Delcath Systems Reports Fourth Quarter and Full Year 2022 Results and Provides Business Update

March 27, 2023

NEW YORK, March 27, 2023 /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 fourth quarter and full year ended December 31, 2022.

Recent Business Highlights

During and since the fourth quarter, Delcath Systems, Inc. (Delcath or the Company):

- Received an acceptance of the NDA resubmission from the U.S. Food and Drug Administration (FDA) for Hepzato Kit® (melphalan hydrochloride for injection/Hepatic Delivery System) with a Prescription Drug User Fee Act (PDUFA) target action date of August 14, 2023,
- Priced a financing that is expected to provide an initial upfront funding of $25 million, with up to an additional $60 million tied to satisfaction of milestones, in gross proceeds to Delcath through a private placement. The financing was led by Vivo Capital with participation from Logos Capital, BVF Partners LP, Stonepine Capital Management, LLC, Serrado Capital LLC and existing investor, Rosalind Advisors,
- Completed in December a private placement with existing investors priced at market for a total of $11.2 million funds raised in 2022,
- Announced the rotation of its Board of Directors with John R. Sylvester appointed as Chairman, and
- Reached terms of settlement to end its dispute with medac, its former distributor in Europe.

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

- Updated results from the CHOPIN phase 1B trial in which seven patients with advanced uveal melanoma treated with CHEMOSAT and ipilimumab plus nivolumab show a median PFS of 29.1 months at a median follow-up of 29.1 months, and
- Results of a Single Center Study in the treatment of Cholangiocarcinoma (CCA) in which the authors concluded that percutaneous hepatic perfusion (PHP) with CHEMOSAT is an effective and safe treatment option for patients with advanced CCA and has the potential to prolong life in patients with inoperable, treatment-refractory liver metastases. The authors highlighted the increasing importance of locoregional forms of therapy in the treatment of CCA and that the new edition of the German S3 cancer guideline "Diagnostics and Therapy of Hepatocellular Carcinoma and Biliary Carcinomas" now includes PHP with melphalan for the treatment of inoperable iCCA or eCCA liver metastases.

"With the FDA setting an August 14, 2023, PDUFA date we have crossed a significant milestone for the Company." said Gerard Michel, Chief Executive Officer of Delcath. Mr. Michel added, "We are gratified with the support from both our existing investors and our new investors, all of whom are highly regarded healthcare-focused funds. Their support, potentially totaling up to

$85 million, subject to satisfaction of milestones, we believe validates the clinical relevance of and the commercial opportunity for Hepzato in metastatic ocular melanoma. Further, it positions Delcath to execute on HEPZATO commercialization plans upon potential FDA approval. Finally, we eagerly await the publication of interim results from the phase II portion of the CHOPIN study which should provide critical additional information about the potential utility of CHEMOSAT used in sequence with immune checkpoint inhibitors."

Income Statement Highlights.

Fourth Quarter 2022 Results

Product revenue for the three months ended December 31, 2022 was approximately $0.6 million, compared to $0.2 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 fourth quarter of 2022 compared to the revenue share arrangement with our distribution partner in Europe during the fourth quarter of 2021. Other income for the three months ended December 31, 2022 was $1.9 million due to the acceleration of deferred revenue caused by the termination of the medac license agreement.

Research and development expenses for the three months ended December 31, 2022 were $4.4 million, compared to $3.6 million in the prior year quarter. The growth in R&D expense is primarily due to increased activity related to the expenses incurred for the preparation of our NDA resubmission which occurred on February 14, 2023. Selling, general and administrative expenses for the three months ended December 31, 2022 were approximately $3.8 million, compared to $3.0 million in the prior year quarter. The increase in general and administrative expenses was primarily due to higher headcount related costs such as higher share-based compensation expense.

The Company recorded a net loss for the three months ended December 31, 2022 of $8.5 million, $0.86 per share (basic and diluted), compared to a net loss of $5.3 million, $0.69 per share (basic and diluted), for the same period in 2021.

Full Year 2022 Results

Product revenue for the year ended December 31, 2022 was approximately $2.5 million, compared to $1.3 million for the prior year from sales of CHEMOSAT in Europe. Other income for the year ended December 31, 2022 was $0.2 million compared to $2.3 million in the prior year primarily due to the termination of the medac license agreement in December last year.

Research and development expenses for the year ended December 31, 2022 were $18.6 million compared to $13.8 million in the prior year with the increase due to preparation for the pre-NDA meeting in April 2022 and expenses related to the NDA resubmission. Selling, general and administrative expenses for the year ended December 31, 2022 were approximately $17.3 million compared to $13.6 million in the prior year with the increase primarily due to the pending launch of HEPZATO in the United States and the accrual for the settlement of the medac litigation.

The Company recorded a net loss for the year ended December 31, 2022, of $36.5 million, $4.12 per share (basic and diluted), compared to a net loss of $25.6 million $3.59 per share (basic and diluted) for the year ended December 31, 2021.

