Delcath Systems Reports Third Quarter 2024 Results and Business Highlights

November 8, 2024

Conference Call Today at 8:30 a.m. Eastern Time

QUEENSBURY, N.Y.--(BUSINESS WIRE)--Nov. 8, 2024-- 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 financial results and business highlights for the third quarter ended September 30, 2024.

Third Quarter and Recent Business Highlights

- Total third quarter revenues of $11.2 million, up 44% from the prior quarter, including $10.0 million from HEPZATO KIT™ (melphalan/Hepatic Delivery System) and $1.2 million from CHEMOSAT®;
- Activated four HEPZATO treatment centers in the U.S. during the third quarter and one more in October, bringing the total to twelve active centers; another center has scheduled their first treatment in November with a further 10 centers having partially or fully completed preceptorship training;
- Reported that CHOPIN, an investigator-initiated study which is evaluating the effect of sequencing immunotherapy with CHEMOSAT liver directed therapy, is now fully enrolled with 76 patients;
- Ended the third quarter with cash and investments of $14.0 million with quarterly cash burn of $3.6 million; and
- Subsequent to September 30, 2024:
    - Submitted the final principal and interest payments of $2.8 million on the Rosalind note payable and as a result have no outstanding debt obligations; and
    - All remaining Tranche B warrants from the March 29, 2023 PIPE were exercised by the November 6, 2024 expiration date resulting in approximately $25 million in proceeds.

“We are pleased with HEPZATO's robust market adoption in the U.S., a testament to its clinical impact and the confidence physicians are showing in its use,” said Gerard Michel, Delcath’s Chief Executive Officer. “Given our strong balance sheet and consistent revenue growth, which puts us on the cusp of profitability, Delcath is in a solid position to expand our development pipeline. Based on broad interest from oncology leaders, we are advancing programs for the use of HEPZATO in liver dominant colorectal and breast cancers.”

Recent Publications

- Presented subgroup analyses data from the FOCUS Phase 3 trial of HEPZATO at ESMO 2024, demonstrating similar outcomes in overall survival, overall response rate, and progression free survival between patients with and without extrahepatic lesions or based on prior therapy. In addition, tumor responses were observed throughout the entire treatment period supporting the strategy to continue treatment until best response is achieved;
- Announced multiple independent investigator-sponsored retrospective studies of HEPZATO and CHEMOSAT:
    - A 30-patient study published in the Annals of Surgical Oncology by researchers at Moffitt Cancer Center in Tampa, Florida. The study reported that HEPZATO used in first- or second-line therapy for metastatic uveal melanoma provided better disease control in the liver and improved progression-free survival compared to both immunotherapy and other liver-directed therapies;
    - A 167-patient study published in the journal Therapeutic Advances in Medical Oncology by investigators from the University of Tübingen, Germany. The study reported that first-line liver-directed therapies, including CHEMOSAT, significantly improve melanoma-specific survival in patients with liver metastases from uveal melanoma, compared to first-line systemic therapies; and
    - A study published in the ESMO journal of Gastrointestinal Oncology by researchers from the University Hospital of Leipzig reporting the results of 33 patients treated with CHEMOSAT. The study included previously treated patients with unresectable intrahepatic metastases from seven different cancer types and reported a hepatic disease control rate of 91% with six patients (18.2%) achieving complete response in the liver. Median hepatic progression-free survival was 52 weeks across all patients.

Third Quarter 2024 Results

Total revenue for the quarter ended September 30, 2024 was $11.2 million compared to $0.4 million for the same period in the prior year. Revenue includes sales of $10.0 million of HEPZATO in the U.S. and $1.2 million of CHEMOSAT in Europe.

Research and development expenses for the quarter ended September 30, 2024, were $3.9 million compared to $4.7 million for the same period in the prior year. The change in research and development expenses is primarily due to lower costs associated with expanded access protocol incurred in previous periods offset by an increase in medical affairs and regulatory costs associated with an approved product.

