

**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 4, 2023**

**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)

**(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, \$0.01 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.

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**Item 7.01. Regulation FD Disclosure.**

As Delcath Systems, Inc. (the “Company”) has previously announced, the Prescription Drug User Fee Act (“PDUFA”) target date for Hepzato is August 14, 2023. In anticipation of that date, the Company prepared a staging site to reflect the possibility that the U.S. Food and Drug Administration (“FDA”) might approve Hepzato. On August 4, 2023, a vendor inadvertently published that staging site. To date, the Company has not received a decision by the FDA as to its approval of Hepzato and the target PDUFA date remains August 14, 2023.

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**SIGNATURE**

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

DELCATH SYSTEMS, INC.

Date: August 4, 2023

By: /s/ David Hoffman

Name: David Hoffman

Title: General Counsel, Chief Compliance Officer and Secretary