



Delcath Systems Announces Second Quarter 2021 Results

August 10, 2021

NEW YORK, Aug. 10, 2021 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (Nasdaq: **DCTH**), an interventional oncology company focused on the treatment of rare primary and metastatic cancers of the liver, today reported business highlights and financial results for the second quarter ended June 30, 2021.

Recent Business Highlights

During and since the second quarter the company:

- Had positive efficacy results presented from its FOCUS Phase III trial of HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system) in patients with liver dominant metastatic ocular melanoma (mOM) at the American Society of Clinical Oncology (ASCO) Annual Meeting. The oral presentation by the study's Lead Investigator, Dr. Jonathan Zager, Chief Academic Officer, Chair, USF Department of Oncologic Sciences, Moffitt Cancer Center, included data based on 79 of 91 treated HEPZATO patients showing an overall response rate of 29.2% with a 95% confidence interval lower bound of 20%. Given the magnitude by which the lower bound exceeded the 8.3% prespecified threshold for success, the primary endpoint of the trial has been met regardless of the outcome of patients who have not yet been evaluated. Patient level response data were also presented for this same patient set, indicating that 44% of evaluable patients in the HEPZATO arm had a 30% or greater reduction in target tumor lesions at one or more time points versus 17% for patients enrolled in the Best Alternative Care arm.
- 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.
- Entered into a debt facility with Avenue Venture Opportunities Fund, L.P. providing up to \$20 million with an initial \$15 million funded at close
- Was added to the Russell Microcap® Index. Membership in the Russell Microcap® Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes.

"During the quarter we announced new patient level data at ASCO that further strengthens the case that HEPZATO would offer a compelling clinical benefit to patients were it approved by the FDA," said Gerard Michel, CEO of Delcath. "With additional capital from the just closed transaction with Avenue Venture Opportunities Fund, Delcath has the required resources to accomplish its strategic priorities – the filing of the HEPZATO NDA in early 2022, preparing for the subsequent US launch when approved, and expanding 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 June 30, 2021 was approximately \$536 thousand, compared to \$379 thousand 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 \$3.5 million compared to \$2.2 million in the prior year quarter. Total operating expenses for the quarter were \$6.8 million compared with \$4.5 million in the prior year quarter. Expenses for the quarter included approximately \$1.6 million of stock option

expense compared to no stock option expense in the prior year quarter.

The company recorded a net loss for the three months ended June 30, 2021, of \$6.4 million, compared to a net income of \$4.3 million for the same period in 2020

Balance Sheet Highlights.

On June 30, 2021, we had cash, cash equivalents and restricted cash totaling \$19.4 million, as compared to cash, cash equivalents and restricted cash totaling \$16.2 million at June 30, 2020. During the three months ended June 30, 2021 and June 30, 2020, we used \$11.7 million and \$13.1 million, respectively, of cash in our operating activities.

On August 6th, we closed a \$20 million venture debt financing transaction with Avenue Venture Opportunities Fund ("Avenue Venture Fund"). The initial tranche of the Loan is \$15 million, including \$4 million which has been funded into a restricted account and will be released upon achievement of certain milestones. The Company may request an additional \$5 million of gross proceeds between October 1, 2022 and December 31, 2022, which will be funded at Avenue Venture Fund's discretion.

Also, on August 6th, we amended two existing convertible notes through an extension of the term of the notes until 2024 and lowered the conversion factor in consideration for the notes becoming subordinate to the Avenue Venture Fund debt.

Additional details concerning the Avenue Venture Fund facility and modification of the existing convertible notes will be contained in the company's Current Report on Form 8-K to be filed with the Securities and Exchange Commission.

Conference Call Information

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

Date: August 10, 2021

Time: 8:30 AM Eastern Time

Toll Free: 877-545-0523; Entry Code: 148562

International: 973-528-0016; Entry Code: 148562

The call will also be available over the Internet and accessible at:

<https://www.webcaster4.com/Webcast/Page/2475/42376>

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, 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 regulated as a Class IIb 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. 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.

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

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 19,274	\$ 28,575
Restricted cash	151	181
Accounts receivable, net	75	57
Inventories	1,221	855
Prepaid expenses and other current assets	2,185	2,670
Total current assets	22,906	32,338
Property, plant and equipment, net	1,361	1,351
Right-of-use assets	650	946
Total assets	\$ 24,917	\$ 34,635
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,224	\$ 1,774
Accrued expenses	3,621	5,241
Deferred revenue, current	509	525
Lease liabilities, current	387	495
Convertible notes payable, current	—	2,000
Total current liabilities	5,741	10,035
Deferred revenue, non-current	1,754	2,072
Lease liabilities, non-current	263	450
Convertible notes payable, non-current	2,000	—
Total liabilities	9,758	12,557
Commitments and contingencies (Note 11)	—	—
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; 11,707 and 20,631 shares issued and outstanding at June 30, 2021, and December 31, 2020, respectively	—	—
Common stock, \$.01 par value; 40,000,000 shares authorized; 7,349,777 and 5,996,101 shares issued and outstanding at June 30, 2021, and December 31, 2020, respectively	74	60
Additional paid-in capital	423,660	417,449
Accumulated deficit	(408,504)	(395,327)
Accumulated other comprehensive loss	(71)	(104)

Total stockholders' equity	15,159	22,078
Total liabilities and stockholders' equity	<u>\$ 24,917</u>	<u>\$ 34,635</u>

DEL CATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Product revenue	\$ 398	\$ 262	\$ 659	\$ 437
Other revenue	138	117	265	235
Cost of goods sold	(202)	(168)	(314)	(246)
Gross profit	<u>334</u>	<u>211</u>	<u>610</u>	<u>426</u>
Operating expenses:				
Research and development expenses	3,497	2,223	7,204	5,197
Selling, general and administrative expenses	3,288	2,257	6,584	4,573
Total operating expenses	<u>6,785</u>	<u>4,480</u>	<u>13,788</u>	<u>9,770</u>
Operating loss	(6,451)	(4,269)	(13,178)	(9,344)
Change in fair value of the warrant liability, net	—	—	—	(2,832)
Interest expense, net	(40)	(52)	(81)	(88)
Other income	61	46	82	128
Net loss	<u>(6,430)</u>	<u>(4,275)</u>	<u>(13,177)</u>	<u>(12,136)</u>
Deemed dividend for triggering of warrant down round feature	—	(55)	—	(55)
Net loss attributable to common stockholders	<u>\$ (6,430)</u>	<u>\$ (4,330)</u>	<u>\$ (13,177)</u>	<u>\$ (12,191)</u>
Net loss	\$ (6,430)	\$ (4,275)	\$ (13,177)	\$ (12,136)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(61)	(1)	33	65
Total other comprehensive loss	<u>\$ (6,491)</u>	<u>\$ (4,276)</u>	<u>\$ (13,144)</u>	<u>\$ (12,071)</u>
Common share data:				
Basic loss per common share	<u>\$ (0.96)</u>	<u>\$ (1.90)</u>	<u>\$ (2.00)</u>	<u>\$ (10.40)</u>
Diluted loss per common share	<u>\$ (0.96)</u>	<u>\$ (1.90)</u>	<u>\$ (2.00)</u>	<u>\$ (10.40)</u>
Weighted average number of basic shares outstanding	<u>6,681,369</u>	<u>2,273,187</u>	<u>6,589,655</u>	<u>1,171,994</u>
Weighted average number of diluted shares outstanding	<u>6,681,369</u>	<u>2,273,187</u>	<u>6,589,655</u>	<u>1,171,994</u>



Source: Delcath Systems, Inc.