Selling, general and administrative expenses for the quarter ended September 30, 2024, were $7.0 million compared to $6.2 million for the same period in the prior year. The increase primarily relates to commercial launch activities including marketing-related expenses and additional personnel in the commercial team.

The Company submitted the final principal payment due to Avenue Venture Opportunities Fund, L.P. on August 1, 2024 for the Loan and Security Agreement entered into in August 2021. As of September 30, 2024 our cash and investments totaled $14.0 million.

Subsequent to the end of the third quarter, we submitted the final principal and interest payment of $2.8 million on the outstanding Rosalind note payable and received approximately $25 million in proceeds from the exercise of Tranche B Warrants from the previous March 29, 2023 PIPE. Currently, there are no outstanding debt obligations.

Conference Call Information

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

Event Date:	Friday, November 8, 2024
Time:	8:30 AM Eastern Time

Participant Numbers

Toll Free:	1-877-407-3982
International:	1-201-493-6780
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1691899&tp_key=9d94cb0736

A replay of the webinar will be available shortly after the conclusion of the call and will be archived on the company's website: https://delcath.com/investors/events-presentations/

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 isolate the hepatic venous blood from the systemic circulation 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.

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

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 8,315	$ 12,646
Restricted cash	—	50
Short-term investments	5,677	19,808
Accounts receivable, net	6,936	241
Inventory	6,642	3,322
Prepaid expenses and other current assets	1,312	1,091
Total current assets	28,882	37,158
Property, plant and equipment, net	1,729	1,352
Right-of-use assets	1,070	103
Total assets	$ 31,681	$ 38,613
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 937	$ 1,012
Accrued expenses	5,706	5,249
Lease liabilities, current	107	37
Loan payable	—	5,239
Convertible notes payable	2,000	4,911
Warrant liability - current	12,834	—
Total current liabilities	21,584	16,448
Warrant liability, non-current	—	5,548
Lease Liabilities, non-current	963	—
Other liabilities, non-current	563	840
Total liabilities	$ 23,110	$ 22,836
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 12,342 and 24,819 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 28,019,599 shares and 22,761,554 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	280	228
Additional paid-in capital	536,430	520,576
Accumulated deficit	(528,150)	(505,162)
Accumulated other comprehensive income	11	135
Total stockholders' equity	8,571	15,777
Total liabilities and stockholders' equity	$ 31,681	$ 38,613

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,	
	2024	**2023**	**2024**	**2023**
Product revenue	$ 11,200	$ 434	$ 22,105	$ 1,526
Cost of goods sold	(1,640)	(133)	(4,062)	(464)
Gross profit	9,560	301	18,043	1,062
Operating expenses:				
Research and development expenses	3,866	4,662	10,960	12,793
Selling, general and administrative expenses	6,953	6,195	22,532	15,147
Total operating expenses	10,819	10,857	33,492	27,940
Operating loss	(1,259)	(10,556)	(15,449)	(26,878)
Change in fair value of warrant liability	2,975	(9,384)	(7,392)	(8,224)
Interest expense, net	113	(395)	(170)	(1,454)
Other (expense) income	35	(5)	23	$ 14
Net income (loss)	1,864	(20,340)	(22,988)	(36,542)
Other comprehensive (loss) income:				
Unrealized gain (loss) on investments	(14)	—	(147)	—
Foreign currency translation adjustments	17	5	23	24
Total comprehensive income (loss)	$ 1,867	$ (20,335)	$ (23,112)	$ (36,518)
Common share data:				
Basic income (loss) per common share	$ 0.06	$ (1.14)	$ (0.84)	$ (2.61)
Weighted average number of basic shares outstanding	28,738,307	17,863,078	27,335,212	13,985,248
Diluted income (loss) per common share	$ 0.06	$ (1.14)	$ (0.84)	$ (2.61)
Weighted average number of dilutive shares outstanding	32,345,672	17,863,078	27,335,212	13,985,248

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