
**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, Esq.
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Boston, Massachusetts 02116
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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.

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.

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

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 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement is effective. This prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, PRELIMINARY PROSPECTUS DATED SEPTEMBER 7, 2022



Up to 1,257,705 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 1,257,705 shares of the Company’s Common Stock, par value \$0.01 per share (the “Common Stock”), which consist of (i) 690,954 shares (the “Shares”) of Common Stock held by the Selling Stockholders and (ii) 566,751 shares of Common Stock (the “Warrant Shares” and together with the Shares, the “Securities”) issuable upon the exercise of pre-funded warrants (the “Warrants”) held by the Selling Stockholders. We are registering the offer and sale of the Common Stock held by the Selling Stockholders to satisfy the registration rights they were granted pursuant to a registration rights agreement entered into on July 18, 2022 in connection with the securities purchase agreement as of even date thereof. While we will not receive any proceeds from the sale of the Common Stock by the Selling Stockholders, we will receive proceeds from the exercise of any Warrants for cash.

Our registration of shares of Common Stock covered by this prospectus does not mean that the Selling Stockholders will offer or sell any such shares. The Selling Stockholders may sell shares of Common Stock 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 of Common Stock 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 Common Stock hereunder. We will bear all costs, expenses and fees in connection with the registration of the Common Stock. 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 September 6, 2022, the closing price for our Common Stock, as reported on The NASDAQ Capital Market, was \$4.21 per share. Our principal executive offices are located at 1633 Broadway, Suite 22C, New York, New York 10019.

Investing in these securities involves certain risks. See “[Risk Factors](#)” on page 5 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 _____, 2022

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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, or the SEC, using a “shelf” registration process. Under this shelf registration process, the Selling Stockholders may from time to time sell the Common Stock 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 Common Stock 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. We take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. The Common Stock is 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.

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.

Overview of the Company

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), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. HEPZATO has not been approved for sale in the United States. 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, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver.

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, or 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, hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and neuroendocrine tumors) and one for doxorubicin in the treatment of patients with hepatocellular carcinoma).

Our most advanced development program is the treatment of ocular melanoma liver metastases, or mOM, a type of primary liver cancer. 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 indications which will maximize the value of the HEPZATO platform. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, we announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint. Based on the FOCUS Trial results, we are preparing to submit a new drug application, or NDA, to the FDA for HEPZATO. We held a pre-NDA meeting with the FDA in April 2022. Based on the feedback from FDA, we do not believe any additional pre-clinical or clinical studies are required to re-file the NDA. Due to vendor delays in delivering certain reports, we plan to submit an NDA to the FDA by the end of the third quarter of 2022. We have opened two Expanded Access Program sites to provide access to patients who meet the inclusion criteria during the pendency of FDA’s review of HEPZATO.

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 have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Private Placement

Securities Purchase Agreement

On July 18, 2022 we entered into a Securities Purchase Agreement with certain accredited investors (each an “Investor” and collectively, the “Investors”) pursuant to which the Company agreed to sell and issue to the

Investors in a private placement (the “Private Placement”) (i) an aggregate of 690,954 Shares, at a purchase price of \$3.98 per share, and (ii) in lieu of shares of Common Stock, 566,751 Warrants, at a purchase price of \$3.97 per Warrant. The Warrants have an exercise price of \$0.01 per share of Common Stock, and are immediately exercisable and remain exercisable until exercised in full.

The Private Placement closed on July 20, 2022. We received gross proceeds from the Private Placement of approximately \$5.0 million, before deducting offering expenses payable by us. We intend to use the net proceeds of the Private Placement for working capital and other general corporate purposes.

Neither the Warrants issued to the Investor nor the Shares were initially registered under the Securities Act or any state securities laws. We have relied on the exemption from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof and Rule 506 of Regulation D thereunder. In connection with the Investor’s execution of the Purchase Agreement, the Investor represented to us that it is an “accredited investor” as defined in Regulation D of the Securities Act and that the Warrants purchased by it were acquired solely for its own account and for investment purposes and not with a view to the future sale or distribution.

