Delcath Systems Reports Second Quarter 2023 Results and Provides Business Update

NEW YORK, Aug. 9, 2023 — Delcath Systems, Inc. (Nasdaq: DCTH) ("Delcath" or the "Company"), 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, 2023.

Recent Business Highlights

During and since the second quarter, Delcath:

- Has continued to communicate with the United States Food and Drug Administration (FDA) as the agency continues its review of the HEPZATO KIT™ New Drug Application (NDA) resubmission with an anticipated PDUFA date of August 14, 2023;
- Received stockholders approval for the potential issuance in excess of 19.99% of Delcath's outstanding common stock upon the conversion of the preferred stock issued pursuant to a private placement that closed on March 29, 2023 and generated $25 million on closing with up to an additional $35 million expected upon the exercise of warrants into additional series of preferred stock upon the approval of the HEPZATO KIT NDA and up to an additional $25 million upon the achievement of $10 million in quarterly revenue;
- Hired Vojislav Vukovic, MD, PhD as Chief Medical Officer; Sandra Pennell as Senior Vice President of Finance; and Zac MacLean as Director of Sales and Strategy; and
- Continued to treat patients at 3 Expanded Access Program sites.

"As we approach the August 14 PDUFA date, the Company has been preparing for the commercialization of HEPZATO KIT, if approved," said Gerard Michel, Chief Executive Officer of Delcath. Mr. Michel added, "As part of this preparation, we continue to add experienced personnel across the key functional areas involved in commercialization."

Delcath will schedule an update call shortly after the FDA's action on the HEPZATO KIT NDA resubmission, which the Company expects to occur on or around the anticipated PDUFA date of August 14, 2023.

Second Quarter 2023 Results

Financial Highlights.

Total revenue for the three months ended June 30, 2023, was approximately $0.5 million, compared to $0.8 million for the prior year period, from our sales of CHEMOSAT in Europe. This decrease in product revenue is primarily due to potential commercial patients in the Netherlands being treated in the CHOPIN trial and reduced demand in Germany, possibly due to tebentefusp usage.

Research and development expenses for the quarter were $3.6 million, compared to $5.6 million in the prior year quarter. The decrease in R&D expense is primarily due to completing clinical trial activities. The prior year quarter included expenses for the preparation of the pre-NDA meeting with the FDA. Selling, general and administrative expenses for the quarter increased to $4.8 million, compared to $4.5 million in the prior year quarter primarily relating to activities to prepare for a commercial launch if the HEPZATO KIT is approved.

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 products, HEPZATO KIT (Hepzato (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP) are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System (HDS). The HDS is used to surgically isolate the liver while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. In the US, HEPZATO KIT was the subject of a February 14, 2023 new drug application resubmission to FDA for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM), also known as metastatic uveal melanoma (mUM). FDA has established an August 14, 2023 PDUFA date for the resubmission. In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used in the conduct of percutaneous hepatic perfusion procedures 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 statements regarding our private placement and expected gross proceeds and 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: anticipated use of proceeds from the private placement, achievement of milestones, the likelihood and timing, or any delays, of the potential approval of HEPZATO by the FDA by the PDUFA date of August 14, 2023, the Company's ability to commercialize HEPZATO, necessary financing to fund commercialization of HEPZATO in the U.S., the Company's ability to generate revenue from HEPZATO, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in; 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; 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; uncertainties related to the continued supply of melphalan, necessary materials and other critical components for the HEPZATO KIT/CHEMOSAT; uncertainties relating to manufacturing delays or difficulties, including in connection with current good manufacturing practices compliance, that may delay the potential approval of HEPZATO by the FDA by the PDUFA date of August 14, 2023; the Company's ability to mitigate risks from single-source suppliers; 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 SEC. 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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DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	June 30, 2023	December 31, 2022
Assets		

Current assets		
Cash and cash equivalents	$ 14,540	$ 7,671
Restricted cash	50	4,151
Accounts receivable, net	127	366
Inventory	2,480	1,998
Prepaid expenses and other current assets	2,275	1,969
Total current assets	19,472	16,155
Property, plant and equipment, net	1,403	1,422
Right-of-use assets	175	285
Total assets	$ 21,050	$ 17,862
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 966	$ 2,018
Accrued expenses	5,546	4,685
Lease liabilities, current	92	186
Loan payable, current	4,510	7,846
Total current liabilities	11,114	14,735
Warrant liability	3,780	–
Other liabilities, non-current	1,146	1,144
Loan payable, non-current	411	3,070
Convertible notes payable, non-current	4,841	4,772
Total liabilities	21,292	23,721
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 20,981 and 11,357 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	–	–
Common stock, $.01 par value; 80,000,000 shares authorized; 15,250,469 shares and 10,046,571 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	153	100
Additional paid-in capital	473,355	451,608
Accumulated deficit	(473,686)	(457,484)
Accumulated other comprehensive loss	(64)	(83)
Total stockholders' equity (deficit)	(242)	(5,859)
Total liabilities and stockholders' equity	$ 21,050	$ 17,862

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,	
	2023	**2022**	**2023**	**2022**
Product revenue	$ 495	$ 797	$ 1,092	$ 1,003
Other revenue	–	–	–	171
Total revenues	495	797	1,092	1,174
Cost of goods sold	(150)	(180)	(331)	(214)

Gross profit	345	617	761	960
Operating expenses:				
Research and development expenses	3,555	5,606	8,131	10,087
Selling, general and administrative expenses	4,787	4,497	8,952	8,699
Total operating expenses	8,342	10,103	17,083	18,786
Operating loss	(7,997)	(9,486)	(16,322)	(17,826)
Change in fair value of warrant liability	1,160	–	1,160	–
Interest expense, net	(371)	(665)	(1,059)	(1,309)
Other income (expense)	6	(8)	19	(24)
Net loss	(7,202)	(10,159)	(16,202)	(19,159)
Other comprehensive income:				
Foreign currency translation adjustments	–	(31)	19	(29)
Total other comprehensive loss	$ (7,202)	$ (10,190)	$ (16,183)	$ (19,188)
Common share data:				
Basic and diluted loss per common share	$ (0.58)	$ (1.24)	$ (1.35)	$ (2.34)
Weighted average number of basic and diluted shares outstanding	12,463,665	8,190,483	12,035,738	8,190,483

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