Delcath Announces First Quarter 2020 Results

Highlights include $22 million public offering, uplisting to Nasdaq, Pivotal Registration Trial enrollment completed, and Pivotal Registration Topline Data Expected in 2020

NEW YORK, May 15, 2020 — Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of rare primary and metastatic cancers of the liver, announces financial results for the quarter ended March 31, 2020.

Highlights

- Completed $22.0 million public offering
- Uplisted to the Nasdaq Capital Market
- Completed enrollment of our Registration Pivotal Trial (FOCUS) investigating Melphalan/HDS in the treatment of patients with unresectable hepatic-dominant ocular melanoma (mOM)
- Elizabeth Czerepak, Steven Salamon and Gilad Aharon joined our board of directors

Milestone Expectations

- Topline data from FOCUS registration trial expected before the end of this year despite COVID-19 impacts
- FDA NDA submission for mOM expected in 2021

“First quarter and year to date, we achieved major milestones,” commented Jennifer Simpson, PhD., M.S.N., C.R.N.P., President & Chief Executive Officer. “During Q1 we completed patient enrollment in our FOCUS registration trial. We expect topline data for the FOCUS trial before the end of this year despite delays resulting from the COVID-19 pandemic.”

Dr. Simpson continued, “Subsequent to the end of the first quarter, we achieved two significant milestones: completing a $22 million public offering and uplisting to Nasdaq. With our financing completed, we expect the markets to assess our company on the fundamentals of our business. We believe we now have the financial and operational resources to move forward with our development plans as we seek to maximize shareholder value.”

Dr. Simpson concluded, “Looking ahead, we expect to have top-line data from our FOCUS trial before the end of 2020 despite the impact of the COVID-19 pandemic and to advance our second registration program in Intrahepatic Cholangiocarcinoma. We believe that focusing on these indications, which are intended for use in the treatment of cancers that remain unmet medical needs, represents our best path forward to market.”

First Quarter 2020 Financial Results

Product revenue for the three months ended March 31, 2020 was approximately $0.2 million, compared to $0.1 million for the prior year period from our sales of CHEMOSAT procedures in Europe. Selling, general and administrative expenses were approximately $2.3 million compared to $2.5 million in the prior year quarter. Research and development expenses for the first quarter were $3.0 million compared to $3.3 million in the prior year quarter. Total operating expenses for the first quarter were $5.3 million compared with $5.8 million in the prior year quarter.

We recorded a net loss for the three months ended March 31, 2020, of $7.9 million, compared to a net loss of $7.9 million for the same period in 2019.

Balance Sheet Highlights

At March 31, 2020 (not including the net proceeds of our recent public offering), we had cash, cash equivalents and restricted cash totaling $4.7 million, as compared to cash, cash equivalents and restricted cash totaling $10.2 million at December 31, 2019 and $1.3 million at March 31, 2019. During the three months ended March 30, 2020 and March 31, 2019, we used $5.2 million and $2.8 million, respectively, of cash in our operating activities. We believe our cash resources, including the net proceeds of the public offering, are adequate to fund our operating activities into mid-year 2021.

About Delcath System, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product – Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) – is designed to administer high-dose chemotherapy to the liver while minimizing systemic exposure and associated side effects. In addition to the FOCUS Trial, we have initiated a global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) called The ALIGN Trial. Melphalan/HDS has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system is marketed under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT) and has been CE Marked and used at major medical centers to treat a wide range of cancers of the liver. CHEMOSAT is being marketed under an exclusive licensing agreement with medac GmbH, a privately held multi-national pharmaceutical company headquartered in Germany that specializes in the treatment and diagnosis of oncological, urological and autoimmune diseases.

Safe Harbor / Forward-Looking Statements

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 OM and ICC clinical trial programs, and timely enrollment and treatment of patients in the global Phase 3 OM and ICC clinical trials and the impact of the COVID-19 pandemic on the enrollment and completion of our clinical trials; IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial protocols from participating sites and the timing of site activation and subject enrollment in each trial; 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 Melphalan HDS/CHEMOSAT system and the potential of the Melphalan HDS/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 Melphalan HDS/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 other 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.

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