Delcath Issues Letter to Stockholders

NEW YORK, April 27, 2017 — Delcath Systems, Inc. (Nasdaq:DCTH) (the "Company"), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces that Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer, has issued a Letter to Stockholders providing a business update. The full text of the Letter, which has also been posted to the Company's website, is as follows.

Dear Shareholders:

The development of oncology therapeutics is a long and sometimes difficult path, but one of **great reward when promising new therapies are brought to patients in need.** I am writing you to affirm Delcath's unwavering commitment to advancing our innovative percutaneous hepatic perfusion (PHP®) therapy and to highlight the important role this therapy can play in treating patients with cancers of the liver. Oftentimes these patients face limited treatment options. Toward that end, I'd like to update you on our progress and plans for the future, as well as to review some of the challenges we faced last year.

Our clinical development programs now provide us with two viable paths to U.S. market approvals. We believe that **it is through these trials that shareholder value will ultimately be realized.** As such, our focus in 2017 remains on advancing the programs for our innovative Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS), as well as on our commercialization efforts for CHEMOSAT® in Europe. The year began with a number of significant developments toward these twin goals, and we are positioned for further **advancement of these programs throughout the balance of the year.**

Our priority for the year is expanding the number of clinical sites and enrolling patients into our global FOCUS Phase 3 clinical trial in hepatic dominant ocular melanoma (the FOCUS Trial). We initiated the FOCUS Trial in January 2016 under a **Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA),** which indicates that the design of this trial adequately addresses objectives that, if met, will support regulatory requirements for approval of Melphalan/HDS in this indication. Throughout 2016 we established a network of participating clinical trial sites that now includes 20 prestigious cancer research centers across the U.S. and Europe that are open for patient enrollment. We are continuing to expand this network and expect to have **up to 40 clinical centers** participating globally in this pivotal study by the end of the summer of 2017.

I'd also like to highlight that the clinical potential of Melphalan/HDS in the treatment of ocular melanoma liver metastases was repeatedly supported by compelling clinical data presented and published throughout the past year. Most recently, a single-center retrospective review

was published in the *American Journal of Clinical Oncology* in which the authors found that investigational PHP with Melphalan/HDS offered promising results with **a doubling of overall survival** (OS) and significantly longer progression-free survival (PFS) and hepatic PFS than other targeted therapies. In addition, an oral presentation at the Regional Cancer Therapies 12th International Symposium reported data from a retrospective, multicenter study demonstrating that 45.7% of patients with ocular melanoma that metastasized to the liver who underwent PHP using investigational Melphalan/HDS experienced a complete or a partial response. That same study further showed that among those who responded to treatment, **OS was projected to be more than three years**. The projected 657-day median OS and 1,207-day median OS in patients with a partial or a complete response is very impressive, and we believe speaks to the potential of our system to provide a meaningful and durable response in a disease that has an average survival of only six to eight months.

We continue to be encouraged that results such as these have been presented or published on several occasions over the last two years, as they provide us with considerable confidence in the potential of the FOCUS Trial to support FDA approval in the U.S. We believe the FOCUS trial represents our fastest path to U.S market approval, and that PHP with Melphalan has the potential to treat up to 2,000 patients with ocular melanoma liver metastases in the U.S. and Europe annually.

Another major clinical goal for 2017 is to advance PHP with Melphalan/HDS for the treatment of intrahepatic cholangiocarcinoma (ICC). Toward this end, we announced a new SPA with the FDA for the design of a pivotal trial in that indication. As with the FOCUS Trial, this SPA agreement indicates that this trial design adequately addresses objectives that, if met, will support regulatory requirements for approval of Melphalan/HDS in the treatment of ICC.

The ICC pivotal trial is a randomized, controlled study comparing the efficacy, safety and pharmacokinetics of Melphalan/HDS treatment administered sequentially following Cisplatin/Gemcitabine (the current standard-of-care) compared with Cisplatin/Gemcitabine alone in approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint is OS and secondary and exploratory endpoints include safety, PFS, overall response rate (ORR) and quality-of-life measures.

