# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM S-3 REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

# **DELCATH SYSTEMS, INC.**

(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

06-1245881 (I.R.S. Employer Identification No.)

1633 Broadway, Suite 22C New York, New York 10019 (212) 489-2100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Gerard Michel Chief Executive Officer Delcath Systems, Inc. 1633 Broadway, Suite 22C New York, New York 10019 (212) 489-2100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Ryan S. Sansom Christina Roupas Cooley LLP 500 Boylston Street Boston, Massachusetts 02116 (617) 937-2300

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement as determined by the selling securityholders.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.  $\Box$ 

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	
Non-accelerated filer	Smaller reporting company	X

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 7(a)(2)(B) of the Securities Act.  $\Box$ 

section 8(a), may determine.			

The information in this prospectus is not complete and may be changed. The Selling Stockholders may not sell these securities or accept an offer to buy these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting offers to buy these securities in any jurisdiction where such offer or sale is not permitted.

SUBJECT TO COMPLETION, PRELIMINARY PROSPECTUS DATED JUNE 14, 2023



# Up to 19,509,749 Shares of Common Stock Offered by the Selling Stockholders

This prospectus relates to the offer and resale, from time to time, by the selling stockholders named under the heading "Selling Stockholders" in this prospectus, or their assigns (the "Selling Stockholders"), of up to 19,509,749 shares (the "Shares") of the Company's Common Stock, par value \$0.01 per share (the "Common Stock") which consist of (i) 2,916,358 shares of Common Stock, issuable upon conversion of 9,624 shares of Series F-2 Convertible Preferred Stock, par value \$0.01 per share (the "Series F-2 Preferred Stock"), (ii) 7,746,436 shares of Common Stock issuable upon conversion of 34,860 shares of F-3 Preferred Stock exercisable pursuant to the preferred stock tranche A warrants (the "Preferred Tranche A Warrant") to acquire shares of Series F-3 Preferred Stock, par value \$0.01 per share (the "Series F-3 Preferred Stock"), (iii) 4,149,994 shares of Common Stock issuable upon conversion of 24,900 shares of F-4 Preferred Stock exercisable pursuant to the preferred stock tranche B warrants (the "Preferred Tranche A Warrant," together with the Preferred Tranche A Warrant, the "Preferred Warrants") to acquire shares of Series F-4 Preferred Stock, par value \$0.01 per share (the "Series F-4 Preferred Stock"), (iv) 4,649,185 shares of Common Stock, (v) 31,110 shares of Common Stock, issuable upon exercise of the common stock tranche A warrants ("Common Tranche A Warrant") and (vi) 16,666 shares of Common Stock issuable upon exercise of common stock tranche B warrants, the "Common Tranche B Warrant").

We are registering the offer and sale of the Shares held by the Selling Stockholders to satisfy the registration rights they were granted pursuant to the Preferred Purchase Agreement (as defined below) and the Common Purchase Agreement (as defined below) (together, the "Purchase Agreements"). While we will not receive any proceeds from the sale of the Shares by the Selling Stockholders, we will receive proceeds from the exercise of any Warrants for cash.

Our registration of the Shares covered by this prospectus does not mean that the Selling Stockholders will offer or sell such Shares. The Selling Stockholders may sell the Shares covered by this prospectus in a number of different ways and at varying prices. For additional information on the possible methods of sale that may be used by the Selling Stockholders, you should refer to the section of this prospectus entitled "Plan of Distribution." The Selling Stockholders may, individually but not severally, be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), of the Shares that they are offering pursuant to this prospectus. The Selling Stockholders will bear all commissions and discounts, if any, attributable to their respective sales of the Shares hereunder. We will bear all costs, expenses and fees in connection with the registration of the Shares. We will not be paying any underwriting discounts or commissions in this offering.

A prospectus supplement may add, update, or change information contained in this prospectus. You should carefully read this prospectus, any applicable prospectus supplement, and the information incorporated by reference in this prospectus and any applicable prospectus supplement before you make your investment decision.

Our Common Stock is traded on The Nasdaq Capital Market under the symbol "DCTH." On June 13, 2023, the closing price for our Common Stock, as reported on The Nasdaq Capital Market, was \$6.91 per share.

Investing in these securities involves certain risks. See "Risk Factors" on page 6 of this prospectus. See also "Risk Factors" in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June , 2023

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#### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3, which we have filed with the Securities and Exchange Commission (the "SEC") using a "shelf" registration process. Under this shelf registration process, the Selling Stockholders may from time to time sell the Shares described in this prospectus in one or more offerings or otherwise as described under "Plan of Distribution."

This prospectus may be supplemented from time to time by one or more prospectus supplements. Such prospectus supplements may also add, update or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you must rely on the information in the prospectus supplement. You should carefully read both this prospectus and any applicable prospectus supplement together with additional information described under the heading "Where You Can Find More Information" before deciding to invest in any Shares being offered.

Neither we nor the Selling Stockholders have authorized anyone to provide any information other than that contained or incorporated by reference in this prospectus or in any applicable prospectus supplement or any applicable free writing prospectus that we have authorized. If anyone provides, or has provided you, with different or inconsistent information, you should not rely on it. The Shares are not being offered in any jurisdiction where the offer is not permitted. You should not assume that the information contained in or incorporated by reference in this prospectus is accurate as of any date other than the respective dates of such document. Our business, financial condition, results of operations and prospects may have changed since those dates.

Unless the context otherwise indicates, references in this prospectus to, "Delcath," "the Company," "we," "our," or "us" mean Delcath Systems, Inc. and its wholly owned subsidiaries. The term "Selling Stockholders" refers, collectively, to the selling stockholders named under the heading "Selling Stockholders" in this prospectus.

When we refer to the Selling Stockholders in this prospectus, we are referring to the persons names as the Selling Stockholders in this prospectus and, as applicable, any donees, pledgees, assignees, transferees or other successors-in-interest selling the Shares received after the date of this prospectus from the Selling Stockholders as a gift, pledge, or other non-sale related transfer.

