UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report: October 18, 2016

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-16133**	**06-1245881**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

1633 Broadway, Suite 22C, New York, New York 10019
(Address of principal executive offices, including zip code)

(212) 489-2100
(Registrant's telephone number, including area code)

NONE
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On October 18, 2016, the Company issued a Letter to Stockholders providing a business update. A copy of the Letter to Stockholders is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
99.1	Letter to Stockholders of the Company, dated October 18, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: October 18, 2016

By: /s/ Jennifer K. Simpson, Ph.D.
Name: Jennifer K. Simpson, Ph.D.
Title: President and Chief Executive Officer

Exhibit Index

Exhibit No.	Description
99.1	Letter to Stockholders of the Company, dated October 18, 2016

Exhibit 99.1

Delcath Issues Letter to Stockholders

NEW YORK (October 18, 2016) – Delcath Systems, Inc. (DCTH) (the "Company"), an interventional oncology company focused on treatments for 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, follows below.

Dear Stockholders:

On behalf of my colleagues at Delcath Systems and our company's Board of Directors, I would like to thank all our stakeholders for your trust and support as we continue to advance our Melphalan/Hepatic Delivery System to the benefit of patients worldwide who are battling primary and metastatic liver cancers.

Throughout 2016 we have made important commercial, clinical and corporate progress that collectively position us for continued growth and further success. These include:

- Expanded the reach of CHEMOSAT® in Europe to include more patients, more clinicians and more medical centers in more countries
- Advanced and expanded our global Phase 3 FOCUS Trial to treat metastatic ocular melanoma and our Phase 2 clinical program in hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC); and
- Strengthened our balance sheet to support these important clinical programs through 2017.

In June we **secured $35 million in committed financing** with two accredited institutional investors that specialize in biotechnology and medical technology investments. Of the $32.2 million in net proceeds, $3.0 million was unrestricted and immediately available for use. The remaining $29.2 million is held in certain control accounts. The timing of the availability of the balance of the funds from this transaction necessitated the recently announced small fundraise of $1.25 million, which will bridge us to receipt of our first cash release from this committed financing, which we expect in December 2016. Assuming all conditions are satisfied, we expect the anticipated quarterly releases throughout 2017 will fund our clinical development plan through the end of 2017, while also supporting our commercial activities in Europe.

We have made great strides with our clinical programs. In January, after reaching a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of our new, **global Phase 3 clinical trial**, we initiated enrollment in *"A Randomized, Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma,"* or the FOCUS Trial.

This trial is evaluating our Melphalan/HDS system versus best alternative care in 240 patients with ocular melanoma liver metastases. The trial's primary endpoint is a comparison of overall survival between the two study arms; secondary and exploratory endpoints include progression-free survival, overall response rate and quality-of-life measures. The SPA provides agreement with the FDA that the Phase 3 trial design adequately addresses objectives that, if met, will support the submission for regulatory approval of Melphalan/HDS.

Most recently, we were pleased to report on the expansion of the Focus Trial to several world- leading oncology centers in Europe and the U.S. We are proud to report that this trial is now actively screening and enrolling patients at eight clinical sites in the U.S. and five clinical sites in

Europe. In recent months we held U.S. and European Investigators Meetings. The investigators' strong interest and excitement in participating gives us further confidence this expansion will enhance our progress and allow us to stay on track to complete enrollment in mid-2018 with the potential for a pre-specified interim analysis around the end of 2017. Including these leading oncology centers increases visibility of our Melphalan/HDS as an innovative potential therapy for cancers of the liver. Importantly, a number of the world's key opinion leaders (KOLs) are participating in the study, which should enhance future commercial efforts.

