

**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): January 10, 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.

Item 8.01. Other Events.

Delcath Systems, Inc. (the “Company”) previously stated in the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2022, the Company’s plan to submit a New Drug Application for its Hepzato™ Kit (the “NDA”) to the U.S. Food and Drug Administration (“FDA”) by the end of 2022. The foregoing has been updated to reflect the Company’s intention to submit the NDA to the FDA during the first quarter of 2023.

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: January 10, 2023

By: /s/ David Hoffman

Name: David Hoffman

Title: General Counsel, Chief Compliance Officer and Secretary