#### PROSPECTUS SUMMARY

This prospectus summary highlights certain information about us and selected information contained elsewhere in or incorporated by reference into this prospectus. This prospectus summary is not complete and does not contain all of the information that you should consider before making an investment decision. For a more complete understanding of the Company, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus and any applicable prospectus supplement or amendment, including the factors described under the heading "Risk Factors," beginning on page 5 of this prospectus, as well as the information incorporated herein by reference, before making an investment decision.

#### **Company Overview**

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system) ("HEPZATO"), is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as HEPZATO, but without the melphalan hydrochloride, and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan ("CHEMOSAT"), where it has been used at major medical centers to treat a wide range of cancers of the liver. Approximately consisting primarily of metastatic ocular melanoma ("mOM"). Approximately 80% of the estimated 800 patients annually with mOM will be eligible for would be candidates of HEPZATO.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration (the "FDA"). Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan in the treatment of patients with ocular (uveal) melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma). HEPZATO has not been approved for sale in the United States.

Our clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "Focus Trial"), a global registration clinical trial that is investigating objective response rate in mOM, a type of primary liver cancer. Our most advanced development program is the treatment of mOM. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO platform. In addition to HEPZATO's use to treat mOM, we believe that HEPZATO has the potential to treat other liver dominant cancers, such as Metastatic Colorectal Cancer and Cholangiocarcinoma, and plan to begin the study of HEPZATO to treat such conditions in the near future. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

On February 14, 2023, we submitted a NDA resubmission to the FDA for the HEPZATO Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval of the HEPZATO Kit in the treatment of patients with unresectable hepatic-dominant mOM. The resubmission is in response to a September 12, 2013 Complete Response Letter ("CRL"), from the FDA for our NDA in December 2010 seeking approval of its first generation melphalan hydrochloride for injection/hepatic delivery system. The NDA resubmission contains comprehensive data and information on Generation Two HEPZATO Kit relating to the matters identified in the CRL. On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023. We continue to have early access

programs in the United States to make HEPZATO available to mOM patients. We are focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States.

On February 28, 2022, CHEMOSAT received Medical Device Regulation certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, we assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

#### **Private Placement**

On March 27, 2023 we entered into the Preferred Purchase Agreement and the Common Purchase Agreement. None of the securities issued pursuant to the Purchase Agreements were initially registered under the Securities Act or any state securities laws, rather, we offered the securities in reliance on exemption from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof and Rule 506 of Regulation D under the Securities Act. The registration statement of which this prospectus is a part relates to the offer and resale of the Shares issued to, or issuable pursuant to, the Purchase Agreements, as applicable.

#### **Preferred Securities Purchase Agreement**

We entered into a securities purchase agreement (the "Preferred Purchase Agreement") pursuant to which we sold (i) 24,900 shares of Series F-1 Preferred Stock, par value \$0.01 per share (the "Series F-1 Preferred Stock" and together with the Series F-2 Preferred Stock, Series F-3 Preferred Stock and Series F-4 Preferred Stock, the "Preferred Stock"), (ii) the Preferred Tranche A Warrants and (iii) the Preferred Tranche B Warrants for an aggregate offering price of \$24.9 million.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Voting Preferred Stock (the "Certificate of Designation"), upon receipt of approval from our stockholders to approve the issuance of (i) all Common Stock issuable upon conversion of the Preferred Stock, each share of Series F-1 Preferred Stock automatically converted into shares of Common Stock and/or, at the election of the holder thereof, shares of Series F-2 Preferred Stock, in lieu of Common Stock. On June 12, 2023, we received such approval from our stockholders and as a result the 24,900 shares of Series F-1 Preferred Stock were subsequently converted into an aggregate of 4,649,185 shares of Common Stock at a conversion price of \$3.30 per share and 9,624 shares of Series F-2 Preferred Stock, which are convertible into shares of Common Stock at a conversion price of \$3.30 per share.

The aggregate exercise price of the Preferred Tranche A Warrants is approximately \$34.8 million, exercisable for an aggregate of up to 34,860 shares of Series F-3 Preferred Stock until the earlier of 21 days following the Company's announcement of receipt of approval from the FDA for HEPZATO and March 31, 2026 (such approval, the "FDA Approval"). The 34,860 shares of Series F-3 Preferred Stock are convertible into an aggregate of 7,746,436 shares of Common Stock at a conversion price of \$4.50 per share.

The aggregate exercise price of the Preferred Tranche B Warrants is approximately \$24.9 million, exercisable for an aggregate of up to 24,900 shares of Series F-4 Preferred Stock until the earlier of 21 days following the Company's announcement of receipt of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO and March 31, 2026; provided, however, that if the FDA Approval occurs on or before February 15, 2024 and the holder of the Preferred Tranche B Warrant has not exercised its Preferred Tranche A Warrant by or before March 7, 2024, then any Series F-4 Preferred Stock not yet exercised pursuant to the Preferred Tranche B Warrant at such time shall expire. The 24,900 shares of Series F-4 Preferred Stock are convertible into an aggregate of 4,150,000 shares of Common Stock at a conversion price of \$6.00 per share.

#### **Common Securities Purchase Agreement**

We entered into a securities purchase agreement (the "Common Purchase Agreement") pursuant to which we sold (i) 19,646 shares of Common Stock, (ii) the Common Tranche A Warrants and (iii) the Common Tranche B Warrants for an approximate aggregate offering price of \$100,000.

The aggregate exercise price of the Common Tranche A Warrants is approximately \$139,997, exercisable for an aggregate of 31,110 shares of Common Stock until the earlier of 21 days following the Company's announcement of receipt of FDA Approval and March 31, 2026.

The aggregate exercise price of the Common Tranche B Warrants is approximately \$99,998, exercisable for an aggregate of 16,666 shares of Common Stock until the earlier of 21 days following the Company's announcement of receipt of recording at least \$10 million in quarterly U.S. revenue from the commercialization of HEPZATO and March 31, 2026; provided, however, that if the FDA Approval occurs on or before February 15, 2024 and the holder of the Common Tranche B Warrant has not exercised its Common Tranche A Warrant by or before March 7, 2024, then any Common Stock not yet exercised pursuant to the Common Tranche B Warrant at such time shall expire.

#### **Corporate Information**

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100. Our website address is http://www.delcath.com. Information contained in, or accessible through, our website does not constitute any part of, and is not incorporated into, this prospectus.

