Delcath Systems Reports Fourth Quarter and Full-Year 2021 Results and Provides Business Update

NEW YORK, March 25, 2022 — 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, 2021.

Recent Business Highlights

During and since the fourth quarter, Delcath:

- Reported updated positive phase 3 FOCUS trial results for HEPZATO™ Kit (melphalan hydrochloride for injection/hepatic delivery system) for the treatment of patients with unresectable liver-dominant metastatic ocular melanoma, including initial survival data analysis
- Confirmed guidance for the mid-year Class 2 resubmission of the NDA to FDA
- Resumed direct responsibility for sales, marketing, and distribution activities for the CHEMOSAT® Hepatic Delivery System in all of Europe
- Achieved medical device regulation certification for CHEMOSAT® in Europe
- Appointed David Hoffman as General Counsel and Chief Compliance Officer and Anthony Dias as Vice President of Finance

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

- *Repeated percutaneous hepatic perfusion with melphalan can maintain long-term response in patients with liver cancers* in the journal Cardiovascular and Interventional Radiology[1]
- *Chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma* in the journal Melanoma Research[2]
- *Percutaneous Hepatic Perfusion (PHP) with Melphalan in Liver-Dominant Metastatic Uveal Melanoma: The German Experience* in the journal Cancers[3]
- *Initiation of Chemosaturation with Percutaneous Hepatic Perfusion Program in*

Interventional Radiology Department in the journal Cureus[4]

“Since the end of the third quarter, we have updated our previously reported positive phase 3 data with survival data, resumed direct sales of CHEMOSAT in Europe, and strengthened our leadership team,” said Gerard Michel, CEO of Delcath. “Each of these achievements support our strategic priorities – filing of the HEPZATO NDA in mid-2022, preparing for the subsequent US launch when approved, and expanding the development of HEPZATO and CHEMOSAT into additional areas of high unmet need. We look forward to a pre-NDA meeting with FDA in the coming weeks.”

Fourth Quarter 2021 Results

Income Statement Highlights.

Product revenue for the three months ended December 31, 2021, was approximately $0.2 million, compared to $0.4 million for the prior year quarter from sales of CHEMOSAT in Europe. Other income for the quarter was $1.9 million compared to $0.1 million in the prior year quarter with the increase primarily due to the acceleration of deferred revenue caused by the termination of the medac license agreement. Research and development expenses for the quarter were $3.6 million compared to $2.7 million in the prior year quarter. Selling, general and administrative expenses for the quarter were approximately $3.0 million compared to $4.5 million in the prior year quarter. Total operating expenses for the quarter were $6.6 million compared with $7.3 million in the prior year quarter. Expenses for the quarter included approximately $1.6 million of stock option expense compared to $3.5 million in the prior year quarter.

The Company recorded a net loss for the three months ended December 31, 2021, of $5.3 million, compared to a net loss of $7.0 million for the same period in 2020.

Full-Year 2021 Results

Product revenue for the year ended December 31, 2021, was approximately $1.3 million, compared to $1.2 million for the prior year from sales of CHEMOSAT in Europe. Other income for the year was $2.2 million compared to $0.5 million in the prior year with the increase primarily due to the acceleration of deferred revenue caused by the termination of the medac license agreement. Research and development expenses for the year were $13.8 million compared to $11.2 million in the prior year. Selling, general and administrative expenses for the year were approximately $13.6 million compared to $11.2 million in the prior year. Total operating expenses for the year were $27.4 million compared with $22.3 million in the prior year. Expenses for the year included approximately $7.8 million of stock option expense compared to $3.9 million in the prior year.

The Company recorded a net loss for the year ended December 31, 2021, of $25.6 million, compared to a net loss of $24.2 million for the year ended December 31, 2020.

Balance Sheet Highlights.

On December 31, 2021, the company had cash, cash equivalents and restricted cash totaling $27.0 million, as compared to cash, cash equivalents and restricted cash totaling $28.7 million on December 31, 2020. During the three months ended December 31, 2021 and December 31, 2020, we used $6.4 million and $5.0 million, respectively, of cash in our operating activities.

Conference Call Information

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

Date: March 25, 2021
Time: 8:30 AM Eastern Time
Toll Free: 888-506-0062; Entry Code: 938572
International: 973-528-0011; Entry Code: 938572
Webcast: https://www.webcaster4.com/Webcast/Page/2475/44898

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 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.

