Delcath Systems Reports Fourth Quarter and Full Year 2023 Results and Provides Business Update

March 26, 2024

Increases 2024 Treatment Site Activation Guidance to 20 Sites

QUEENSBURY, N.Y., March 26, 2024 /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 recent business highlights and financial results for the fourth quarter and full year ended December 31, 2023.

Recent Business Highlights
During and since the fourth quarter, Delcath:

- Announced the first commercial use of HEPZATO KIT™ for the treatment of metastatic uveal melanoma (mUM) at Moffitt Cancer Center;
- Activated three treating sites which are fully trained to treat commercial patients with a fourth expected to be active before the end of the first quarter and an additional three sites expected to become active in the first few weeks of the second quarter of 2024;
- Updated site activation guidance from 15 active sites to a total of 20 active sites by the end of 2024;
- Received notification that a permanent, product-specific J-code (J9248) and transitional pass-through payment status for HEPZATO, was established by the Centers for Medicare & Medicaid Services (CMS) and will become effective on April 1, 2024;
- Finalized its patient access program and launched websites relating to the HEPZATO KIT, including HEPZATOKIT.com, HEPZATOKITREMS.com, and HEPZATOKITACCESS.com, to support the commercial launch;
- Raised $7.0 million in a private placement transaction with certain accredited investors comprised of existing investors, Delcath senior executives, and members of its Board of Directors;
- Appointed Martha S. Rook, Ph.D as Chief Operating Officer on March 18, 2024. Ms. Rook is an experienced industry leader who brings more than 25 years of academic and industry experience in molecular biology, diagnostics development, biologics process development and combination products manufacturing; and
- 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; and
    - A clinical study entitled "Quality of Life After Melphalan Hepatic Perfusion for Uveal Melanoma" in which the authors concluded utilizing Delcath's CHEMOSAT to administer high-dose melphalan to the liver is well tolerated by patients and does not negatively affect their quality of life.

"We have made tremendous progress since the January launch of HEPZATO KIT in the US," said Gerard Michel, Delcath's Chief Executive Officer. "We have successfully secured a product specific J-Code and, with over 90 preceptorships completed by healthcare professionals across approximately 20 institutions in the US, are on track to train and activate 20 sites by year end. Furthermore, we have strengthened our balance sheet with additional investment from senior management and existing investors. I am proud of the team's success in providing access to a new treatment for patients suffering from metastatic uveal melanoma."

Fourth Quarter and Full Year 2023 Results
Cash, cash equivalents and investment totaled $32.5 million as of December 31, 2023. Subsequent to year-end, on March 19, 2024, the company closed a $7.0 million private placement financing.

Total revenue for the quarter and year-ended December 31, 2023, was approximately $0.5 million and $2.1 million, respectively, compared to $0.6 million and $2.7 million for the same periods in the prior year, respectively, from our sales of CHEMOSAT in Europe.

Research and development expenses for the quarter and year-ended December 31, 2023, were $4.7 million and $17.5 million, respectively, compared to $4.4 and $18.6 million, respectively, for the same periods in the prior year. The change in research and development expenses is primarily due to a decrease in clinical trial activities and expenses related to the FDA inspection offset by an increase in personnel related expenses.

Selling, general and administrative expenses for the quarter and year-ended December 31, 2023, increased to $7.0 million and $22.1 million, respectively, compared to $3.8 million and $17.3 million, respectively for the same periods in the prior year. The increase primarily relates to activities to prepare for a commercial launch including marketing-related expenses and additional personnel in the commercial team.

About Delcath Systems, Inc., HEPZATO KIT and CHEMOSAT
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 press release contains forward-looking statements, which are subject to certain risks and uncertainties, that can cause actual results to differ materially from those described. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; the Company's successful management of the HEPZATO KIT supply chain, including securing adequate supply of critical components necessary to manufacture and assemble the HEPZATO KIT; successful FDA inspections of the facilities of the Company and those of its third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential benefits of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; the Company's ability to obtain reimbursement for the HEPZATO KIT; and the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT. For additional information about these factors, and others that may impact the Company, please see the Company's filings with the Securities and Exchange Commission, including those on Forms 10-K, 10-Q, and 8-K. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, 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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Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
	$	$
Cash and cash equivalents	12,646	7,671
Restricted cash	50	4,151
Short-term investments	19,808	—
Accounts receivable, net	241	366
Inventories	3,322	1,998
Prepaid expenses and other current assets	1,091	1,969
Total current assets	37,158	16,155
Property, plant and equipment, net	1,352	1,422
Right-of-use assets	103	285
	$	$
Total assets	38,613	17,862
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
	$	$
Accounts payable	1,012	2,018
Accrued expenses	5,249	4,685
Lease liabilities, current	37	186
Loan payable, current	5,239	7,846
Convertible notes payable, current	4,911	—
Total current liabilities	16,448	14,735
Warrant Liability	5,548	—
Other liabilities, non-current	840	1,144
Loan payable, non-current	—	3,070
Convertible notes payable, non-current	—	4,772
Total liabilities	22,836	23,721
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 24,819 and 11,357 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, $.01 par value; 80,000,000 shares authorized; 22,761,554 shares and 10,046,571 shares issued and outstanding at December 31, 2023 and 2022, respectively	228	100
Additional paid-in capital	520,576	451,608
Accumulated deficit	(505,162)	(457,484)
Accumulated other comprehensive income (loss)	135	(83)
Total stockholders' equity (deficit)	15,777	(5,859)
	$	$
Total liabilities and stockholders' equity	38,613	17,862

DELCATH SYSTEMS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Product revenue	$ 539	$ 639	$ 2,065	$ 2,548
Other revenue	—	—	—	171

Total revenues	539	639	2,065	2,719
Cost of goods sold	(171)	(237)	(635)	(686)
Gross profit	368	402	1,430	2,033
Operating expenses:				
Research and development expenses	4,709	4,431	17,502	18,583
Selling, general and administrative expenses	6,963	3,826	22,110	17,303
Total operating expenses	11,672	8,257	39,612	35,886
Operating loss	(11,304)	(7,855)	(38,182)	(33,853)
Change in fair value of warrant liability	226	—	(7,998)	—
Interest income (expense), net	15	(645)	(1,439)	(2,685)
Other income (expense)	(73)	28	(59)	30
Net loss	(11,136)	(8,472)	(47,678)	(36,508)
Other comprehensive income:				
Unrealized gain (loss) on investments	157	—	157	—
Foreign currency translation adjustments	37	(19)	61	101
Total other comprehensive loss	$ (10,942)	$ (8,491)	$ (47,460)	$ (36,407)
Common share data:				
Basic and diluted loss per common share	$ (0.48)	$ (0.86)	$ (2.94)	$ (4.12)
Weighted average number of basic and diluted shares outstanding	23,088,685	9,871,669	16,229,931	8,864,615

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