#### THE OFFERING

Common Stock offered by the Selling Stockholders

(i) 2,916,358 shares of Common Stock, issuable upon conversion of 9,624 shares of Series F-2 Preferred Stock, (ii) 7,746,436 shares of Common Stock issuable upon conversion of 34,860 shares of F-3 Preferred Stock exercisable pursuant to the Preferred Tranche A Warrant, (iii) 4,149,994 shares of Common Stock issuable upon conversion of 24,900 shares of F-4 Preferred Stock exercisable pursuant to the Preferred Tranche B Warrant, (iv) 4,649,185 shares of Common Stock, (v) 31,110 shares of Common Stock, issuable upon exercise of Common Tranche A Warrant, and (vi) 16,666 shares of Common Stock, issuable upon exercise of the Common Tranche B Warrant. See "Selling Stockholders."

Use of Proceeds

We will not receive any of the proceeds from the sale of the Shares covered by this prospectus, except with respect to amounts received by us due to the exercise of any Warrants for cash. We intend to use the proceeds from the exercise of any Warrants for cash for working capital and general corporate purposes. See the section of this prospectus titled "Use of Proceeds."

**Risk Factors** 

Investing in our Common Stock involves a high degree of risk. For a discussion of factors to consider before deciding to invest in our Common Stock, you should carefully review and consider the "Risk Factors" section of this prospectus, as well as the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement or amendment.

Nasdaq Capital Market Symbol

**DCTH** 

#### **RISK FACTORS**

Investing in our Common Stock involves a high degree of risk. Before deciding whether to invest in our Common Stock, you should consider carefully the risks and uncertainties discussed in this section and under the sections titled Risk Factors contained in our most recent Annual Report on Form 10-K and in our subsequent Quarterly Reports on Form 10-Q for the quarterly periods ended subsequent to our filing of such Annual Report on Form 10-K, as well as any amendments or updates to our risk factors reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus, together with other information in this prospectus, the documents incorporated by reference, any prospectus supplement and any free writing prospectus that we may authorize. These risks and uncertainties are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us, or that we currently view as immaterial, may also impair our business. If any of the risks or uncertainties described in our SEC filings or any additional risks and uncertainties actually occur, our business, financial condition, results of operations and cash flow could be materially and adversely affected. In that case, the trading price of our Common Stock could decline and you might lose all or part of your investment. Please also read carefully the section titled "Cautionary Note Regarding Forward-Looking Statements."

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, and the documents incorporated by reference herein, contain, or will contain, "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "intends," "believes," "anticipates," "indicates," "plans," "expects," "suggests," "may," "would," "should," "potential," "designed to," "will," "ongoing," "estimate," "forecast," "predict," "could," and similar references, although not all forward-looking statements contain these words. Forward-looking statements are neither historical facts nor assurances of future performance. These statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Risks that could cause actual results to vary from expected results expressed in our forward-looking statements include, but are not limited to:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- actions by the FDA relating to our New Drug Application resubmission;
- the ability of the Company to respond to FDA queries related to our scheduled Prescription Drug User Fee Act target action dated of August 14, 2023;
- our successful inspections by the FDA or foreign regulatory agencies;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and HEPZATO, generate revenue and successfully obtain reimbursement for the procedure and system;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of CHEMOSAT and HEPZATO and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and HEPZATO;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners;
- our estimates of potential market opportunities and our ability to successfully realize these opportunities; and
- any other factors discussed under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our most recent Annual Report on Form 10-K and in our subsequent Quarterly Reports on Form 10-Q for the quarterly periods ended subsequent to our filing of such Annual Report on Form 10-K, as well as any amendments or updates to our risk factors reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus, together with other information in this prospectus, the documents incorporated by reference, any prospectus supplement and any free writing prospectus that we may authorize.

Forward-looking statements speak only as of the date the statements are made. Except as required under the federal securities laws and rules and regulations of the SEC, we undertake no obligation to update or revise forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information. We caution you not to unduly rely on the forward-looking statements when evaluating the information presented herein.

# **USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of the Shares covered by this prospectus, except with respect to amounts received by us due to the exercise of any Warrants for cash. We intend to use the proceeds from the exercise of any Warrants for cash for working capital and general corporate purposes.

#### SELLING STOCKHOLDERS

The Shares being offered by the Selling Stockholders are those previously issued to the Selling Stockholders, including Common Stock issued upon conversion of the Series F-1 Preferred Stock, and the Common Stock issuable to the Selling Stockholders upon exercise, and, if applicable, conversion of the Preferred Warrant Shares. We are registering the Shares in order to permit the Selling Stockholders to offer the shares for resale from time to time. For additional information regarding the Shares being offered by the Selling Stockholders pursuant to this prospectus, see "Summary—Private Placement" above.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the Common Stock by each of the Selling Stockholders. The second column lists the number of Common Stock beneficially owned by each selling stockholder, based on its beneficial ownership of the Shares, as of June 5, 2023, assuming exercise of the Warrants held by the Selling Stockholders on that date.

The fourth column lists the Shares being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of the Purchase Agreements, as applicable, this prospectus generally covers the resale of the sum of (i) the aggregate number of Common Stock issued or issuable to the Selling Stockholders as a result of conversion of the Series F-1 Preferred Stock and/or Series F-2 Preferred Stock, (ii) the number of shares of Common Stock issued pursuant to the Common Purchase Agreement and (iii) the number of shares of Common Stock issuable upon exercise of the Warrants (and conversion, if necessary, of the Preferred Warrant Shares). The fourth column assumes the sale of all of the Shares offered by the Selling Stockholders pursuant to this prospectus.

Pursuant to the Certificate of Designation, a Selling Stockholder shall not have the right to convert any portion of the Series F Preferred Stock and such Series F Preferred Stock shall not be automatically converted, to the extent that after giving effect to such conversion, such Selling Stockholder, together with its affiliates, any other persons acting as a group together, and any other persons whose beneficial ownership of Common Stock would be aggregated with the Selling Stockholder's and the other attribution parties for purposes of Section 13(d) of the Exchange Act would beneficially own in excess of 9.99% of the shares of Common Stock outstanding immediately after giving effect to such conversion, excluding for purposes of such determination shares of Common Stock which would be issuable upon exercise of the remaining, unconverted portion of the Series F Preferred Stock beneficially owned (the "Preferred F Stock Blocker"). Under the terms of the Common Warrants, a Selling Stockholder may not exercise the Warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of Common Stock which would exceed 9.99% of our then outstanding Common Stock following such exercise, excluding for purposes of such determination Common Stock issuable upon exercise of the Warrants which have not been exercised.

