webcast/Page/2475/45401

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 percutaneous hepatic perfusion (PHP) system is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In the United States, the PHP system is being developed under the tradename HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM) and is considered a combination drug and device product regulated by the United States Food and Drug Administration (FDA).

In Europe, the PHP system is now regulated as a Class lll medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used 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. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the timing and results of the Company's clinical trials, including without limitation the mOM and ICC clinical trial programs, as well as the receipt of additional data and the performance of additional analyses with respect to the mOM clinical trial, our determination whether to continue the ICC clinical trial program or to focus on other alternative indications, and timely monitoring and treatment of patients in the global Phase 3 mOM clinical trial and the impact of the COVID-19 pandemic on the completion of our clinical trials; the impact of the presentations at major medical conferences and future clinical results consistent with the data presented; approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure; the impact, if any, of ZE reimbursement on potential CHEMOSAT product use and sales in Germany; clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK; 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; our ability to obtain reimbursement for the CHEMOSAT system in various markets; 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; the Company's ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same; 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 Securities and Exchange Commission. 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.

Contact:

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DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share data)

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 16,340	$ 22,802
Restricted cash	4,151	4,151
Accounts receivable, net	178	44
Inventories	2,011	1,412
Prepaid expenses and other current assets	2,704	2,743
Total current assets	25,384	31,152
Property, plant and equipment, net	1,406	1,348
Right-of-use assets	527	624
Total assets	$ 27,317	$ 33,124
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,243	$ 638
Accrued expenses	4,495	4,109
Deferred revenue, current	—	170
Lease liabilities, current	404	416
Loan payable, current	2,520	621
Total current liabilities	8,662	5,954
Lease liabilities, non-current	122	207
Loan payable, non-current	8,633	10,372
Convertible notes payable, non-current	4,675	4,639
Total liabilities	22,092	21,172
Commitments and contingencies (Note 13)	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 11,357 shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 7,906,728 shares issued and outstanding at March 31, 2022 and December 31, 2021	79	79
Additional paid-in capital	434,305	432,831
Accumulated deficit	(429,179)	(420,976)
Accumulated other comprehensive income	20	18
Total stockholders' equity	5,225	11,952
Total liabilities and stockholders' equity	$ 27,317	$ 33,124

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended March 31,	
	2022	**2021**
Product revenue	$ 207	$ 261
Other revenue	171	127
Cost of goods sold	(33)	(112)
Gross profit	345	276
Operating expenses:		
Research and development expenses	4,240	3,707
Selling, general and administrative expenses	3,648	3,296
Total operating expenses	7,888	7,003
Operating loss	(7,543)	(6,727)
Interest expense, net	(645)	(41)
Other income (expense), net	(15)	21
Net loss	(8,203)	(6,747)
Other comprehensive income:		
Foreign currency translation adjustments	2	94
Total other comprehensive loss	$ (8,201)	$ (6,653)
Common share data:		
Basic and diluted loss per common share	$ (1.00)	$ (1.04)
Weighted average number of basic and diluted shares outstanding	8,190,483	6,496,922