Registration Rights Agreement

On July 18, 2022, in connection with the Private Placement, we entered into a registration rights agreement (the “Registration Rights Agreement”) with the Investors, providing for the registration for resale of the Securities (including the shares of Common Stock underlying the Warrants) that are not then registered on an effective registration statement, pursuant to a registration statement (the “Registration Statement”) to be filed with the Securities and Exchange Commission on or prior to September 16, 2022. We have agreed to use our best efforts to cause the Registration Statement to be declared effective as soon as possible, but in no event later than 75 days of the closing of the Private Placement (or 120 days in the event of a full review of the Registration Statement by the SEC) (the “Effectiveness Date”), and to keep the Registration Statement continuously effective for a period that extends from the first date on which the SEC issues an order of effectiveness in relation to the Registration Statement until such date that all registrable securities (as such term is defined in the Registration Rights Agreement) covered by the Registration Statement have been sold thereunder or pursuant to Rule 144 or may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144. We have agreed to be responsible for all reasonable fees and expenses incurred in connection with the registration of the registrable securities under the Registration Rights Agreement. Additionally, we have agreed to indemnify the Selling Stockholders for losses, claims, damages or liabilities, joint or several, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission of any material fact contained in any registration statement, subject to certain exceptions.

The registration statement of which this prospectus is a part relates to the offer and resale of the shares of Common Stock issued to the Purchasers pursuant to the Purchase Agreement, including the shares issuable upon exercise of the Warrants. When we refer to the Selling Stockholders in this prospectus, we are referring to the Investors named in this prospectus as the Selling Stockholders and, as applicable, any donees, pledgees, assignees, transferees or other successors-in-interest selling the Securities received after the date of this prospectus from the Selling Stockholders as a gift, pledge, or other non-sale related transfer.

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

This prospectus relates to the resale from time to time by the Selling Stockholders identified in this prospectus of up to 1,257,705 shares of the Company's Common Stock, which consist of (i) 690,954 shares of Common Stock held by the Selling Stockholders and (ii) 566,751 shares of Common Stock (the "Warrant Shares" and together with the Shares, the "Securities") issuable upon the exercise of pre-funded warrants held by the Selling Stockholders. We are registering the offer and sale of the Common Stock held by the Selling Stockholders to satisfy the registration rights they were granted pursuant to a registration rights agreement entered into on July 18, 2022 in connection with the securities purchase agreement as of even date thereof. While we will not receive any proceeds from the sale of the Common Stock by the Selling Stockholders, we will receive proceeds from the exercise of any Warrants for cash.

| | |
|---|--|
| Issuer | Delcath Systems, Inc. |
| Common Stock offered by the Selling Stockholders | (i) 690,954 shares of the Company's Common Stock and (ii) 566,751 shares of Common Stock issuable upon the exercise of the Warrants. See "Description of the Transactions," "Selling Stockholders". |
| Common Stock currently outstanding | 8,597,682 (as of July 31, 2022) |
| Common Stock to be outstanding assuming exercise of the Warrants | 9,164,433 |
| The Warrants | The Warrants had a purchase price of \$3.97 per warrant. The exercise price of the Warrants is \$0.01 per share of Common Stock. The Warrants are exercisable immediately and for an indefinite term. |
| Use of Proceeds | <p>We will not receive any of the proceeds from the shares of Common Stock sold by the Selling Stockholders hereunder. See "The Offering" and "Use of Proceeds" for more details.</p> <p>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."</p> |
| Trading Market and Ticker Symbol for Common Stock | Our Common Stock is listed on The Nasdaq Capital Market under the symbol "DCTH." |
| Risk Factors | Investing in our securities 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. |

Unless otherwise indicated, all information in this prospectus assumes the exercise of the Warrants with an exercise price of \$0.01 per share of Common Stock.

