

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): July 24, 2019

DELCATH SYSTEMS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16133
(Commission
File Number)

06-1245881
(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))
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	OTC Pink

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. []

Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Item 5.02.

On July 24, 2019, by unanimous action of the Board of Directors of Delcath Systems, Inc. (the “Company”), upon the recommendation of the Nominating and Corporate Governance Committee, the Board appointed John R. Sylvester to fill the vacancy on the Board created by the resignation of Simon Pedder, such appointment to be effective immediately.

Mr. Sylvester is currently serving as Chief Commercial Officer of BTG plc, an international specialist healthcare company that develops and commercializes products targeting critical care, cancer and other disorders. Mr. Sylvester joined BTG in 2011 and has had roles leading both BTG’s Interventional Oncology and Interventional Vascular businesses as well as a period as Chief Development Officer accountable for Strategy, M&A and Market access. Mr. Sylvester has been involved in several significant business turn-arounds as well as establishing new innovative healthcare technologies as the standard of care. His previous leadership positions include Managing Director at Biocompatibles PLC, Vice President Marketing, European Medicines Delivery at Baxter International Inc., and General Manager, Europe and Asia at Imerys SA.

Mr. Sylvester has not yet been appointed to any Board committees. There is no arrangement or understanding between Mr. Sylvester and any other person pursuant to which he was selected as a director nor are there any disclosable arrangements under Item 404(a) of Regulation S-K.

Item 8.01. Other Events.

On July 29, 2019, the Company issued a press release announcing the completion the appointment of Mr. Sylvester to the Company’s Board of Directors. 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 July 29, 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.

Dated: July 30, 2019

By: /s/ Barbra Keck
Name: Barbra Keck
Title: Chief Financial Officer

DELCATH ENHANCES BOARD OF DIRECTORS WITH APPOINTMENT OF COMMERCIAL LEADER, JOHN R. SYLVESTER

Seasoned leader with successful track record joins to help Delcath in the next phase of its development.

NEW YORK (July 29, 2019) – Delcath Systems, Inc. (OTC Pink: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces that John R. Sylvester, a pharmaceutical and medical device executive with a greater than 30-year career focused on growing business, creating markets and implementing commercialization strategies, has joined the Delcath Board of Directors effective July 24, 2019.

Mr. Sylvester currently serves as Chief Commercial Officer at BTG PLC, an international specialist healthcare company that develops and commercializes products targeting critical care, cancer and other disorders. During his career, Mr. Sylvester has been involved in establishing new innovative healthcare technologies as the standard of care. His previous leadership positions include Managing Director at Biocompatibles PLC, Vice President Marketing, European Medicines Delivery at Baxter International Inc, and General Manager, Europe and Asia at Imerys SA.

Mr. Sylvester was the architect of BTG's Interventional Medicine Strategy and has led the Interventional Oncology and Vascular Franchises as well as heading the Strategy, Market Access and Business development functions. The quality of the \$400m interventional medicine business of BTG played an integral part in its sale to Boston Scientific for \$4.2Bn. The Board of Delcath has determined that Mr. Sylvester is a key addition due to his expertise in setting up commercialization infrastructure to assure our preparation in both the US and ex-US markets.

“It is with great pleasure that we welcome John to our Board. His considerable industry experience bringing new therapies to market and his deep insight into successful commercialization strategies will be extremely valuable as we continue to advance the Melphalan/HDS program,” said Roger G. Stoll, Ph.D., Chairman of the Board of Delcath.

Jennifer K. Simpson, Ph.D., President & CEO of Delcath added, “John brings a proven track record of establishing and opening new markets. With the increasing importance of the interventional oncology space in the treatment of patients, John's experience in creating that market while at BTG will be invaluable as we prepare to bring our therapy to market in the United States.”

John Sylvester commented. “I am delighted to join the Board of Delcath. This is an exciting technology with the potential to make a meaningful improvement in a lot of patients' lives with the current indication under study and others beyond.”

Mr. Sylvester received his BSc (Hons) in Biochemistry and Applied Molecular Biology at The University of Manchester in England.

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 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) .Since January 2019 CHEMOSAT is marketed under an exclusive licensing agreement with medac, a privately held multi-national pharmaceutical company headquartered in Germany which specializes in the diagnosis and treatment of oncological, urological and autoimmune diseases.

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 OM and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 OM and ICC Registration 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, 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 impact of the Company’s exclusive licensing agreement with medac on commercial adoption in Europe and resulting revenue, if any, the Company’s ability to successfully enter into other strategic partnerships 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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