1. Veelken R, Maiwald B, Strocka S, Petersen TO, Moche M, Ebel S, Denecke T, Rehak M, Struck MF, Forstmeyer D, Rademacher S, Seehofer D, Berg T, van Bömmel F. Repeated percutaneous hepatic perfusion with melphalan can maintain long-term response in patients with liver cancers. Cardiovasc Intervent Radiol. 2021 Oct 29. doi: 10.1007/s00270-021-02983-2. Epub ahead of print.

2. Modi S, Gibson T, Vigneswaran G, Patel S, Wheater M, Karydis I, Gupta S, Takhar A, Pearce N, Ottensmeier C, Stedman B. Chemosaturation with percutaneous hepatic perfusion of melphalan for metastatic uveal melanoma. Melanoma research. 2022 Feb 2;32(2):103-11.

3. Dewald CLA, Warnke MM, Brüning R, Schneider MA, Wohlmuth P, Hinrichs JB,

Saborowski A, Vogel A, Wacker FK. Percutaneous Hepatic Perfusion (PHP) with Melphalan in Liver-Dominant Metastatic Uveal Melanoma: The German Experience. Cancers 2022, 14, 118. https://doi.org/10.3390/cancers14010118.

4. Öcal O, Eldem G, Karagoz AH, Kılıçkap S, Yalcin S, Balkanci F, Peynircioglu B. Initiation of Chemosaturation With Percutaneous Hepatic Perfusion Program in Interventional Radiology Department. Cureus 13(9): e17880. doi:10.7759/cureus.17880.

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

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 22,802	$ 28,575
Restricted cash	4,151	181
Accounts receivable, net	44	57
Inventories	1,412	855
Prepaid expenses and other current assets	2,743	2,670
Total current assets	31,152	32,338
Property, plant and equipment, net	1,348	1,351
Right-of-use assets	624	946
Total assets	$ 33,124	$ 34,635
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 638	$ 1,774
Accrued expenses	4,109	5,241
Deferred revenue, current	170	525
Lease liabilities, current	416	495
Loan payable, current	621	–

Convertible notes payable, current	–	2,000
Total current liabilities	5,954	10,035
Deferred revenue, non-current	–	2,072
Lease liabilities, non-current	207	450
Loan payable, non-current	10,372	–
Convertible notes payable, non-current	4,639	–
Total liabilities	21,172	12,557
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 11,357 and 20,631 shares issued and outstanding at December 31, 2021 and 2020, respectively	–	–
Common stock, $.01 par value; 40,000,000 shares authorized; 7,906,728 and 5,996,101 shares issued and outstanding at December 31, 2021 and 2020, respectively	79	60
Additional paid-in capital	432,831	417,449
Accumulated deficit	(420,976)	(395,327)
Accumulated other comprehensive loss	18	(104)
Total stockholders' equity	11,952	22,078
Total liabilities and stockholders' equity	$ 33,124	$ 34,635

DELCATH SYSTEMS, INC.

Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited, in thousands, except share and per share data)

	For the Year December 31,		For the Three Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
Product revenue	$ 1,300	$ 1,156	$ 246	$ 379
Other revenue	2,255	490	1,862	129
Cost of goods sold	(671)	(640)	(130)	(206)
Gross profit	2,884	1,006	1,977	301
Operating expenses:				
Research and development expenses	13,778	11,201	3,619	2,744
Selling, general and administrative expenses	13,637	11,108	3,017	4,537
Total operating expenses	27,415	22,309	6,636	7,281
Operating loss	(24,531)	(21,303)	(4,658)	(6,980)
Change in fair value of the warrant liability, net	–	(2,832)	–	–
Interest expense, net	(1,186)	(175)	(684)	(43)
Other income, net	68	154	(6)	(6)
Net loss	(25,649)	(24,156)	(5,348)	(7,029)
				–

Deemed dividend for triggering of warrant down round feature	–	(55)	–	–
Net loss attributable to common stockholders	$ (25,649)	$ (24,211)	$ (5,348)	$ (7,029)
				–
Net loss	$ (25,649)	$ (24,156)	$ (5,348)	$ (7,029)
				–
Other comprehensive income (loss):				–
Foreign currency translation adjustments	122	(132)	37	(93)
Total other comprehensive loss	$ (25,527)	$ (24,288)	$ (5,311)	$ (7,122)
				–
Common share data:				–
Basic and diluted loss per common share	$ (3.59)	$ (8.35)	$ (0.69)	$ (1.66)
			–	–
Weighted average number of basic and diluted shares outstanding	7,145,754	2,897,827	7,797,357	4,223,687