Balance Sheet Highlights

On December 31, 2022, the Company had cash, cash equivalents and restricted cash totaling $11.8 million, as compared to cash, cash equivalents and restricted cash totaling $26.9 million on December 31, 2021. During the years ended December 31, 2022, and December 31, 2021, the Company used $25.0 million and $22.6 million, respectively, of cash in our operating activities. The use of cash in operating activities was partially offset by two private placements during 2022 resulting in net proceeds of $10.9 million. On March 15, 2023, the Company returned to Avenue Venture Opportunity Fund L.P. the $4.0 million held in the restricted cash to paydown a portion of the outstanding loan balance.

On December 13, 2022, the Company closed a private placement for the issuance and sale of 1,448,889 shares of common stock and 692,042 pre-funded warrants to purchase common stock to certain investors. Each share of common stock was sold at a price per share of $2.90 and the pre-funded warrants were sold at a price of $2.89 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.01 per share of common stock and are immediately exercisable. The Company received gross proceeds from the private placement of approximately $6.2 million before deducting offering expenses.

Conference Call Information

Delcath will host a conference call today, on March 27, 2023, at 4:30 PM Eastern Time to discuss results for its fourth quarter and full year ended December 31, 2022 and provide a business update.

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

Event Date: Monday March 27, 2023

Time: 4:30 PM Eastern Time

Participant Numbers: Toll Free: 1-833-630-1960
International: 1-412-317-1841

Webcast: https://app.webinar.net/RQwvVK8NyzM

CONFERENCE REPLAY

US Toll Free: 1-877-344-7529

International Toll: 1-412-317-0088

Replay Access Code: 7305121

End Date: April 03, 2023

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 (melphalan hydrochloride 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 an investigational drug/device combination product regulated as a drug by the United States Food and Drug Administration (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). The FDA has established an August 14, 2023 PDUFA target action 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: achievement of milestones, the likelihood and timing of the FDA's potential approval of the NDA for HEPZATO by the FDA by the PDUFA date of August 14, 2023, the Company's ability to commercialize HEPZATO, the receipt of stockholder approval to allow for the conversion of the Series F Preferred Stock into shares of the Company's common stock; 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 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
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		

Current assets		
	$	$
Cash and cash equivalents	7,671	22,802
Restricted cash	4,151	4,151
Accounts receivable, net	366	44
Inventories	1,998	1,412
Prepaid expenses and other current assets	1,969	2,743
Total current assets	16,155	31,152
Property, plant and equipment, net	1,422	1,348
Right-of-use assets	285	624
	$	$
Total assets	17,862	33,124
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
	$	$
Accounts payable	2,018	638
Accrued expenses	4,685	4,109
Deferred revenue	—	170
Lease liabilities, current	186	416
Loan payable, current	7,846	621
Total current liabilities	14,735	5,954
Other liabilities, non-current	1,144	207
Loan payable, non-current	3,070	10,372
Convertible notes payable, non-current	4,772	4,639
Total liabilities	23,721	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 December 31, 2022 and 2021	—	—
Common stock, $.01 par value; 40,000,000 shares authorized; 10,046,571 shares and 7,906,728 shares issued and outstanding at December 31, 2022 and 2021, respectively	100	79
Additional paid-in capital	451,608	432,831
Accumulated deficit	(457,484)	(420,976)
Accumulated other comprehensive (loss) income	(83)	18
Total stockholders' equity (deficit)	(5,859)	11,952
	$	$
Total liabilities and stockholders' equity (deficit)	17,862	33,124

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands)

	Three months ended December 31,		Year ended December 31,	
	2022	**2021**	**2022**	**2021**
Product revenue	$ 639	$ 246	$ 2,548	$ 1,300
Other revenue	—	1,862	171	2,255
Total revenues	639	2,108	2,719	3,555
Cost of goods sold	(237)	(130)	(686)	(671)
Gross profit	402	1,978	2,033	2,884
Operating expenses:				

Research and development expenses	4,431	3,619	18,583	13,778
Selling, general and administrative expenses	3,826	3,017	17,303	13,637
Total operating expenses	8,257	6,636	35,886	27,415
Operating loss	(7,855)	(4,658)	(33,853)	(24,531)
Interest expense, net	(646)	(683)	(2,685)	(1,186)
Other income	29	(6)	30	68
Net loss	(8,472)	(5,347)	(36,508)	(25,649)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(27)	45	101	122
Total other comprehensive loss	$ (8,499)	$ (5,302)	$ (36,407)	$ (25,527)
Common share data:				
Basic and diluted loss per common share	$ (0.86)	$ (0.69)	$ (4.12)	$ (3.59)
Weighted average number of basic and diluted shares outstanding	9,871,669	7,797,357	8,864,615	7,145,754

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