The information in the following table has been provided to us by or on behalf of the Selling Stockholders and the Selling Stockholders may have sold, transferred or otherwise disposed of all or a portion of their securities after the date on which they provided us with information regarding their securities. The Selling Stockholders may sell all, some or none of their Shares in this offering. See "Plan of Distribution."

Name of Selling Stockholder	Total Shares of Common Stock Beneficially Owned Prior to Offering (1)	% of Shares of Common Stock Beneficially Owned Prior to Offering (1)	Maximum Number of Shares of Common Stock to be Sold Pursuant to the Prospectus (2)	Number of Shares of Common Stock Beneficially Owned After Offering (2)	% of Shares of Common Stock Beneficially Owned After Offering*
Vivo Opportunity Fund Holdings, L.P. (3)	1,178,787	9.99%	4,880,741		
Entities affiliated with Logos Capital (4)	1,178,787	9.99%	4,880,351	_	_
Entities affiliated with BVF Partners (5)	1,178,787	9.99%	4,880,044	_	_
Entities affiliated with Rosalind Advisors, Inc. (6)	1,178,787	9.99%	1,678,736	3,010,009	9.99%
Stonepine Capital, LP (7)	976,008	8.42%	976,008	_	_
Mitchell Robbins (8)	1,178,787	9.99%	701,812	1,025,000	3.40%
Serrado Opportunity Fund LLC (9)	468,484	4.22%	468,484	_	_
Bigger Capital Fund, LP (10)	663,709	5.88%	195,200	468,509	1.55%
District 2 Capital Fund LP (11)	390,550	3.55%	195,200	157,222	*
ADAR1 Partners, LP (12)	400,497	3.63%	390,403	10,094	*
Triple Gate Partners, LP (13)	512,380	4.60%	195,200	317,176	1.05%
Gerard Michael (14)	870,867	7.58%	67,423	803,444	2.67%

- \* Percentage not listed if less than 1%.
- (1) "Beneficial ownership" means that a person, directly or indirectly, has or shares voting or investment power with respect to a security or has the right to acquire such power within 60 days. The number of shares beneficially owned is determined as of June 5, 2023, and the percentage is based upon 10,620,930 shares of our Common Stock outstanding as of June 5, 2023. In computing the number of shares of our Common Stock beneficially owned by a Selling Stockholder and the percentage ownership of such Selling Stockholder, we deemed outstanding shares of Common Stock issuable upon the exercise (and conversion, if applicable) of the Warrants and Series F-2 Preferred Stock, held by that Selling Stockholder. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other Selling Stockholder.
- (2) Assumes sale of all Shares covered by this prospectus and no further acquisitions of shares of Common Stock by the Selling Stockholders.
- (3) Consists of 1,178,787 shares of Common Stock. In addition to the foregoing shares of Common Stock, as of June 5, 2023, Vivo Opportunity Fund Holdings, L.P. held (i) 715,454 shares of Common Stock issuable upon conversion of 2,361 shares of Series F-2 Preferred Stock, (ii) 1,944,666 shares of Common Stock issuable upon conversion of 8,751 shares of Series F-3 Preferred Stock and (iii) 1,041,833 shares of Common Stock issuable upon conversion of 6,251 shares of Series F-4 Preferred Stock that are not included in the shares reported under "Total Shares of Common Stock Beneficially Owned Prior to Offering" because they are subject to limitations on exercisability if such exercise would result in Vivo Opportunity Fund Holdings, L.P. beneficially owning more than 9.99% of our outstanding Common Stock. Vivo Opportunity, LLC is the general partner of Vivo Opportunity Fund Holdings, L.P. and Gaurav Aggarwal, Kevin Dai, Hongbo Lu, Frank Kung and Michael Chang are the voting members of Vivo Opportunity, LLC. The Selling Stockholder's address is c/o Vivo Capital LLC, 192 Lytton Avenue, Palo Alto, CA 94301.
- (4) Consists of 884,090 shares of Common Stock held by Logos Global Master Fund, LP ("Logos Global") and 294,697 shares of Common Stock held by Logos Opportunities Fund III, LP ("Logos Opportunities", and together with Logos Global, the "Logos Entities"). In addition to the foregoing shares of Common Stock, as of June 5, 2023, (i) Logos Global held 536,566 shares of Common Stock issuable upon conversion of 1,771 shares of Series F-2 Preferred Stock, 486,000 shares of Common Stock issuable upon conversion of 2,187

