Delcath Systems Reports Second Quarter 2022 Results and Provides Business Update

NEW YORK, Aug. 8, 2022 — 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 second quarter ended June 30, 2022.

Recent Business Highlights

During and since the second quarter, Delcath:

- Held a pre-NDA meeting with FDA and locked the phase 3 FOCUS Trial database for the purpose of resubmitting the NDA for the Hepzato Kit® (melphalan hydrochloride for injection/hepatic delivery system) in the third quarter of 2022,
- Presented a poster updating the results from the FOCUS Trial at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting,
- Opened two Expanded Access Program (NCT05022901) sites, and
- Raised $5 million in a private placement priced at market.

In addition, during and since the fourth quarter, independent investigators:

- Published *Predictive Parameters in Patients Undergoing Percutaneous Hepatic Perfusion with Melphalan for Unresectable Liver Metastases from Uveal Melanoma: A Retrospective Pooled Analysis* in the journal Cardiovascular and Interventional Radiology,
- Presented two abstracts on the use of Chemosat® Hepatic Delivery System with Melphalan in the treatment of metastatic uveal melanoma at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting, including:
    - *Safety and efficacy of combined melphalan percutaneous hepatic perfusion (M-PHP) and ipilimumab plus nivolumab (IPI+NIVO) in metastasized uveal melanoma: First results of the phase Ib part of the CHOPIN trial,* and
    - *Temporal evolution in quality-of-life following melphalan percutaneous hepatic perfusion for patients with metastatic uveal melanoma.*

“As we prepare to resubmit the Hepzato Kit NDA by the end of the third quarter, Chemosat

usage in Europe continues to result in publications supportive of both Chemosat and by extension the Hepzato Kit," said Gerard Michel, Chief Executive Officer of Delcath. Mr. Michel continued, "We would expect that within 30 days of the resubmission, the FDA will confirm receipt of the submission and, if they agree the resubmission is sufficiently complete to warrant review, establish a PDUFA date sometime late in the first quarter of 2023."

First Quarter 2022 Results

Income Statement Highlights.

Total revenue for the three months ended June 30, 2022, was approximately $0.8 million, compared to $0.5 million for the prior year period, from our sales of CHEMOSAT in Europe. This increase in product revenue is primarily due to a full quarter of direct product sales by Delcath compared to the revenue share arrangement with our distribution partner in Europe in 2021.

Research and development expenses for the quarter were $5.5 million, compared to $3.5 million in the prior year quarter. The growth in R&D expense is primarily due to increased activity related to the NDA preparation. Selling, general and administrative expenses for the quarter were approximately $4.1 million, compared to $3.3 million in the prior year quarter. Total operating expenses for the quarter were $9.6 million, compared with $6.8 million in the prior year quarter.

The Company recorded a net loss for the three months ended June 30, 2022, of $9.7 million, compared to a net loss of $6.4 million for the same period in 2021.

Balance Sheet Highlights

On June 30, 2022, the Company had cash, cash equivalents and restricted cash totaling $14.4 million, as compared to cash, cash equivalents and restricted cash totaling $27.0 million on December 31, 2021. During the three months ended June 30, 2022, and June 30, 2021, we used $6.1 million and $7.1 million, respectively, of cash in our operating activities.

On July 20, 2022, Delcath closed a private placement for the issuance and sale of 690,954 shares of common stock (the "Common Stock") and 566,751 pre-funded warrants to purchase Common Stock (the "Pre-Funded Warrants") to certain investors. Each share of Common Stock was sold at a price per share of $3.98 and the Pre-Funded Warrants were sold at a price of $3.97 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.01 per share of Common Stock and are immediately exercisable. Delcath received gross proceeds from the Private Placement of approximately $5.0 million before deducting offering expenses payable by Delcath. Delcath intends to use the net proceeds from the Private Placement for working capital purposes and other general corporate purposes.

Conference Call Information

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

Event Date: Monday August 8, 2022

Time: 8:30 AM Eastern Time

Participant Numbers: Toll Free: 1-844-836-8745
International: 1-412-317-6797
Webcast: https://app.webinar.net/leg9qEP2vWK

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, in particular, 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: 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.

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

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 10,203	$ 22,802
Restricted cash	4,151	4,151
Accounts receivable, net	438	44
Inventories	2,040	1,412
Prepaid expenses and other current assets	2,370	2,743
Total current assets	19,202	31,152
Property, plant and equipment, net	1,457	1,348
Right-of-use assets	407	624
Total assets	$ 21,066	$ 33,124
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,067	$ 638
Accrued expenses	5,417	4,109
Deferred revenue	–	170
Lease liabilities	294	416
Loan payable, current	4,474	621
Total current liabilities	12,252	5,954
Lease liabilities, non-current	113	207
Loan payable, non-current	6,838	10,372
Convertible notes payable, non-current	4,709	4,639
Total liabilities	23,912	21,172
Commitments and contingencies	–	–
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 11,357 shares issued and outstanding at June 30, 2022 and December 31, 2021	–	–

Common stock, $.01 par value; 40,000,000 shares authorized; 7,906,728 shares issued and outstanding at June 30, 2022 and December 31, 2021	79	79
Additional paid-in capital	435,922	432,831
Accumulated deficit	(438,836)	(420,976)
Accumulated other comprehensive (loss) income	(11)	18
Total stockholders' equity (deficit)	(2,846)	11,952
Total liabilities and stockholders' equity (deficit)	$ 21,066	$ 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Product revenue	$ 797	$ 398	$ 1,003	$ 659
Other revenue	–	138	171	265
Cost of goods sold	(180)	(202)	(214)	(314)
Gross profit	617	334	960	610
Operating expenses:				
Research and development expenses	5,456	3,497	9,696	7,204
Selling, general and administrative expenses	4,145	3,288	7,791	6,584
Total operating expenses	9,601	6,785	17,487	13,788
Operating loss	(8,984)	(6,451)	(16,527)	(13,178)
Interest expense, net	(665)	(40)	(1,309)	(81)
Other (loss) income	(8)	61	(24)	82
Net loss	(9,657)	(6,430)	(17,860)	(13,177)
Other comprehensive income:				
Foreign currency translation adjustments	(31)	(61)	(29)	33
Total other comprehensive loss	$ (9,688)	$ (6,491)	$ (17,889)	$ (13,144)
Common share data:				
Basic and diluted loss per common share	$ (1.18)	$ (0.96)	$ (2.18)	$ (2.00)
Weighted average number of basic and diluted shares outstanding	8,190,483	6,681,369	8,190,483	6,589,655

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