Delcath Systems Reports Third Quarter 2022 Results and Provides Business Update

November 8, 2022

NEW YORK, Nov. 8, 2022 /PRNewswire/ -- 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, 2022.

Recent Business Highlights

During and since the third quarter, Delcath:

- Confirmed the pending resubmission of the NDA for the Hepzato Kit® (melphalan hydrochloride for injection/Hepatic Delivery System) to the FDA by the end of the year,
- Attracted a growing number of sites to our Expanded Access Program (EAP),
- Strengthened its balance sheet by raising $5 million in a private placement priced at market,
- Reached terms of settlement to end its dispute with medac, its former distributor in Europe, and
- Announced that 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

"We are excited by the level of clinician interest in Hepzato and have enrolled three EAP sites with an additional four sites in process" said Gerard Michel, Chief Executive Officer of Delcath. Mr. Michel added, "We continue to make progress toward the resubmission of the Hepzato Kit NDA by the end of this year, and assuming a six-month review, we consequently would expect a PDUFA date by the end of June 2023."

Third Quarter 2022 Results

Income Statement Highlights.

Total revenue for the three months ended September 30, 2022, was approximately $0.9 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 direct product sales for the third quarter of 2022 compared to the revenue share arrangement with our distribution partner in Europe during the third quarter of 2021.

Research and development expenses for the quarter were $4.0 million, compared to $3.0 million in the prior year quarter. The growth in R&D expense is primarily due to increased activity related to the expenses incurred in preparation for our NDA filing by the end of the year. Selling, general and administrative expenses for the quarter were approximately $4.5 million, compared to $4.0 million in the prior year quarter. The increase in general and administrative expenses was primarily due to the settlement of the medac litigation offset by lower share-based compensation expense.

The Company recorded a net loss for the three months ended September 30, 2022 of $8.5 million, $0.92 per share (basic and diluted), compared to a net loss of $7.1 million, $0.94 per share (basic and diluted), for the same period in 2021.

Balance Sheet Highlights

On September 30, 2022, the Company had cash, cash equivalents and restricted cash totaling $14.0 million, as compared to cash, cash equivalents and restricted cash totaling $27.0 million on December 31, 2021. During the three months ended September 30, 2022, and September 30, 2021, we used $5.2 million and $4.9 million, respectively, of cash in our operating activities.

On July 20, 2022, we closed a private placement for the issuance and sale of 690,954 shares of 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. We received gross proceeds from the Private Placement of approximately $5.0 million before deducting offering expenses.

Conference Call Information

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

Event Date: Tuesday November 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/X9na2DKgekK

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. 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.

Investor Relations Contact:

Ben Shamsian
Lytham Partners
646-829-9701
shamsian@lythampartners.com

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

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 9,831	$ 22,802
Restricted cash	4,151	4,151
Accounts receivable, net	537	44
Inventories	1,926	1,412
Prepaid expenses and other current assets	2,035	2,743
Total current assets	18,480	31,152
Property, plant and equipment, net	1,452	1,348
Right-of-use assets	294	624
Total assets	$ 20,226	$ 33,124
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,632	$ 638
Accrued expenses	5,137	4,109
Deferred revenue	—	170
Lease liabilities, current	196	416
Loan payable, current	6,481	621
Total current liabilities	14,446	5,954
Other liabilities, non-current	1,299	207
Loan payable, non-current	4,990	10,372
Convertible notes payable, non-current	4,737	4,639
Total liabilities	25,472	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 September 30, 2022 and December 31, 2021	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 8,597,682 shares and 7,906,728 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	86	79
Additional paid-in capital	442,066	432,831
Accumulated deficit	(447,341)	(420,976)
Accumulated other comprehensive (loss) income	(57)	18
Total stockholders' equity (deficit)	(5,246)	11,952
Total liabilities and stockholders' equity (deficit)	$ 20,226	$ 33,124

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Product revenue	$ 906	$ 395	$ 1,909	$ 1,054
Other revenue	—	127	171	393

Cost of goods sold	(235)	(227)	(449)	(541)
Gross profit	671	295	1,631	906
Operating expenses:				
Research and development expenses	3,953	2,955	13,649	10,159
Selling, general and administrative expenses	4,519	4,036	12,309	10,621
Total operating expenses	8,472	6,991	25,958	20,780
Operating loss	(7,801)	(6,696)	(24,327)	(19,874)
Interest expense, net	(730)	(420)	(2,040)	(501)
Other income (expense)	26	(9)	2	73
Net loss	(8,505)	(7,125)	(26,365)	(20,302)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(46)	51	(82)	84
Total other comprehensive loss	$ (8,551)	$ (7,074)	$ (26,447)	$ (20,218)
Common share data:				
Basic and diluted loss per common share	$ (0.92)	$ (0.94)	$ (3.09)	$ (2.93)
Weighted average number of basic and diluted shares outstanding	9,215,786	7,587,643	8,536,006	6,923,541

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