Delcath Systems, Inc. Announces Fourth Quarter 2020 Results, Highlights Preliminary Positive FOCUS Trial Results; Conference Call Today at 8:00am Eastern Time

NEW YORK, March 31, 2021 — 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 fourth quarter ended December 31, 2020, and earlier today reported preliminary topline data. The company will host its quarterly call at 8:00am ET today, with a primary focus on discussing the preliminary top line data.

Recent Business Highlights

During and since the fourth quarter of 2020, the company:

- Reported positive preliminary results from the FOCUS Clinical Trial (NCT02678572) for Patients with Hepatic Dominant Ocular Melanoma treated with HEPZATO 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), as determined by an independent review committee, exceeded the prespecified threshold for success. Additionally, both prespecified ORR and Progression Free Survival comparative analyses against 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.

- Initiated a consulting engagement to select a portfolio of follow-on indications which will maximize the value of the HEPZATO Kit and CHEMOSAT platform.

- Completed an underwritten public offering of common stock at a price of $13.25 per share yielding $22.2 million in gross proceeds.

- Strengthened the executive team with the appointment of Gerard Michel as Chief Executive Officer and Kevin Muir as Vice President of Commercial Operations.

“The fourth quarter marked the start of a critical transformation for Delcath,” said Gerard Michel, CEO of Delcath. “Since October, we have attracted new investors, strengthened the management team and, most importantly, released preliminary results from the FOCUS trial which, as of this compilation, suggests a significant improvement in the benefit risk ratio

versus an earlier generation of Delcath's proprietary percutaneous hepatic perfusion system. We look forward to continued progress in 2021, as we prepare both to file an NDA in early 2022 and expand the development of HEPZATO into additional areas of high unmet need."

Fourth Quarter 2020 Financial Results:

Income Statement Highlights.

Product revenue for the three months ended December 31, 2020 was approximately $379 thousand, compared to $398 thousand for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately $4.5 million compared to $2.1 million in the prior year quarter. Research and development expenses for the quarter were $2.7 million compared to $2.7 million in the prior year quarter. Total operating expenses for the quarter were $7.3 million compared with $4.8 million in the prior year quarter.

We recorded a net loss for the three months ended December 31, 2020, of $7.0 million, compared to a net income of $12.5 million for the same period in 2019.

Balance Sheet Highlights.

At December 31, 2020, we had cash, cash equivalents and restricted cash totaling $28.8 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019. During the three months ended December 31, 2020 and December 31, 2019, we used $4.6 million and $5.4 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: March 31, 2021
Time: 8:00 AM Eastern Time
Toll Free: 877-407-8035
International: 201-689-8035

The call will also be available over the Internet and accessible at:
https://www.webcaster4.com/Webcast/Page/2475/40544

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.

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

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 28,575	$ 10,002
Restricted cash	181	181
Accounts receivables, net	57	21
Inventories	855	654
Prepaid expenses and other current assets	2,670	1,759
Total current assets	32,338	12,617
Property, plant and equipment, net	1,351	735
Right-of-use assets	946	860
Total assets	$ 34,635	$ 14,212
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,774	$ 4,533
Accrued expenses	5,241	6,947
Deferred revenue, current	525	482
Lease liabilities, current	495	664
Convertible notes payable, current	2,000	–

Warrant liability	–	3,368
Total current liabilities	10,035	15,994
Deferred revenue, non-current	2,072	2,378
Lease liabilities, non-current	450	197
Convertible notes payable, non-current	–	2,000
Total liabilities	12,557	20,569
Commitments and contingencies (Note 13)		
Stockholders' Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 20,631 and 41,517 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	–	–
Common stock, $.01 par value; 40,000,000 and 1,000,000,000 shares authorized; 5,996,101 and 67,091 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively*	60	1
Additional paid-in capital	417,449	364,785
Accumulated deficit	(395,327)	(371,171)
Accumulated other comprehensive (loss) income	(104)	28
Total stockholders' equity (deficit)	22,078	(6,357)
Total liabilities and stockholders' equity (deficit)	$ 34,635	$ 14,212

* reflects, a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

DELCATH SYSTEMS, INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year ended December 31,	
	2020	**2019**
Product revenue	$ 1,156	$ 1,101
Other revenue	490	479
Cost of goods sold	(640)	(719)
Gross profit	1,006	861
Operating expenses:		
Research and development expenses	11,201	9,490
Selling, general and administrative expenses	11,108	11,279
Total operating expenses	22,309	20,769
Operating loss	(21,303)	(19,908)
Change in fair value of the warrant liability, net	(2,832)	17,493
Loss on issuance of financial instrument	–	(1,720)

Interest expense	(175)	(4,746)
Other income	154	2
Net loss	(24,156)	(8,879)
Deemed dividend for triggering of warrant down round feature	(55)	–
Net loss attributable to common stockholders	$ (24,211)	$ (8,879)
Net loss	$ (24,156)	$ (8,879)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	(132)	$ (22)
Total other comprehensive loss	$ (24,288)	$ (8,901)
Common share data:		
Basic loss per common share*	$ (8.35)	$ (342.83)
Diluted loss per common share*	$ (8.35)	$ (342.83)
Weighted average number of basic shares outstanding*	2,897,827	25,900
Weighted average number of diluted shares outstanding*	2,897,827	25,900

* reflects, one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

Delcath Systems, Inc.
Concentrating the Power of Chemotherapy™