Delcath Systems, Inc. Announces Third Quarter 2020 Results

Conference Call Today at 8:30am Eastern Time

NEW YORK, Nov. 11, 2020 — 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 third quarter ended September 30, 2020.

Recent Business Highlights

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

- Strengthened the executive team with the appointment of Gerard Michel as Chief Executive Officer.
- Announced the conditional acceptance by the FDA of the trade name HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system) for Melphalan/HDS.
- Announced the treatment of the final patient in the FOCUS trial; to date, 91 patients have been treated with a total of 356 treatments.
- Confirmed the expected announcement of topline data in early 2021 and updated the expected NDA submission timing to the first quarter of 2022.
- Provided details that for analytical purposes, the FOCUS trial should demonstrate an overall response rate of at least 21% to show superiority over a meta-analysis of immuno-oncology trials in metastatic ocular melanoma (mOM).
- Held a key opinion leader call with Dr. Mark Burgmans, Head of Interventional Radiology at the Leiden University Medical Center, to discuss the results of a prospective study, published in August 2020 in the Annals of Surgical Oncology, which reported an overall response rate of 72% in patients with metastatic ocular melanoma with metastases confined to the liver. As stated in the publication, treating the patients early in the disease cycle and the exclusion of patients with extra-hepatic disease likely contributed to the favorable outcome observed in this study. Observed safety events were primarily hematological in nature and deemed to be expected and manageable.

“I have joined the Delcath team at an exciting moment in the company’s history as we approach the announcement of the FOCUS trial’s topline results and the evidence continues to build that HEPZATO has the potential to be an important treatment for metastatic ocular melanoma,” said Gerard Michel, CEO of Delcath. “2021 will represent an inflection point for

the company as we execute on four key priorities including compiling the HEPZATO KIT NDA, preparing for commercialization, raising awareness with investors and expanding the development of HEPZATO into additional areas of high unmet need."

Third Quarter 2020 Financial Results:

Income Statement Highlights.

Product revenue for the three months ended September 30, 2020 was approximately $340 thousand, compared to $216 thousand for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately $2.0 million compared to $4.0 million in the prior year quarter. Research and development expenses for the third quarter were $3.3 million compared to $1.8 million in the prior year quarter. Total operating expenses for the third quarter were $5.3 million compared with $5.8 million in the prior year quarter.

We recorded a net loss for the three months ended September 30, 2020, of $5.0 million, compared to a net loss of $7.5 million for the same period in 2019.

Balance Sheet Highlights.

At September 30, 2020, we had cash, cash equivalents and restricted cash totaling $11.1 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019 and $15.5 million at September 30, 2019. During the three months ended September 30, 2020 and September 30, 2019, we used $5.2 million and $12.4 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: November 11, 2020
Time: 8:30 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/2475/38241

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

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 10,899	$ 10,002
Restricted cash	181	181
Accounts receivables, net	103	21
Inventories	839	654
Prepaid expenses and other current assets	1,860	1,759
Total current assets	13,882	12,617
Property, plant and equipment, net	1,318	735
Deferred offering costs	268	–
Right-of-use assets	1,097	860
Total assets	$ 16,565	$ 14,212
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,502	$ 4,533
Accrued expenses	6,085	6,947
Deferred revenue, current	501	482
Lease liabilities, current	556	664

Convertible notes payable, current	2,000	–
Warrant liability	–	3,368
Total current liabilities	10,644	15,994
Deferred revenue, non-current	2,103	2,378
Lease liabilities, non-current	542	197
Convertible notes payable, non-current	–	2,000
Total liabilities	13,289	20,569
Commitments and contingencies (Note 13)	–	–
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 21,473 and 41,517 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	–	–
Common stock, $.01 par value; 1,000,000,000 shares authorized; 4,035,558 and 67,091 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively*	40	1
Additional paid-in capital	391,545	364,785
Accumulated deficit	(388,298)	(371,171)
Accumulated other comprehensive income	(11)	28
Total stockholders' equity (deficit)	3,276	(6,357)
Total liabilities and stockholders' equity (deficit)	$ 16,565	$ 14,212

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

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
Product revenue	$ 340	$ 216	$ 778	$ 528
Other revenue	126	164	361	535
Cost of goods sold	(188)	(172)	(434)	(440)
Gross profit	278	208	705	623
Operating expenses:				
Research and development expenses	3,260	1,778	8,457	6,789
Selling, general and administrative expenses	1,998	4,002	6,571	9,204
Total operating expenses	5,258	5,780	15,028	15,993
Operating loss	(4,980)	(5,572)	(14,323)	(15,370)
Change in fair value of the warrant liability, net	–	434	(2,832)	451
Loss on issuance of financial instrument	–	(1,714)	–	(1,721)
Interest expense	(44)	(671)	(154)	(4,735)
Other income	33	4	182	4
Net loss	(4,991)	(7,519)	(17,127)	(21,371)

Deemed dividend for triggering of warrant down round feature	–	–	(55)	–
Net loss attributable to common stockholders	$ (4,991)	$ (7,519)	$ (17,182)	$ (21,371)
Net loss	$ (4,991)	$ (7,519)	$ (17,127)	$ (21,371)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(103)	89	(39)	39
Total other comprehensive loss	$ (5,094)	$ (7,430)	$ (17,166)	$ (21,332)
Common share data:				
Basic loss per common share*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Diluted loss per common share*	$ (1.16)	$ (73.82)	$ (7.75)	$ (207.58)
Weighted average number of basic shares outstanding*	4,288,593	101,862	2,217,611	102,956
Weighted average number of diluted shares outstanding*	4,288,593	101,862	2,217,611	102,956

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