RISK FACTORS

Investing in shares of our Common Stock involves a high degree of risk. Before deciding whether to invest in shares of 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 most recent Quarterly Report on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus in their entirety, together with other information in this prospectus, the documents incorporated by reference, any prospectus supplement and any free writing prospectus that we may authorize. Please also read carefully the section titled “Cautionary Note Regarding Forward-Looking Statements.”

The market price of our Common Stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The trading price of our Common Stock has been, and we expect it to continue to be, volatile. The price at which our Common Stock trades depends upon a number of factors, including historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital needed and the terms on which it may be raised, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our Common Stock and affect the volume of trading, regardless of our financial condition, results of operations, business or prospects. Among the factors that may cause the market price of our Common Stock to fluctuate are the risks described elsewhere in this “Risk Factors” section and other factors, including:

- fluctuations in our quarterly operating results or the operating results of competitors;
- variance in financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;
- conditions and trends in the markets served;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of competitors;
- changes in pricing policies or the pricing policies of competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- potentially negative announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatements of previously reported financial results or delays in our filings with the SEC;
- the commencement or outcome of litigation involving us, our general industry or both;
- our filing for protection under federal bankruptcy laws;
- changes in capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of Common Stock by stockholders; and
- the trading volume of our Common Stock.

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In addition, the stock markets and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our Common Stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our Common Stock and expose the Company to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

Sales of a substantial number of shares of our Common Stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our Common Stock and could impair our ability to raise additional equity capital.

Sales of a substantial number of shares of our Common Stock in the public market, or the perception that such sales may occur, could cause the market price of our Common Stock to decline and could impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of shares of our Common Stock or other equity-related securities would have on the market price of our Common Stock.

We have a history of reverse splits, which have severely impacted our Common Stock price.

Since our initial public offering in 2000, we have effected five reverse stock splits, for a cumulative ratio since our initial public offering of 1:31,360,000,000. Each such reverse split has resulted in an effective decline in the price of our Common Stock. There can be no assurance that we will not be required to effect one or more additional reverse stock splits which could further impact the market price and liquidity of our Common Stock.

Anti-takeover provisions in our Amended and Restated Certificate of Incorporation and By-laws may reduce the likelihood of a potential change of control or make it more difficult for our stockholders to replace management.

Certain provisions of our Amended and Restated Certificate of Incorporation and By-laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of stockholders might favor a change in management. These provisions include:

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of the board of directors.

, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the Common Stock with respect to dividends, liquidation rights and, possibly, voting rights. The board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our Common Stock.

We have never declared or paid any dividends to the holders of our Common Stock and we do not expect to pay cash dividends in the foreseeable future.

We intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. The board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that may be authorized and issued. We do not expect to pay dividends in the foreseeable future. As a result, holders of our Common Stock must rely on stock appreciation for any return on their investment.

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 the Private Securities Litigation Reform Act of 1995. 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;
- 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 Delcath Hepatic Delivery 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 CHEMOSTAT 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
- 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 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 thereto reflected in subsequent filings with the SEC, which sections are incorporated by reference.

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 shares of Common Stock sold by the Selling Stockholders hereunder.

We may receive proceeds from the exercise of the Warrants to the extent the Warrants are exercised. We can make no assurances that any of the Warrants will be exercised, or if exercised, the quantity that will be exercised or the period in which such Warrants will be exercised.

We intend to use the net proceeds from any exercise of the Warrants for working capital and general corporate purposes.

SELLING STOCKHOLDERS

The Common Stock being offered by the Selling Stockholders are those previously issued to the Selling Stockholders, and those issuable to the Selling Stockholders, upon exercise of the Warrants. For additional information regarding the issuances of those shares of Common Stock and warrants, see “Summary—Private Placement” above. We are registering the Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time.

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 ownership of the Common Stock and the Warrants, as of July 31, 2022, assuming exercise of the Warrants held by the Selling Stockholders on that date, without regard to any limitations on exercises.

