
**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): August 19, 2019

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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$.01 par value	DCTH	OTC QB

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 1.01 Entry into a Material Definitive Agreement.

On August 19, 2019, Delcath Systems, Inc. (the “Company”) closed on its previously reported securities purchase agreement, dated August 15, 2019 (the “Securities Purchase Agreement”), entered into with certain accredited investors (each an “Investor” and, collectively, the “Investors”) pursuant to which the Company issued to the Investors an aggregate of 9,510 shares of Series E-1 Convertible Preferred Stock, par value \$0.01 per share (the “Series E-1 Preferred Stock”), at a price of \$1,000 per share (the “Private Placement”). Pursuant to the Securities Purchase Agreement, the Company also issued to each Investor a warrant (a “Warrant”) to purchase a number of shares of common stock of the Company, par value \$0.01 per share (“Common Stock”), equal to the number of shares of Common Stock issuable upon conversion of the Series E-1 Preferred Stock purchased by the Investor. Each Warrant has an exercise price equal to \$0.06, subject to adjustment in accordance with the terms of the Warrants (the “Exercise Price”), and are exercisable at any time beginning on the date that the Company effects a reverse stock split until 5:00 p.m. (NYC time) on the date that is five years following the date that the Company effects a reverse stock split.

The Company has now raised a total of \$29.5 million since July 2019. As previously reported, on July 15, 2019, the Company received gross proceeds of \$20 million from the private placement of the Company’s Series E Convertible Preferred Stock, par value \$0.01 per share (the “Series E Preferred Stock”).

The offering of the Series E-1 Preferred Stock is being led by fundamental healthcare investors, including Rosalind Advisors and Altium Capital.

As previously reported, each share of the Series E-1 Preferred Stock has a par value of \$0.01 per share and a stated value equal to \$1,000 (the “Stated Value”) and is convertible at any time at the option of the holder into the number of shares of Common Stock determined by dividing the stated value by the conversion price of \$0.06, subject to certain limitations and adjustments (the “Conversion Price”). Except for certain adjustments, the holders of Series E-1 Preferred Stock are entitled to receive dividends on shares of Series E-1 Preferred Stock equal (on an “as converted” basis) to and in the same form as dividends paid on shares of the Common Stock. Any such dividends that are not paid to the holders of the Series E-1 Preferred Stock will increase the Stated Value. No other dividends will be paid on shares of Series E-1 Preferred Stock. The Series E-1 Preferred Stock vote on an “as converted” basis on all matters submitted to the holders of Common Stock for approval, subject to certain limitations and exceptions. The affirmative vote of the holders of a majority of the then outstanding shares of the Series E-1 Preferred Stock is required to increase the number of authorized shares of Series E-1 Preferred Stock or to alter or change adversely the powers, preferences or rights given to the Series E-1 Preferred Stock, or to amend the Company’s organizational documents in any manner that adversely affects the rights of the holders of the Series E-1 Preferred Stock. Upon any liquidation of the Company, the holders of the Series E-1 Preferred Stock and the holders of the Series E Preferred Stock will be entitled to receive out of the assets of the Company, on a *pari passu* basis, an amount equal to the Stated Value plus any accrued and unpaid dividends thereon for each share of Series E-1 Preferred Stock and Series E Preferred Stock before any distribution or payment is made to the holders of the Common Stock.

The Conversion Price and the Exercise Price may, upon each of (i) the third trading day following the date that the Company effects a reverse stock split, (ii) the date that the initial registration statement to be filed pursuant to the Registration Rights Agreement (as further discussed below) is declared effective by the United States Securities and Exchange Commission (“SEC”), and (iii) in the event that all of the registrable securities (as defined in the Registration Rights Agreement) are not then registered on an effective registration statement, the date that all of the shares underlying the Preferred Stock and Warrants may be sold pursuant to Rule 144, be reduced, and only reduced, to equal the lesser of (x) the then effective Conversion Price or Exercise Price, as applicable, and (y) 90% of the

average of the five daily volume weighted average prices of the Common Stock immediately prior to such dates. In the event of a reduction in the Exercise Price, the aggregate number of Warrant Shares shall be increased such that the aggregate Exercise Price of the Warrants on the day immediately following such reduction in the Exercise Price is equal to the aggregate Exercise Price immediately prior to such adjustment. In addition, from the date of issuance of the Preferred Stock and Warrants until such time that the Company's Common Stock is listed or quoted on a national exchange, the Conversion Price and the Exercise Price are subject to price-based anti-dilution protections.

The Company received gross proceeds from the Private Placement of approximately \$9.5 million, before deducting cash fees in the amount of \$738,285 payable to Roth Capital Partners, LLC for serving as placement agent for the Private Placement, and other transaction costs, fees and expenses payable by the Company. The Company intends to use the net proceeds of the Private Placement to support the Company's general working capital requirements.

The sale and issuance of the Series E-1 Preferred Stock and Warrants to the Investors have been determined to be exempt from registration under the United States Securities Act of 1933, as amended (the "Act"), in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder.

