

**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 11, 2021

DELCATH SYSTEMS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-16133
(Commission
File Number)

06-1245881
(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 11, 2021, 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, 2021.

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 11, 2021, announcing financial results for the fiscal quarter ended March 31, 2021.](#)

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 12, 2021

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



Delcath Systems, Inc. Announces First Quarter 2021 Results

NEW YORK (GLOBE NEWSWIRE) — 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, 2021.

Recent Business Highlights

During and since the first quarter the company:

- Reported positive preliminary results from the FOCUS Clinical Trial (NCT02678572) for Patients with Hepatic Dominant Ocular Melanoma treated with HEPZATO KIT based on an analysis of currently evaluable patients. The preliminary analysis included 87% of treated patients and final results are expected later in the year.
 - The primary endpoint, overall response rate (ORR), exceeded the prespecified threshold for success by a large enough margin to ensure that final results based on 100% of patients will be positive.
 - Both prespecified ORR and Progression Free Survival comparative analyses versus the best alternative care arm demonstrated a statistically significant improvement.
 - The safety profile was consistent with the safety profile of CHEMOSAT treatment described in previous European single-center and multi-center publications with no new safety signals observed in this patient population and no treatment related deaths on study.
- Announced that the United Kingdom's National Institute for Health and Care Excellence, has updated its guidance for the Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) in the treatment of patients with metastases in the liver from Ocular Melanoma. Under this designation, private insurance may be more likely to fund treatment with CHEMOSAT, some regional funding may be more accessible, and a process is now available to seek national reimbursement.
- Announced an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting to be held virtually June 4-8, 2021.

“The recently released preliminary results from the FOCUS trial strongly indicates that HEPZATO’s benefit risk ratio is a significant improvement versus an earlier generation of Delcath’s proprietary percutaneous hepatic perfusion system” said Gerard Michel, CEO of Delcath. “We look forward to continued progress in the balance of the year, as we prepare both to file an NDA in early 2022 and expand the development of HEPZATO into additional areas of high unmet need.”

First Quarter 2021 Financial Results:

Income Statement Highlights.

Product revenue for the three months ended March 31, 2021 was approximately \$0.4 million, compared to \$0.3 million for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately \$3.3 million compared to \$2.3 million in the prior year quarter. Research and development expenses for the quarter were \$3.7 million compared to \$3.0 million in the prior year quarter. Total operating expenses for the quarter were \$7.0 million compared with \$5.3 million in the prior year quarter. First quarter expenses included approximately \$2.2 million of stock option expense compared to no material stock option expense in the prior year quarter.

We recorded a net loss for the three months ended March 31, 2021, of \$6.8 million, compared to a net income of \$7.9 million for the same period in 2020

Balance Sheet Highlights.

At March 31, 2021, we had cash, cash equivalents and restricted cash totaling \$26.7 million, as compared to cash, cash equivalents and restricted cash totaling \$4.7 million at March 31, 2020. During the three months ended March 31, 2021 and March 31, 2020, we used \$4.6 million and \$5.2 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.

Date: May 11, 2021 Time: 8:30 AM Eastern Time Toll Free: 888-506-0062; Entry Code: 626332 International: 973-528-0011; Entry Code: 626332

The call will also be available over the Internet and accessible at: <https://www.webcaster4.com/Webcast/Page/2475/41204>

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial which is investigating the treatment of mOM, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called the ALIGN Trial. We have paused our work on the ALIGN Trial while we reevaluate the trial design. HEPZATO KIT has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system is marketed under the trade name Delcath CHEMOSAT® Hepatic Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

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:

Delcath Investor Relations

Email: investorrelations@delcath.com

Hayden IR

James Carbonara

(646)-755-7412

james@haydenir.com

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

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 26,600	\$ 28,575
Restricted cash	50	181
Accounts receivable, net	75	57
Inventories	1,109	855
Prepaid expenses and other current assets	2,369	2,670
Total current assets	30,203	32,338
Property, plant and equipment, net	1,321	1,351
Right-of-use assets	791	946
Total assets	<u>\$ 32,315</u>	<u>\$ 34,635</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,234	\$ 1,774
Accrued expenses	5,927	5,241
Deferred revenue, current	502	525
Lease liabilities, current	433	495
Convertible notes payable, current	2,000	2,000
Total current liabilities	10,096	10,035
Deferred revenue, non-current	1,856	2,072
Lease liabilities, non-current	357	450
Total liabilities	<u>12,309</u>	<u>12,557</u>
Commitments and contingencies (Note 13)	—	—
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; 20,480 and 20,631 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, \$.01 par value; 40,000,000 shares authorized; 6,251,257 and 5,996,101 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	63	60
Additional paid-in capital	422,027	417,449
Accumulated deficit	(402,074)	(395,327)
Accumulated other comprehensive income	(10)	(104)
Total stockholders' equity	<u>20,006</u>	<u>22,078</u>
Total liabilities and stockholders' equity	<u>\$ 32,315</u>	<u>\$ 34,635</u>

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,	
	2021	2020
Product revenue	\$ 261	\$ 176
Other revenue	127	118
Cost of goods sold	<u>(112)</u>	<u>(78)</u>
Gross profit	<u>276</u>	<u>216</u>
Operating expenses:		
Research and development expenses	3,707	2,974
Selling, general and administrative expenses	<u>3,296</u>	<u>2,316</u>
Total operating expenses	<u>7,003</u>	<u>5,290</u>
Operating loss	(6,727)	(5,074)
Change in fair value of the warrant liability, net	—	(2,832)
Interest expense, net	(41)	(36)
Other income	<u>21</u>	<u>81</u>
Net loss	(6,747)	(7,861)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	<u>94</u>	<u>65</u>
Total other comprehensive loss	<u>\$ (6,653)</u>	<u>\$ (7,796)</u>
Common share data:		
Basic loss per common share	<u>\$ (1.04)</u>	<u>\$(108.07)</u>
Diluted loss per common share	<u>\$ (1.04)</u>	<u>\$(108.07)</u>
Weighted average number of basic shares outstanding	<u>6,496,922</u>	<u>72,740</u>
Weighted average number of diluted shares outstanding	<u>6,496,922</u>	<u>72,740</u>