DELCATH SYSTEMS, INC.
Form DEFA14A
April 29, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

SCHEDULE 14A

(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the

Securities Exchange Act of 1934

Filed by the Registrant x Filed by a Party other than the Registrant ¨

Check the appropriate box:

¨ Preliminary Proxy Statement
¨ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
¨ Definitive Proxy Statement
x Definitive Additional Materials
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Delcath Systems, Inc.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than The Registrant)

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April 2015

Dear Stockholders:

Throughout 2014 the team at Delcath Systems made significant progress on all aspects of our strategic plan including the activation and expansion of clinical programs and steady growth in the adoption of our Delcath Hepatic® Delivery System (CHEMOSAT) in key European commercial markets, while significantly reducing operating expenses.

We are especially pleased with achievements in our Clinical Development Plan (CDP) for Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS). Our global Phase 2 program in hepatocellular carcinoma (HCC) opened for enrollment at several centers in the U.S. and Europe, and the first patients have been treated. We look forward to adding U.S. and European sites to this study in 2015.

Recently we announced European regulatory approval for the expansion of this trial to include a cohort of patients with intrahepatic cholangiocarcinoma (ICC). ICC is the second most common primary liver tumor, and represents 3% of all gastrointestinal cancers and 15% of HCC cases diagnosed in the U.S. and Europe annually. A positive efficacy signal in ICC may provide a regulatory path to a U.S. registration trial, and consolidated safety data from the HCC and ICC cohorts of this global Phase 2 trial will provide us with valuable information to share with the FDA. We believe our Melphalan/HDS treatment may offer significant clinical benefit for ICC patients who face limited treatment options, and we look forward to beginning patient enrollment in this cohort in the second quarter of 2015.

During 2014 and early 2015 we also advanced preparations for a global pivotal Phase 3 clinical trial in ocular melanoma (OM) that has metastasized to the liver. Underlying our enthusiasm for this trial is statistically significant hepatic progression-free survival data in OM metastases observed in our previous Phase 3 clinical trial in this tumor type. Combined with the positive patient outcomes and improved safety profile that have been reported by treating physicians using CHEMOSAT in commercial settings in Europe, we believe this Phase 3 program offers the fastest path to potential approval of Melphalan/HDS in the U.S. We hope to begin enrolling subjects in this trial by the end of 2015.

In addition, we recently activated our prospective European patient registry. This registry will provide valuable benefit/risk analyses and important outcomes data that should be instrumental in furthering both reimbursement and market adoption of CHEMOSAT in Europe. Through this registry we also hope to obtain efficacy signals in various tumor types, which will help guide other aspects of our CDP.

We are supporting two European investigator-initiated trials, one in colorectal carcinoma metastatic to the liver and one in HCC. We believe these studies will serve to build clinical experience at key cancer centers, identify additional efficacy signals and support efforts to obtain reimbursement in Europe. We continue to evaluate proposals for additional investigator-initiated trials with an aim to support data generation in a variety of oncology indications that affect the liver.

Another important clinical milestone we recently achieved is the submission of results from our previous Phase 3 study for publication in a leading peer-reviewed medical journal. If published, we believe these study results will be an important tool in support of our efforts to obtain reimbursement in a number of European countries and will also help increase awareness of the value of this therapy

On the commercialization front, we continue to see steady progress in the clinical adoption of CHEMOSAT in Europe. A total of 79 CHEMOSAT commercial treatments were performed during 2014, with 34 of these representing retreatments. This is a nearly 100% increase in treatments and a nearly 200% increase in retreatments compared with 2013. During 2014 we also treated our 100th patient in Europe, which is an important symbolic milestone indicating growing physician acceptance of CHEMOSAT. To date, treatments in Europe have been reimbursed primarily via interim mechanisms such as individual funding requests in Germany and private insurance coverage in the United Kingdom. We expect these mechanisms will remain the primary funding mechanisms for CHEMOSAT reimbursement in 2015.

Product revenue in 2014 was $1.1 million, an increase of 118% compared with product revenue in 2013 of $0.8 million, of which $0.3 million related to the recognition of previously deferred revenue. During the year we also significantly reduced our cash utilization to $15.6 million, a 54% reduction compared with 2013. The decrease in cash utilization was achieved in part by improved organizational and operational efficiencies. In early 2015 we raised gross proceeds of $2.8 million in a public offering of common stock and warrants to further support our strategic plan.

For the remainder of 2015, we look forward to continuing to execute on our strategic plan in a cost-efficient manner and expect to achieve a number of value-creating milestones throughout the year in support of the Company s mission to make CHEMOSAT/Melphalan/HDS therapy available to patients with cancers of the liver worldwide.

Sincerely,

Jennifer K. Simpson, Ph.D, MSN, CRNP.

Interim President and Chief Executive Officer

Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf within the meaning of the federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including, but not limited to, uncertainties relating to: the timing and results of future clinical trials including without limitation the OM, HCC, ICC, and mCRC trials in the Company s Clinical Development Program, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system in Europe, our ability to obtain reimbursement for the CHEMOSAT system in various markets including without limitation Germany and the United Kingdom, our ability to successfully commercialize the Melphalan/HDS system and the potential of the Melphalan/HDS system as a treatment for patients with primary and metastatic disease in the liver, the Company s ability to satisfy the requirements of the FDA s Complete Response Letter relating to the ocular melanoma indication and the timing of the same, approval of the Melphalan/HDS system by the U.S. FDA, acceptance of the Phase 3 trial publication, approval of the current or future Melphalan/HDS 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, our 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 our ability to obtain financial and other resources for any clinical trials, research, development, and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission including the section entitled Risk

Factors in our most recent Annual Report on Form 10-K and our Reports on Form 10-Q and Form 8-K.