Delcath Systems Reports Third Quarter 2023 Results and Provides Business Update

November 13, 2023

NEW YORK, Nov. 13, 2023 /PRNewswire/ -- 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 third quarter ended September 30, 2023.

Recent Business Highlights

- Received approval from the US Food and Drug Administration (FDA) for HEPZATO KIT™ (melphalan)/Hepatic Delivery System) as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation;
- Raised approximately $35 million through the exercise of all the Tranche A warrants issued as part the previously announced March 29, 2023, financing with up to an additional $25 million available upon the achievement of $10 million in quarterly revenue;
- Announced publication by independent investigators of a retrospective comparative study of CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP) and Selective Internal Radiation Therapy (SIRT) citing a statistically significant difference in median overall survival with 301 days for SIRT and 516 days for PHP;
- Announced that independent investigators at Leiden University recruited 55 of 76 planned patients in the CHOPIN trial studying the impact of CHEMOSAT and immune checkpoint inhibitor combination therapy in the treatment of metastatic uveal melanoma and expect the trial to be fully enrolled mid-2024. An interim futility analysis conducted in September resulted in the independent data monitoring committee recommending continuing the study without modification; and
- Partnered with seven clinical treatment sites to satisfy the initial training requirements to be able to treat their first commercial patient, subject to proctor availability and the sites' value analysis committee approvals, upon the planned launch in January.

"The Company has been preparing for a January launch of HEPZATO KIT by building our commercial team and engaging with potential treating centers," said Gerard Michel, Chief Executive Officer of Delcath. Mr. Michel added, "We have been encouraged by the reception that HEPZATO KIT has received from the medical oncologist community and are confident that by the end of 2024 at least 15 centers will be actively treating metastatic uveal melanoma patients with HEPZATO KIT."

Third Quarter 2023 Results

Total revenue for the three months ended September 30, 2023, was approximately $0.4 million, compared to $0.9 million for the prior year period, from our sales of CHEMOSAT in Europe.

Research and development expenses for the quarter were $4.7 million, compared to $4.1 million in the prior year quarter. The increase in R&D expense is primarily due to completing clinical trial activities and expenses related to the FDA inspection and other requests in advance of the approval received for HEPZATO.

Selling, general and administrative expenses for the quarter increased to $6.2 million, compared to $4.8 million in the prior year quarter primarily relating to activities to prepare for a commercial launch. The increase in fair value warrant liability adjustment during the quarter ended September 20, 20223 was a result of our final valuation for the Tranche A warrants exercised and outstanding Tranche B warrants.

About Delcath Systems, Inc., CHEMOSAT and HEPZATO KIT

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 and approved for sale 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. HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

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 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 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; 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 40,462	$ 7,671
Restricted cash	50	4,151
Accounts receivable, net	205	366
Inventory	2,667	1,998
Prepaid expenses and other current assets	2,712	1,969
Total current assets	46,096	16,155
Property, plant and equipment, net	1,374	1,422
Right-of-use assets	107	285
Total assets	$ 47,577	$ 17,862
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 753	$ 2,018
Accrued expenses	5,230	4,685
Lease liabilities, current	35	186
Loan payable, current	5,080	7,846
Convertible notes payable, current	2,876	—
Total current liabilities	13,974	14,735
Warrant liability	5,773	—
Other liabilities, non-current	1,111	1,144
Loan payable, non-current	—	3,070
Convertible notes payable, non-current	2,000	4,772
Total liabilities	22,858	23,721
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 37,787 and 11,357 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—

Common stock, $.01 par value; 80,000,000 shares authorized; 19,688,991 shares and 10,046,571 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	197	100
Additional paid-in capital	518,607	451,608
Accumulated deficit	(494,026)	(457,484)
Accumulated other comprehensive loss	(59)	(83)
Total stockholders' equity (deficit)	24,719	(5,859)
Total liabilities and stockholders' equity	$ 47,577	$ 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 September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Product revenue	$ 434	$ 906	$ 1,526	$ 1,909
Other revenue	—	—	—	171
Total revenues	434	906	1,526	2,080
Cost of goods sold	(133)	(235)	(464)	(449)
Gross profit	301	671	1,062	1,631
Operating expenses:				
Research and development expenses	4,662	4,065	12,793	14,152
Selling, general and administrative expenses	6,195	4,779	15,147	13,477
Total operating expenses	10,857	8,844	27,940	27,629
Operating loss	(10,556)	(8,173)	(26,878)	(25,998)
Change in fair value of warrant liability	(9,384)	—	(8,224)	—
Interest expense, net	(395)	(730)	(1,454)	(2,040)
Other income (expense)	(5)	26	14	2
Net loss	(20,340)	(8,877)	(36,542)	(28,036)
Other comprehensive income:				
Foreign currency translation adjustments	5	(46)	24	(82)
Total other comprehensive loss	$ (20,335)	$ (8,923)	$ (36,518)	$ (28,118)
Common share data:				
Basic and diluted loss per common share	$ (1.14)	$ (0.96)	$ (2.61)	$ (3.29)
Weighted average number of basic and diluted shares outstanding	17,863,078	9,215,786	13,985,248	8,536,006

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