Our **global Phase 2 clinical program in HCC and ICC** continues to move forward. As we have discussed, the HCC portion of this study is enrolling at a slower pace than the ICC portion due to the stringent HCC inclusion criteria, the small target patient population and competition from other trials seeking to recruit similar patients. We are near completion of the 11-patient cohort of ICC patients and expect to report top-line results by the end of this year. In addition, European Investigators have undertaken a retrospective data collection for patients with ICC in Europe. These promising outcomes and observations were discussed with our KOLs at a Delcath-organized Medical Advisory Panel Meeting and led to the agreement that the CHEMOSAT treatment does, indeed, demonstrate an efficacy signal and is worthy of immediate full clinical investigation. As a consequence, we are **focusing our resources on advancing the ICC indication**, an area where we have strong KOL support, an established efficacy signal and a development program ready to be discussed with the FDA.

Also underway is a **patient registry study in Europe** with the goal of gathering safety, efficacy and quality-of-life data in multiple tumor types from commercial cases performed by participating cancer centers in Germany, the U.K. and the Netherlands. We are pleased that the first 20 patients, all of whom have ocular melanoma, have been entered. Enrollment in this registry continues with a variety of tumor types to be entered. These data will be used as supportive evidence in our global Health Authority submissions.

One of the benefits of the robust clinical development we have underway is the bolus of data these studies generate. Throughout 2016 a number of important clinical studies have been presented at prestigious medical meetings and published in peer-reviewed journals. A white paper from an Expert Forum held in February 2015 to share information and clinical experiences using CHEMOSAT to treat primary and metastatic liver cancers has also been accepted for publication in a peer-reviewed journal. The **ongoing presentation and publication of positive clinical data** in support of CHEMOSAT is encouraging and holds untold benefit.

We continue to make inroads with market access and commercial clinical adoption in Europe where our system is CE-marked and sold under the CHEMOSAT® name. With a number of company-sponsored clinical trials, interest in investigator-led trials and the European registry underway, we are seeing an uptick in usage. Yet we caution that we do not expect this to translate into a significant increase in commercial revenue in the near term. A key driver for converting usage into sales is reimbursement, which in Europe is painstakingly negotiated on a country-by-country basis.

Last October we were pleased to report that the German Institute for the Hospital Remuneration System (InEK) issued a ZE diagnostic-related group (DRG) code for CHEMOSAT. The application for nationwide coverage under the ZE scheme was made by the German Radiology Society and was widely supported by major German cancer hospitals, which speaks to the confidence the German clinical community has in CHEMOSAT. Since then we have been working with hospitals to support their negotiation for **German reimbursement levels.** We are pleased with our progress and with the rates we have been securing. These positive negotiations are expected to support our efforts for payment in other markets where we are leveraging this German experience, such as the Netherlands.

As always, we are extremely grateful to our stockholders for their support as we execute on our mission and advance our goal of making a difference in the lives of liver cancer patients with few or inadequate treatment options.

Importantly, we thank the clinical collaborators and their patients who participate in our clinical trials with the hope of improving not only their own outcomes, but also the outcomes of future patients. None of the progress we have made would be possible without their support.

We have a number of important milestones before year end and we look forward to providing ongoing updates on our clinical and commercial progress.

Sincerely,

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

About Delcath

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 a global Phase 2 clinical trial in Europe and the U.S. to investigate the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC). 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.

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: our ability to repay and comply with the obligations under our senior secured convertible notes, the timing and results of the Company's clinical trials including without limitation the OM, HCC ,and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma and the global Phase 2 HCC and ICC clinical trials, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM protocols from participating sites and the timing of site activation and subject enrollment in each trial, the impact, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, the impact of the presentations at major medical conferences and future clinical results consistent with the data presented, 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, the

Company's ability to successfully commercialize the CHEMOSAT®/Melphalan HDS system and the potential of the CHEMOSAT®/Melphalan HDS 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, the Company's ability to satisfy the remaining requirements of the FDA's Complete Response Letter and provide the same in a timely manner, approval of the current or future Melphalan HDS/CHEMOSAT® system for delivery and filtration of melphalan 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.

Contact:

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