The foregoing description of the Securities Purchase Agreement and the Warrants does not purport to be complete and is qualified in its entirety by reference to the complete text of the Securities Purchase Agreement and the form of the Warrant, which is attached as Exhibits 10.1 and 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 16, 2019 and is hereby incorporated by reference into this Item 1.01.

Item 3.02 Unregistered Sales of Equity Securities

The information disclosed in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 3.02. The sale and issuance of the Series E-1 Preferred Stock and Warrants in the Private Placement have been determined to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering, in which the investors are accredited and have acquired the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof. Such securities may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

Item 8.01 Other Events.

On August 20, 2019, the Company issued a press release announcing the completion of the Private Placement. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release issued on August 20, 2019 by the Company

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 thereunto duly authorized.

DELCATH SYSTEMS, INC.

Date: August 20, 2019

By: /s/ Barbra Keck

Name: Barbra Keck

Title: Chief Financial Officer

Delcath Systems Closes \$9.5 Million Private Placement*Bringing total financial amount raised since July 2019 to \$29.5M**Cash runway past top-line results in 1H2020 with NDA submission anticipated by end of 2020**Recapitalization provides possible path to NASDAQ listing*

NEW YORK, NY, Aug 19, 2019 – Delcath Systems, Inc. (“Delcath,” the “Company”, “we”, “our” or “us” (OTCQB: DCTH) has closed on its previously announced private placement with gross proceeds of \$9.5 million at a combined price of \$1,000 per Unit. Each Unit consists of one preferred share initially convertible into 16,667 shares of common stock at an initial conversion price of \$0.06 per share and a common stock purchase warrant. Each whole warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$0.06 for a period of five years from the date of the Company’s anticipated reverse stock split. The Company has now raised a total of \$29.5 million since July 2019.

The offering is being led by fundamental healthcare investors, including Rosalind Advisors and Altium Capital.

Commenting on the announcement, Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath stated, “With this transaction completed, we have a cash runway beyond top line data, a clean capitalization table and the foundation for a possible path to NASDAQ listing. Looking forward, we are positioned for success through multiple value inflection points including full enrollment, top line data and NDA filing – targeted for Q4 2019, 1H 2020 and Q4 2020, respectively, in our registration trial for the treatment of metastatic Ocular Melanoma (mOM). mOM is a devastating disease of high unmet-need for which there is no approved standard-of-care in the United States and for which the Company has orphan drug designation.”

Dr. Simpson added, “the management team has laid the foundation for a leading interventional oncology platform company and now has the resources, capital structure and operational resources to move forward its long-term priorities and growth plans, to maximize shareholder value.”

The recapitalization enables Delcath to pursue its business plan to:

- Develop therapies for cancers of the liver with high unmet medical need and no established standards of care, addressing a multi-billion-dollar opportunity in the United States and Europe;
- Expand development of our platform to other indications, chemotherapies and organs; and;
- Support our commercial partner medac in Europe (where CHEMOSTAT® is approved) to maximize the opportunities set out in our December 2018 commercialization agreement.

The company recently announced the addition of John R. Sylvester to its Board of Directors. Mr. Sylvester is currently Chief Commercial Officer at BTG PLC, an international specialist healthcare company that develops and commercializes products targeting critical care, cancer and other disorders. The quality of BTG’s interventional medicine business played an integral part in its sale to Boston Scientific for \$4.2 billion. The Company intends to leverage John’s expertise and experience in the commercialization of new medical technologies as Delcath prepares to enter US and ex-US markets.

Dr. Simpson concluded by stating, “I would like to thank the investors who took the time to assess this incredible opportunity and as a result have recognized the substantial value of Delcath’s assets, technology and clinical programs. Management and the Board are excited to work with our team of clinicians and key opinion leaders to make Melphalan/HDS available as a treatment option to improve patients’ lives and outcomes.”

Roth Capital Partners acted as the sole placement agent for the offering. After the placement agent fees and estimated offering expenses payable by the Company, the Company has received net proceeds of approximately \$8.6 million. The offering closed on Aug 19, 2019.

The securities offered in the private placement have not been registered under the Securities Act of 1933, as amended or applicable under state securities laws. Accordingly, the securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws. As part of the transaction, the Company has agreed to file a resale registration statement on Form S-1 with the Securities and Exchange Commission by August 21, 2019 for purposes of registering the resale of the shares of common stock issuable upon conversion of the preferred shares and upon exercise of the warrants issued in the private placement.

This notice does not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the securities under the resale registration statement will only be by means of a prospectus.

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 controlling systemic exposure and associated side effects. We have been enrolling a global Registration clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) called The FOCUS Trial and 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 used at major medical centers to treat a wide range of cancers of the liver. Since January 2019 CHEMOSAT is marketed under an exclusive licensing agreement with medac, a privately held multi-national pharmaceutical company headquartered in Germany and specializing 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: successful completion of the Company’s Rights Offering

and related transactions and the amount of gross proceeds, if any; 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 and ICC 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.

Contact:

Delcath Investor Relations

Email: investorrelations@delcath.com

#