- shares of Series F-3 Preferred Stock and 260,333 shares of Common Stock issuable upon conversion of 1,562 shares of Series F-4 Preferred Stock and (ii) Logos Opportunities held 178,787 shares of Common Stock issuable upon conversion of 590 shares of Series F-2 Preferred Stock, 1,458,444 shares of Common Stock issuable upon conversion of 6,563 shares of Series F-3 Preferred Stock and 781,333 shares of Common Stock issuable upon conversion of 4,688 shares of Series F-4 Preferred Stock that are not included in the shares reported under "Total Shares of Common Stock Beneficially Owned Prior to Offering" because they are subject to limitations on exercisability if such exercise would result in the Logos Entities beneficially owning more than 9.99% of our outstanding Common Stock.
- Consists of 630,303 shares of Common Stock held by Biotechnology Value Fund, L.P. ("BVF LP"), 481,515 shares of Common Stock held by Biotechnology Value Fund II, L.P. ("BVF2 LP"), 51,515 shares of Common Stock held by Biotechnology Value Trading Fund OS LP ("BVF OS") and 15,454 shares of Common Stock held by MSI BVF SPV, LLC ("MSI BVF"), and together with BVF LP, BVF2 LP and BVF OS, the "BVF Entities"). In addition to the foregoing shares of Common Stock, as of June 5, 2023, (i) BVF LP held 381,818 shares of Common Stock issuable upon conversion of 1,260 shares of Series F-2 Preferred Stock, 1,039,111 shares of Common Stock issuable upon conversion of 4,676 shares of Series F-3 Preferred Stock and 556,666 shares of Common Stock issuable upon conversion of 3,340 shares of Series F-4 Preferred Stock, (ii) BVF2 LP held 288,181 shares of Common Stock issuable upon conversion of 951 shares of Series F-2 Preferred Stock, 790,222 shares of Common Stock issuable upon conversion of 3,556 shares of Series F-3 Preferred Stock and 423,333 shares of Common Stock issuable upon conversion of 2,540 shares of Series F-4 Preferred Stock, (iii) BVF OS held 36,363 shares of Common Stock issuable upon conversion of 120 shares of Series F-2 Preferred Stock, 90,222 shares of Common Stock issuable upon conversion of 406 shares of Series F-3 Preferred Stock and 48,333 shares of Common Stock issuable upon conversion of 290 shares of Series F-4 Preferred Stock and (iv) MSI BVF held 8,787 shares of Common Stock issuable upon conversion of 29 shares of Series F-2 Preferred Stock, 24,888 shares of Common Stock issuable upon conversion of 112 shares of Series F-3 Preferred Stock and 13,333 shares of Common Stock issuable upon conversion of 80 shares of Series F-4 Preferred Stock, certain of which are not included in the shares reported under "Total Shares of Common Stock Beneficially Owned Prior to Offering" because they are subject to limitations on conversion if such conversion would result in the BVF Entities beneficially owning more than 9.99% of our outstanding Common Stock, BVF I GP LLC is the general partner of BVF LP, BVF II GP LLC is the general partner of BVF2 LP, BVF Partners OS Ltd. is the general partner of BVF OS. BVF GP Holdings is the sole member of BVF I GP LLC and BVF II GP LLC. BVF Partners L.P. is the sole member of BVF Partners OS Ltd. and investment manager of BVF LP, BVF QS and MSI BVF. BVF Inc. is the general partner of BVF Partners L.P. Mark N. Lampert is director and officer of BVF Inc. Each of BVF I GP LLC, BVF II GP LLC, BVF Partners OS Ltd., BVF GP Holdings LLC, BVF Partners L.P. BVF Inc. and Mr. Lampert disclaims beneficial ownership of securities beneficially owned by the Selling Stockholders. The Selling Stockholder's address is c/o BVF Partners L.P., 44 Montgomery St, 40th Floor, San Francisco, CA 94104.
- Consists of 938,828 shares of Common Stock and 239,959 shares of Common Stock held by entities affiliated with Rosalind Advisors, Inc. which includes Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. ("Rosalind") issuable upon exercise of 239,959 warrants (the "Rosalind Warrants"). In addition to the foregoing shares of Common Stock, as of June 5, 2023, Rosalind held (i) an aggregate of 219,180 shares of Common Stock issuable upon the conversion of an aggregate 2,192 shares of Series E Preferred Stock, at a conversion rate of \$1,198 per share, following an election by Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. to convert an aggregate \$2 million principal amount of 8% senior secured promissory notes issued by the Company to such Selling Stockholders, together and with all accrued interest thereon into shares of Series E Preferred Stock (ii) 914,865 shares of Common Stock issuable upon conversion of 9,148 shares of Series E-1 Preferred Stock, (iii) an aggregate of 175,256 shares of Common Stock issuable upon the conversion of an aggregate 1,752 shares of Series E-1 Preferred Stock, (iv) 480,006 shares of Common Stock issuable upon exercise of the Rosalind Warrants, (v) 651,515 shares of Common Stock issuable upon conversion of 2,150 shares of Series F-2 Preferred Stock, (vi) 668,888 shares of Common Stock issuable upon conversion of Series F-4 Preferred Stock. The

foregoing clauses (i) through (vii) reflect securities convertible into shares of Common Stock, all of which are subject to a beneficial ownership blocker that otherwise limits their ability to exercise or convert such security if such exercise would result in beneficially owning more than 9.99% of our outstanding Common Stock and therefore such securities are not included in the shares reported under "Total Shares of Common Stock Beneficially Owned Prior to Offering." Mr. Salamon and Dr. Aharon are members of the Board of Directors of the Company pursuant to a Board Appointment Agreement. Mr. Salamon and Dr. Aharon disclaim beneficial ownership with respect to these securities. The Selling Stockholder's address is c/o Rosalind Advisors, Inc., 15 Wellesley Street West, Suite 326, Toronto, ON M4Y OG7.

- (7) Consists of (i) 378,787 shares of Common Stock, (ii) 388,888 shares of Common Stock issuable upon conversion of 1,750 shares of Series F-3 Preferred Stock and (iii) 208,333 shares of Common Stock issuable upon conversion of 1,250 shares of Series F-4 Preferred Stock. The Selling Stockholder's address is Stonepine Capital Management, Attn: Jeff Nunnenkamp, 919 NW Bond Street, Suite 204, Bend, OR 97703.
- (8) Consists of 1,178,787 shares of Common Stock. In addition to the foregoing shares of Common Stock, as of June 5, 2023, Mitchell Robbins held (i) 118,787 shares of Common Stock issuable upon conversion of 392 shares of Series F-2 Preferred Stock, (ii) 279,555 shares of Common Stock issuable upon conversion of 1,258 shares of Series F-3 Preferred Stock and (iii) 149,833 shares of Common Stock issuable upon conversion of 899 shares of Series F-4 Preferred Stock that are not included in the shares reported under "Total Shares of Common Stock Beneficially Owned Prior to Offering" because they are subject to limitations on exercisability if such exercise would result in Mitchell Robbins beneficially owning more than 9.99% of our outstanding Common Stock. The Selling Stockholder's address is 461 South Maya Palm Drive, Boca Raton, FL 33432.
- (9) Consists of (i) 181,818 shares of Common Stock, (ii) 186,666 shares of Common Stock issuable upon conversion of 840 shares of Series F-3 Preferred Stock and (iii) 100,000 shares of Common Stock issuable upon conversion of 600 shares of Series F-4 Preferred Stock. The Selling Stockholder's address is Serrado Capital LLC (c/o Stewart Hen), 40 Worth Street, Suite 702, New York, NY 10013.
- (10) Consists of (i) 386,712 shares of Common Stock, (ii) 77,777 shares of Common Stock issuable upon conversion of 350 shares of Series F-3 Preferred Stock, (iii) 41,666 shares of Common Stock issuable upon conversion of 250 shares of Series F-4 Preferred Stock and (iv) 157,554 shares of Common Stock which may be acquired upon exercise of certain common stock warrants. Michael Bigger has the power to vote or dispose of the shares owned by Bigger Capital Fund, LP, Matthias Bigger—UTMA and the Andreas Bigger Irrevocable Trust Agreement. The Selling Stockholder's address is 11700 W Charleston Blvd 170-659, Las Vegas, NV 89135. Michael Bigger disclaims beneficial ownership over these securities.
- (11) Consists of (i) 236,385 shares of Common Stock, (ii) 34,722 shares of Common Stock which may be acquired upon exercise of certain common stock warrants, (iii) 77,777 shares of Common Stock issuable upon conversion of 350 shares of Series F-3 Preferred Stock and (iv) 41,666 shares of Common Stock issuable upon conversion of 250 shares of Series F-4 Preferred Stock. Michael Bigger has the power to vote or dispose of the shares owned by District 2 Capital Fund LP. The Selling Stockholder's address is 14 Wall Street, 2nd Floor, Huntington, New York 11743.

