
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 8, 2020

DELCATH SYSTEMS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-16133
(Commission
File Number)

06-1245881
(IRS Employer
Identification No.)

1633 Broadway, Suite 22C, New York, New York 10019
(Address of principal executive offices) (Zip Code)

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

Not Applicable
(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:

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$.01 par value	DCTH	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 — Other Events.

On December 8, 2020, Delcath Systems, Inc. (the “Company”) announced the commencement of a proposed underwritten public offering of its common stock (the “Offering”). Canaccord Genuity and Roth Capital Partners are acting as joint book-running managers for the proposed Offering.

In connection with the Company’s proposed Offering, the Company suspended and is no longer offering any securities pursuant to the prospectus supplement filed with the SEC on August 18, 2020 relating to the offer and sale of shares of our Common Stock pursuant to the Controlled Equity OfferingSM Sales Agreement, dated August 18, 2020, with Cantor Fitzgerald & Co., as Sales Agent (the “Sales Agreement”). The Company will not make any sales of common stock pursuant to the Sales Agreement unless and until a new prospectus supplement is filed with the SEC; however, the Sales Agreement remains in full force and effect.

On December 8, 2020, the Company issued a press release announcing the launch of the Offering. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of the Company, dated December 8, 2020.</u>

SIGNATURE

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.

Date: December 8, 2020

DELCATH SYSTEMS, INC.

By: /s/ Gerard Michel

Name: Gerard Michel

Title: Chief Executive Officer

Delcath Systems Announces Proposed Public Offering of Common Stock

New York, December 8, 2020 (GLOBE NEWSWIRE) – Delcath Systems, Inc. (Nasdaq: DCTH), an interventional oncology company focused on the treatment of rare primary and metastatic cancers of the liver, today announced that it intends to offer and sell, subject to market conditions, shares of its common stock in an underwritten public offering. All of the shares of common stock to be sold in the offering will be offered by Delcath. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering. Delcath also expects to grant the underwriters a 30-day option to purchase up to an additional 15% of the number of shares sold in the public offering.

Delcath intends to use the net proceeds from this offering for (i) the completion of its FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the “Focus Trial”), a global registration clinical trial that is investigating the primary endpoint of objective response rate, as well as other secondary and exploratory endpoints, in metastatic ocular melanoma, or mOM; (ii) preparation of the federal regulatory application for the HEPZATO™ KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO™, a drug/device combination product regulated as a drug, designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects; (iii) preparation for the commercial launch of HEPZATO; (iv) continued clinical development, including additional indications and expanded access trials in metastatic ocular melanoma; and (v) general corporate purposes, which may include capital expenditures and other operating expenses.

Canaccord Genuity and Roth Capital Partners are acting as joint book-running managers for the proposed offering.

A shelf registration statement relating to these securities has been filed with the U.S. Securities and Exchange Commission (SEC) and became effective on December 21, 2018. The offering is being made only by means of a preliminary prospectus supplement and accompanying prospectus relating to the offering that form a part of the registration statement, which will be filed with the SEC and will be available on the SEC’s website at www.sec.gov. Copies of the preliminary prospectus supplement and the accompanying prospectus relating to this offering may be obtained, when available, by contacting Canaccord Genuity LLC, Attention: Syndicate Department, 99 High Street, Suite 1200, Boston, MA 02110, by telephone at (617) 371-3900 or by email at prospectus@cgf.com or Roth Capital Partners, LLC, 888 San Clemente, Newport Beach, CA 92660, Attention: Prospectus Department, or by telephone at (800) 678-9147.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Delcath Systems, Inc.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product, HEPZATO KIT (melphalan hydrochloride for injection/hepatic delivery system), is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. HEPZATO KIT 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 CHEMOSAT® Hepatic 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

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, 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 product; 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.

Contact:

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