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): August 17, 2020

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 Number)**

1633 Broadway, Suite 22C, New York, New York 10019
(Address of principal executive offices, including zip code)

(212) 489-2100
(Registrant's telephone number, including area code)

NONE
(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 (see General Instruction A.2. below):

☐ 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 August 13, 2020, Delcath Systems, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

99.1 Press release, dated August 13, 2020, issued by Delcath Systems, Inc.

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: August 17, 2020

By: /s/ John Purpura
Name: John Purpura

Title: Interim Chief Executive Officer

Exhibit 99.1

Delcath Systems, Inc. Announces Second Quarter 2020 Results

NEW YORK, August 13, 2020 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of rare primary and metastatic cancers of the liver, announces financial results for the quarter ended June 30, 2020, and will host an earnings call on August 13, 2020 at 4:30 p.m.

Recent Corporate Highlights:

- Completed a $22 million public offering, led by healthcare-focused investors, to allow completion of the Company's Phase 3 registration trial of Melphalan/HDS in liver-dominant metastatic ocular melanoma (mOM) and refiling of a New Drug Application (NDA) with FDA.
- Uplisted to the NASDAQ Capital Market.
- Announced management and board transitions.
- Initiated pre-commercialization work for Melphalan/HDS in mOM.
- Initial physician and payer surveys have highlighted the high-unmet medical need in mOM as well as the expectation of ultra-orphan oncology pricing dynamic for Melphalan/HDS.

Expected Milestones:

- Late 2020/early 2021 – Covid-19 has affected clinical trials globally, including our Phase 3 FOCUS registration trial for Melphalan/HDS in liver-dominant ocular melanoma. Importantly, however, throughout these months, the trial protocol remained intact and ongoing trial patients continued to receive treatments. While access to clinical sites for data entry and monitoring was severely restricted during the quarter, the majority of the study's European and US sites began to ease these restrictions subsequent to quarter end. In addition, we implemented a number of steps to increase data monitoring efforts in light of the impact of the pandemic. Based on the current trajectory of site access, management is focused on delivering top-line results by year-end 2020/early 2021.
- Mid-2021– New Drug Application (NDA) submission of Melphalan/HDS in liver-dominant mOM. During the quarter management took steps to ensure progress on key elements of our NDA submission. Those included, among other things, required non-clinical studies and Chemistry, Manufacturing and Controls (CMC) work to ensure that any potential Covid-19 clinical data delays would not affect our timelines to NDA submission.

- Initiation of additional clinical studies for Melphalan/HDS in liver-dominant orphan cancers of high unmet-medical need. During the quarter, in-line with the overall restructuring efforts, management initiated a comprehensive review of the multitude of potential pipeline opportunities available for the Company to pursue, as potential label-expansion, beyond mOM. The analysis comprises available clinical evidence, based on the European commercial experience, where Melphalan/HDS is approved as a device-only configuration under the brand name CHEMOSAT®, as well as the potential US commercial opportunity. Based on the conclusions of this analysis Delcath expects to initiate at least one additional clinical development program of Melphalan/HDS in coming quarters.

John Purpura, interim CEO of Delcath commented, “Q2 was a transformational quarter for Delcath. The recent $22 million public offering along with our Nasdaq uplisting have been the culmination of a strategic restructuring achieved over the last year. With $51.5 million raised in the 12-month period ended June 30, 2020, led by fundamental healthcare focused investors, Delcath has been restructured, recapitalized and refocused. Our current cash resources, along with expected cash milestones from our European commercialization partner, medac GmBH, provide us with a sufficient runway through multiple value inflection points. These include completion of our Phase 3 FOCUS trial in metastatic ocular melanoma and the refiling of a New Drug Application (NDA) with FDA by mid-2021.”

Mr. Purpura added, “Working towards the possibility of having Melphalan/HDS available as a treatment for mOM patients, who have limited therapeutic options, is Delcath’s top priority. With Melphalan/HDS set for potential FDA approval in the second half of 2021, as the only labelled mOM-specific therapy in the US, Delcath has begun pre-commercialization activities which it intends to accelerate in coming quarters. Initial work has highlighted oncologists’ perceptions of the high-unmet medical need of mOM patients, the potential front-line positioning of Melphalan/HDS in this setting and the expectation of attractive ultra-orphan pricing dynamics for our therapy.”

Mr. Purpura concluded, “Interventional Oncology has become, in recent years, an integrated, fast-growing segment of cancer care. We believe that Melphalan/HDS is uniquely positioned as a potentially well differentiated, high-value, interventional oncology treatment paradigm targeting orphan and ultra-orphan indications of high unmet medical need. Beyond mOM, Delcath is currently looking to initiate additional studies in one or more liver-dominant metastatic indications for which Melphalan/HDS could be applicable. We expect the next 12 months to be transformational for Delcath and are looking forward to providing updates on our progress throughout.”