  Michael Bigger disclaims beneficial ownership over these securities.
- (12) Consists of (i) 161,608 shares of Common Stock, (ii) 155,555 shares of Common Stock issuable upon conversion of 700 shares of Series F-3 Preferred Stock and (iii) 83,333 shares of Common Stock issuable upon conversion of 500 shares of Series F-4 Preferred Stock. The Selling Stockholder's address is 3503 Wild Cherry Drive, Building 9, Austin, TX 78738.
- (13) Consists of (i) 392,935 shares of Common Stock,(ii) 77,777 shares of Common Stock issuable upon conversion of 350 shares of Series F-3 Preferred Stock and (iii) 41,667 shares of Common Stock issuable upon conversion of 250 shares of Series F-4 Preferred Stock. The Selling Stockholder's address is 445 Central Ave, Suite 317, Cedarhurst, NY 11516.
- (14) Consists of (i) 177,589 shares of Common Stock, (ii) 645,502 shares of Common Stock that may be acquired through the exercise of options, (iii) 47,776 shares of Common Stock, issuable upon exercise of the Common Warrants.

# **Relationship with Selling Stockholders**

On April 8, 2020, we entered into a Board Appointment Agreement, dated as of April 8, 2020, with Rosalind, pursuant to which Steven Salamon and Gil Aharon, who are principals of Rosalind, have been appointed as directors of the Company's board of Directors. Certain shares of Common Stock registered for resale hereunder are also held by Gerard Michel, who is the Chief Executive Officer of the Company.

Other than this relationship with Rosalind and Gerard Michel, none of the Selling Stockholders has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares of Common Stock or other securities.

#### PLAN OF DISTRIBUTION

The Selling Stockholders, which includes any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their Shares covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the Common Stock are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling the Shares:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplements to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholder may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses that we incur incident to the registration of the Shares covered by this prospectus. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective continuously effective under the Securities Act until the date that all the Shares being offered by the Selling Stockholders (i) have been sold pursuant to this registration statement or pursuant to Rule 144, or (ii) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for us to be in compliance with the current public information requirement under Rule 144. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

#### **LEGAL MATTERS**

The validity of the shares of Common Stock to be offered for resale by the Selling Stockholders under this prospectus will be passed upon for us by Cooley LLP, Boston, Massachusetts.

#### **EXPERTS**

The consolidated financial statements as of December 31, 2022 and 2021 and for each of the two years in the period ended December 31, 2022 incorporated by reference in this prospectus have been so incorporated in reliance on the report of Marcum, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

#### WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and does not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus for a copy of such contract, agreement or other document. Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov.

You may also access our SEC filings at our website www.delcath.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities.

#### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information contained in other documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded, for purposes of this prospectus, to the extent that a statement contained in or omitted from this prospectus, or in any other subsequently filed document that also is or is deemed to be incorporated by reference herein, modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below which have been filed by us:

- Our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 27, 2023, including those portions of the Form 10-K incorporated by reference from our <u>definitive proxy statement</u> filed with the SEC on May 1, 2023;
- Our Quarterly Report on Form 10-Q for the period ended March 31, 2023, filed with the SEC on May 22, 2023;
- Our Current Reports on Form 8-K, filed with the SEC on March 28, 2023, March 30, 2023, June 7, 2023 and June 13, 2023; and
- The description of our Common Stock contained in our registration on <u>Form 8-Al2B</u> (File No. 001-16133) filed with the SEC on April 30, 2020, including any amendment or report filed for the purpose of updating such description.

All documents we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any report or documents that is not deemed filed under such provisions, (1) on or after the date of filing of the registration statement containing this prospectus and prior to the effectiveness of the registration statement and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn, shall be deemed incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of those documents and will be automatically updated and, to the extent described above, supersede information contained or incorporated by reference in this prospectus and previously filed documents that are incorporated by reference in this prospectus.

Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC pursuant to Item 2.02, 7.01 or 9.01 of Form 8-K. Upon written or oral request, we will provide without charge to each person, including any beneficial owner, to whom a copy of the prospectus is delivered a copy of any or all of the reports or documents incorporated by reference herein (other than exhibits to such documents, unless such exhibits are specifically incorporated by reference herein). You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019.

\* \* \*



# Up to 19,509,749 Shares of Common Stock Offered by the Selling Stockholders

PROSPECTUS

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth various expenses being borne by the Company in connection with the sale and distribution of the securities being registered. All of the amounts shown are estimates except for the Securities and Exchange Commission Registration Fee.

Securities and Exchange Commission registration fee	\$ 14,963
Accountants' fees and expenses	10,000
Legal fees and expenses	125,000
Miscellaneous	137
Total:	\$150,100

#### Item 15. Indemnification of Directors and Officers.

The Company is incorporated under the laws of the State of Delaware. Section 102(b)(7) of Delaware's General Corporation Law (the "DGCL") allows a corporation to provide in its certificate of incorporation that a director of the corporation will not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except where the director breached the duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides for this limitation of liability.