This is an important program because the current standard of care, surgical resection, is not possible for an estimated 80% to 90% of the approximately 14,000 patients in the U.S. and Europe diagnosed with ICC each year. The promising outcomes and observations for PHP with Melphalan/HDS in the treatment of ICC identified by European investigators at our global Key Opinion Leader Forum last year were discussed at length with the FDA, and provide us with considerable confidence in the **potential of our therapy as a treatment for this rare and difficult-to-treat tumor type**. We expect the European investigators to submit a manuscript of their data to a peer-reviewed journal for publication later this year.

We intend to initiate the ICC study this fall. The trial is designed to be cost-effective, utilizing many trial sites already participating in our FOCUS Trial, and will be pursued in a financially prudent manner. Given the sequential nature of the trial design, our investment will be modest in 2017 as the Melphalan/HDS segment of the study will not begin until late in the year.

Commercially, we continue to make steady progress with CHEMOSAT in Europe. Although they remain modest, **product sales increased 18%** in 2016, to $2.0 million, and were driven by the establishment of ZE diagnostic-related group (DRG) reimbursement for CHEMOSAT procedures in Germany. Throughout 2016 we worked with local and regional hospitals in Germany to support their negotiations for **reimbursement levels,** and we are pleased with the rates that have been established. With coverage under the ZE system now in place, we expect product sales growth from this market in 2017.

Elsewhere in Europe our commercial efforts are focused on building the clinical and pharmacoeconomic data to support reimbursement applications in other key markets. We expect that the positive negotiations for coverage in Germany will support our efforts for payment levels in other markets such as the U.K. and the Netherlands. Securing reimbursement coverage in additional European markets remains critical to future revenue growth for CHEMOSAT.

Though more robust revenue growth in Europe remains contingent on wider reimbursement, our market access efforts in Europe have yielded significant achievements thus far. Of note, SPIRE Southampton Hospital in the U.K. recently surpassed 100 treatments with CHEMOSAT since beginning procedures in December 2013. This includes a record eight treatments on a single patient. Since introducing CHEMOSAT in 2012, we have built a significant network of expertise in Europe that has led to the steady flow of abstracts, presentations and publications. These efforts have also established deep relationships with major cancer research centers in Europe that are participating in our pivotal clinical trials.

To fund the ongoing development of our clinical and commercial programs, last year we **secured $35 million in committed financing** through a securities purchase agreement with two institutional investors, which consisted of senior convertible notes and common stock purchase warrants. This committed financing was the best option available to the Company at that time, and it has provided the resources necessary to advance our clinical development programs toward market approvals where shareholder value ultimately resides. We are regularly evaluating additional alternatives for capital and are committed to acting in the best, long-term interest of our shareholders in all that we do.

Recently, we entered into separate **warrant repurchase agreements** under which each investor agreed to a Controlled Account Release, in an aggregate amount of $7,876,312, in exchange for cancellation of the Warrants issued under the original agreement. This

transaction **simplifies our capital structure**, and we continue to expect that the cash remaining in the Controlled Accounts after the warrant repurchase will be sufficient to fund our operating activities through the end of 2017.

On behalf of Delcath's management team and Board of Directors, I thank you for your support as we continue to build Delcath into a **leading interventional oncology company** bringing **life-saving therapy to patients suffering with cancers of the liver** who have few treatment options.

We look forward to reporting on our continued clinical and commercial progress.

Sincerely,

Jennifer K. Simpson, Ph.D., MSN, CRNP
President and Chief Executive Officer

About Delcath Systems

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 controlling systemic exposure and associated side effects. We have commenced a global Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and plan to initiate a Registration trial for intrahepatic cholangiocarcinoma (ICC) in the fall of 2017. Melphalan/HDS has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system has been commercially available since 2012 under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT), where it has been used at major medical centers to treat a wide range of cancers of the liver.

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, timely enrollment and treatment of patients in the global Phase 3 OM clinical trial, 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, our ability to maintain NASDAQ listing, 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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