Second Quarter 2020 Financial Results:

Income Statement Highlights. Product revenue for the three months ended June 30, 2020 was approximately $262 thousand, compared to $221 thousand for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were

approximately $2.3 million compared to $2.7 million in the prior year quarter. Research and development expenses for the second quarter were $2.2 million compared to $1.7 million in the prior year quarter. Total operating expenses for the second quarter were $4.5 million compared with $4.4 million in the prior year quarter.

We recorded a net loss for the three months ended June 30, 2020, of $4.3 million, compared to a net loss of $6.0 million for the same period in 2019.

Balance Sheet Highlights. At June 30, 2020, we had cash, cash equivalents and restricted cash totaling $16.2 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019 and $1.4 million at June 30, 2019. During the three months ended June 30, 2020 and June 30, 2019, we used $7.9 million and $3.2 million, respectively, of cash in our operating activities. In Q2 we made a number of one-time cash payments not indicative of the usual cash usage trend totaling approximately $3.3 million, including compensation payable subsequent to resignations of executives and a director, and past-due payables.

We believe our cash resources and anticipated milestone payments, are adequate to fund our operating activities into mid-year 2021.

Conference Call Information

To participate in this event, dial approximately 5 to 10 minutes before the beginning of the call. Please ask for the Delcath Second Quarter Conference Call when reaching an operator.

Date: August 13, 2020
Time: 4:30 PM Eastern Time
Toll Free: (833) 937-1050
International: (845) 403-8302

The call will also be available over the Internet and accessible at: https://www.webcaster4.com/Webcast/Page/2475/36568.

DELCATH SYSTEMS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands)

	Three months ended June 30,		Six months end
	2020	2019	2020
Product revenue	$ 262	$ 221	$ 437
Other revenue	117	191	235
Cost of goods sold	(168)	(172)	(246)
Gross profit	211	240	426
Operating expenses:			
Research and development expenses	2,223	1,714	5,197
Selling, general and administrative expenses	2,257	2,653	4,573
Total operating expenses	4,480	4,367	9,770
Operating loss	(4,269)	(4,127)	(9,344)
Change in fair value of the warrant liability, net	—	10	(2,832)
Loss on issuance of financial instrument	—	(6)	—
Interest expense	(52)	(1,837)	(109)
Other income	46	1	149
Net loss	(4,275)	(5,959)	(12,136)
Deemed dividend for triggering of warrant down round feature	(55)	—	(55)
Net loss attributable to common stockholders	$ (4,330)	$ (5,959)	$ (12,191)
Net loss	$ (4,275)	$ (5,959)	$ (12,136)
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(1)	(23)	65
Total other comprehensive loss	$ (4,276)	$ (5,982)	$ (12,071)
Common share data:			
Basic loss per common share	$ (1.90)	$ (58.50)	$ (10.40)
Diluted loss per common share	$ (1.90)	$ (58.50)	$ (10.40)
Weighted average number of basic shares outstanding	2,273,187	101,862	1,171,994
Weighted average number of diluted shares outstanding	2,273,187	101,862	1,171,994

DELCATH SYSTEMS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands)

	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 16,011	$ 10,002
Restricted cash	181	181
Accounts receivables, net	147	21
Inventories	723	654
Prepaid expenses and other current assets	1,992	1,759
Total current assets	19,054	12,617
Property, plant and equipment, net	864	735
Right-of-use assets	525	860
Total assets	$ 20,443	$ 14,212
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,174	$ 4,533
Accrued expenses	5,429	6,947
Lease liabilities, current portion	508	664
Warrant liability	—	3,368
Total current liabilities	8,111	15,512
Deferred revenue	2,613	2,860
Lease liabilities, long-term portion	17	197
Convertible notes payable, long-term	2,000	2,000
Total liabilities	12,741	20,569
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 25,950 and 41,517 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 3,521,641 and 67,091 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	35	1
Additional paid-in capital	390,882	364,785
Accumulated deficit	(383,307)	(371,171)
Accumulated other comprehensive income	92	28
Total stockholders' equity (deficit)	7,702	(6,357)
Total liabilities and stockholders' equity (deficit)	$ 20,443	$ 14,212

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 – Melphalan Hydrochloride for

Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called The ALIGN Trial. Melphalan/HDS 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 OM and ICC clinical trial programs, and timely enrollment and treatment of patients in the global Phase 3 OM and ICC clinical trials and the impact of the COVID-19 pandemic on the enrollment and completion of our clinical trials; IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial protocols from participating sites and the timing of site activation and subject enrollment in each trial; 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 Melphalan HDS/CHEMOSAT system and the potential of the Melphalan HDS/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 Melphalan HDS/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.

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