Section 145 of the DGCL ("Section 145"), provides that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, were or are a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests, provided that no indemnification is permitted without judicial approval if the officer, director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his or her status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145.

Article SEVENTH of the Company's amended and restated certificate of incorporation provides that no person serving as a director of the Company shall be personally liable to the Company or its stockholders for

breach of his or her fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or a knowing violation of law, authorized the payment of a dividend or approved a stock repurchase in violation of the DGCL or obtained an improper personal benefit.

Article EIGHTH of the Company's amended and restated certificate of incorporation requires the Company to indemnify any person who may be indemnified by a Delaware corporation pursuant to Section 145 of the DGCL in each situation where the Company is permitted to indemnify such persons.

We have entered into indemnification agreements with our executive officers and directors pursuant to which we have agreed to indemnify such persons against all expenses and liabilities incurred or paid by such person in connection with any proceeding arising from the fact that such person is or was an officer or director of our company, and to advance expenses as incurred by or on behalf of such person in connection therewith.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, provision of our certificate of incorporation, our bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

In addition, we maintain standard policies of insurance that provide coverage (1) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (2) to us with respect to indemnification payments that we may make to such directors and officers.

#### Item 16. Exhibits.

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

Exhibit Number	Exhibit Description	Schedule / Form	File Number	Exhibit	File Date
3.1	Restated Certificate of Incorporation of the Registrant	Form S-1/A	333-233396	3.1	September 25, 2019
3.2	Amendment to the Amended and Restated Certificate of Incorporation of the Registrant dated October 17, 2019	Form 8-K	001-16133	3.1	October 23, 2019
3.3	Certificate of Correction to Amendment to the Amended and Restated Certificate of Incorporation of the Registrant dated October 22, 2019	Form 8-K	001-16133	3.2	October 23, 2019
3.4	Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, effective December 24, 2019	Form 8-K	001-16133	3.1	December 30, 2019
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated November 23, 2020	Form 8-K	001-16133	3.1	November 24, 2020
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated June 12, 2023	Form 8-K	001-16133	3.1	June 13, 2023
3.6	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the Company's Registration Statement on Form SB-2)				

Exhibit Number	Exhibit Description	Schedule / Form	File Number	Exhibit	File Date
4.1	Form of Preferred Tranche A Warrant	Form 8-K	001-16133	4.1	March 30, 2023
4.2	Form of Preferred Tranche B Warrant	Form 8-K	001-16133	4.2	March 30, 2023
4.3	Form of Common Tranche A Warrant	Form 8-K	001-16133	4.3	March 30, 2023
4.4	Form of Common Tranche B Warrant	Form 8-K	001-16133	4.4	March 30, 2023
5.1	Opinion of Cooley LLP				Filed Herewith
10.1	Form of Securities Purchase Agreement, dated March 27, 2023, by and among Delcath Systems, Inc. and the purchasers named therein	Form 8-K	001-16133	10.1	March 27, 2023
10.2	Form of Securities Purchase Agreement, dated March 27, 2023, by and between Delcath Systems, Inc. and the purchaser named therein	Form 8-K	001-16133	10.2	March 27, 2023
23.1	Consent of Marcum LLP, independent registered public accounting firm				Filed Herewith
23.2	Consent of Cooley LLP (included in Exhibit 5.1)				Filed Herewith
24.1	Power of Attorney (see signature page to this registration statement)				Filed Herewith
107	Filing Fee Table				Filed Herewith

### Item 17. Undertakings.

The Registrant hereby undertakes:

(a)

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
  - (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, however, that paragraphs a(i), a(ii) and a(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
  - (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
- (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
- (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(l)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date;
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on June 14, 2023.

#### POWER OF ATTORNEY

We, the undersigned officers and directors of Delcath Systems, Inc. hereby severally constitute and appoint Gerard Michel our true and lawful attorney with full power to sign for us and in our names in the capacities indicated below the Registration Statement on Form S-3 filed herewith and any and all amendments (including post-effective amendments) to said Registration Statement, and any registration statement filed pursuant to Rule 462 under the Securities Act of 1933, as amended, in connection with said Registration Statement, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, and generally to do all such things in our name and on our behalf in our capacities as officers and directors to enable Delcath Systems, Inc. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney, or his substitute or substitutes, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

#### **DELCATH SYSTEMS, INC.**

By: /s/ Gerard Michel
Gerard Michel
Chief Executive Officer

Signature	Title	Date
/s/ Gerard Michel Gerard Michel	Chief Executive Officer and Director (Principal Executive Officer)	June 14, 2023
/s/ Sandra Pennell Sandra Pennell	Senior Vice President of Finance (Principal Accounting and Financial Officer)	June 14, 2023
/s/ John R. Sylvester John R. Sylvester	Chairman of the Board	June 14, 2023
/s/ Elizabeth Czerepak Elizabeth Czerepak	Director	June 14, 2023
/s/ Steven Salamon Steven Salamon	Director	June 14, 2023
/s/ Roger G. Stoll, Ph.D. Roger G. Stoll, Ph.D.	Director	June 14, 2023
/s/ Gilad Aharon Gilad Aharon	Director	June 14, 2023



Christina T. Roupas +1 312-861-6670 croupas@cooley.com

June 14, 2023

Delcath Systems, Inc. 1633 Broadway, Suite 22C New York, New York 10019

#### Ladies and Gentlemen:

We have acted as counsel to Delcath Systems, Inc., a Delaware corporation (the "Company"), in connection with the filing of a Registration Statement on Form S-3 (the "Registration Statement") by the Company under the Securities Act of 1933, as amended (the "Securities Act"), covering the resale by certain selling stockholders of up to 19,509,749 shares (the "Shares") of the Company's common stock, par value \$0.01 per share ("Common Stock"), consisting of (i) 4,649,185 shares of Common Stock (the "Common Shares") that are currently outstanding, (ii) up to 2,916,358 shares of Common Stock issuable upon conversion of 9,624 shares of Series F-2 Convertible Preferred Stock, par value \$0.01 per share (the "Series F-2 Shares") that are currently outstanding and (iii) up to 11,944,206 shares of Common Stock (the "Warrant Shares") consisting of (a) 7,746,436 shares of Common Stock issuable upon conversion of 34,860 shares of Series F-3 Preferred Stock, par value \$0.01 per share (the "Series F-3 Shares"), issuable upon the exercise of preferred stock tranche A warrants (the "Preferred Tranche A Warrants"), (b) 4,149,994 shares of Common Stock issuable upon conversion of 24,900 shares of Series F-4 Preferred Stock, par value \$0.01 per share (together with the Series F-3 Shares, the "Preferred Shares"), issuable upon the exercise of preferred stock tranche B warrants (together with the Preferred Tranche A Warrants, the "Preferred Warrants"), (c) 31,110 shares of Common Stock, issuable upon exercise of the common stock tranche A warrants ("Common Tranche A Warrants") and (d) 16,666 shares of Common Stock issuable upon exercise of common stock tranche B warrants (together with the Common Tranche A Warrants, the "Common Warrants," and together with the Preferred Warrants, the "Warrants"). The Common Shares, the Series F-2 Shares and the Warrants were issued pursuant to a Securities Purchase Agreement, dated March 27, 2023 by and between the Company and the purchaser named therein (the "Common Purchase Agreement") and a Securities Purchase Agreement, dated March 27, 2023, by and among the Company and the purchasers named therein (the "Preferred Purchase Agreement," together with the Common Purchase Agreement, the "Purchase Agreements").

In connection with this opinion, we have examined and relied upon the Registration Statement and related prospectus, the Company's certificate of incorporation and bylaws, each as currently in effect, the Purchase Agreements, the Warrants and such other documents, records, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery of all documents by all persons other than the Company where execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

COOLEY LLP 110 N. WACKER DRIVE, SUITE 4200 CHICAGO, IL 60606 T: (312) 881-5000 F: (312) 896-9584 COOLEY.COM



Delcath Systems, Inc. June 14, 2023 Page Two

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion as to whether any particular laws other than those identified above are applicable to the subject matter hereof. We are not rendering any opinion as to compliance with any federal or state antifraud law, rule or regulation relating to securities, or to the sale or issuance thereof.

With respect to the Warrant Shares, the Series F-2 Shares and the Preferred Shares, we express no opinion to the extent that future issuances of securities of the Company, adjustments to outstanding securities of the Company and/or other matters cause the Warrants to be exercisable for more shares of Common Stock than the number available for issuance by the Company. Further, we have assumed the exercise price of the Warrants will not be adjusted to an amount below the par value per share of the Common Stock or the Preferred Shares.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that (i) the Common Shares are validly issued, fully paid and nonassessable, (ii) the portion of the other Shares issuable upon conversion or exercise of the Series F-2 Shares or the Common Warrants, when issued in accordance with the terms of the Series F-2 Shares or the Common Warrants will be validly issued, fully paid and nonassessable and (iii) the portion of the other Shares issuable upon conversion of the Preferred Shares, when issued in accordance with the terms of the Preferred Shares following issuance of the Preferred Shares in accordance with the terms of the Preferred Warrants, will be validly issued, fully paid and nonassessable.

We hereby consent to the reference to our firm under the caption "Legal Matters" in the prospectus included in the Registration Statement and to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Securities and Exchange Commission thereunder.

Very truly yours,

COOLEY LLP

By: /s/ Christina T. Roupas
Christina T. Roupas

COOLEY LLP 110 N. WACKER DRIVE, SUITE 4200 CHICAGO, IL 60606 T: (312) 881-5000 F: (312) 896-9584 COOLEY.COM

#### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in this Registration Statement of Delcath Systems, Inc. and Subsidiaries on Form S-3 of our report dated March 27, 2023, which includes an explanatory paragraph about the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Delcath Systems, Inc. as of December 31, 2022 and 2021 and for the years ended December 31, 2022 and 2021 appearing in the Annual Report on Form 10-K of Delcath Systems, Inc. for the year ended December 31, 2022. We also consent to the reference to our firm under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Marcum LLP

Marcum LLP New York, NY June 14, 2023

#### **Calculation of Filing Fee Tables**

S-3 (Form Type)

#### Delcath Systems, Inc.

(Exact Name of Registrant as Specified in its Charter)

#### **Table 1: Newly Registered Securities**

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1)	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Common stock, par value \$0.01 per share	Rule 457(c)	19,509,749 (2)		\$135,007,463.08	0.0001102	\$14,877.83
	Total Offering Amounts			\$135,007,463.08		\$14,877.83		
	Total Fees Previously Paid					—		
	Total Fee Offsets					_		
	Net Fee Due						\$14,877.83	

- (1) Represents the shares of common stock, \$0.01 par value per share (the "Common Stock"), of Delcath Systems, Inc. (the "Registrant") that will be offered for resale by the selling stockholders pursuant to the registration statement to which this exhibit is attached. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the shares being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable as a result of stock splits, stock dividends or similar transactions with respect to the shares being registered hereunder.
- (2) Consists of an aggregate of 19,509,749 shares of the Registrant's common stock, including 2,916,358 shares of Common Stock, issuable upon conversion of 9,624 shares of Series F-2 Convertible Preferred Stock, par value \$0.01 per share, (ii) 7,746,436 shares of Common Stock issuable upon conversion of 34,860 shares of F-3 Preferred Stock exercisable pursuant to the preferred stock tranche A warrants to acquire shares of Series F-3 Preferred Stock, par value \$0.01 per share, (iii) 4,149,994 shares of Common Stock issuable upon conversion of 24,900 shares of F-4 Preferred Stock exercisable pursuant to the preferred stock tranche B warrants to acquire shares of Series F-4 Preferred Stock, par value \$0.01 per share, (iv) 4,649,185 shares of Common Stock, (v) 31,110 shares of Common Stock, issuable upon exercise of the common stock tranche A warrants and (vi) 16,666 shares of Common Stock issuable upon exercise of common stock tranche B warrants of the Registrant.
- (3) This estimate is made pursuant to Rule 457(c) of the Securities Act solely for purposes of calculating the registration fee. The price per share and aggregate offering price are based upon the average of the high and low prices of the Registrant's common stock on June 14, 2023, as reported on the Nasdaq Global Market.