The third column lists the Common Stock being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of a registration rights agreement with the Selling Stockholders, this prospectus generally covers the resale of the sum of (i) the number of Common Stock issued to the Selling Stockholders in the Private Placement and (ii) all shares of Common Stock issuable upon exercise of the Warrants issued in the Private Placement. The fourth column assumes the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

In accordance with the terms of a registration rights agreement with the Selling Stockholders, we are required to use commercially reasonable efforts to keep this registration statement continuously effective under the Securities Act until the date that all the registrable securities covered by this registration statement (i) have been sold, hereunder 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.

Under the terms of the 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 number of shares in the second column does not reflect this limitation. The Selling Stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

SELLING STOCKHOLDER TABLE

| Name of Selling Stockholder | Total Shares Beneficially Owned Prior to Offering (1) | Maximum Number of Shares to be Sold Pursuant to the Prospectus (2) | Number of Shares Beneficially Owned After Offering (2) | % of Class After Offering* |
|--|--|---|---|-----------------------------------|
| Rosalind Opportunities Fund I L.P. (3) | | | | |
| Rosalind Master Fund L.P. | 3,561,348 | 566,751 | 2,949,597 | 25.6% |
| Bigger Capital Fund, LP (4) | 127,461 | 125,628 | 1,833* | — |
| District 2 Capital Fund LP (5) | 160,351 | 125,628 | 34,723* | — |
| Gerard Michel (6) | 542,612 | 62,814 | 479,798 | 5.3% |
| Mitchell Robbins (7) | 546,000 | 376,884 | 169,116 | 2.0% |

* Percentage not listed if less than 1%.

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- (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 July 31, 2022, and the percentage is based upon 8,597,682 shares of our Common Stock outstanding as of July 31, 2022.
- (2) Assumes sale of all shares of Common Stock covered by this prospectus and no further acquisitions of shares of Common Stock by the Selling Stockholders.
- (3) Based partially on the Company’s records and, in part, on information provided in a Statement on Schedule 13D/A jointly filed with the SEC on July 21, 2022, by and on behalf of Rosalind Advisors, Inc., Rosalind Opportunities Fund I L.P., Rosalind Master Fund L.P., Steven Salamon and Dr. Gilad Aharon (collectively, “Rosalind”), Rosalind Advisors, Inc. (advisor to Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P.), Mr. Salamon and Dr. Aharon have shared voting power and dispositive power of (i) 400,000 shares of Common Stock, (ii) 1,090,121 shares of Common Stock issuable upon conversion of 10,901 shares of Series E Preferred Stock, (iii) an aggregate of 206,418 shares of Common Stock issuable upon the conversion of an aggregate 1,988 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 and (iv) 1,820,709 shares of Common Stock issuable upon exercise of warrants (the “Rosalind Warrants”). The foregoing clauses (ii), (iii) and (iv) indicate the number of share of Common Stock issuable to the Selling Stockholders upon a full conversion of the Series E Preferred Stock and a full exercise of the Rosalind Warrants without giving effect to the Blockers (as defined below). Pursuant to the terms of (i) the certificate of designations containing the terms of the Series E Preferred Stock, the Selling Stockholders cannot convert the Series E Preferred Stock to the extent that the Selling Stockholders would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of the Common Stock (the “Preferred Stock Blockers”) and (ii) the Rosalind Warrants, the Selling Stockholders cannot exercise the Rosalind Warrants to the extent that the Selling Stockholders would beneficially own, after any such exercise, more than 4.99% of the outstanding shares of Common Stock (the “Rosalind Warrant Blockers” and collectively with the Preferred Stock Blockers, the “Blockers”). The table indicates the number of shares of Common Stock beneficially owned by the Selling Stockholders and the percentage ownership of the Selling Stockholders after giving effect to the Blockers. 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., 175 Bloor Street East, Suite 1316, North Tower, Toronto, ON M4W 3R8
- (4) Consists of 125,628 shares of Common Stock and 1,833 shares of Common Stock which may be acquired within 60 days of the date above upon exercise of Common Stock warrants with an exercise price of \$10.00 per share. 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
- (5) Consists of 125,628 shares of Common Stock and 34,723 shares of Common Stock which may be acquired within 60 days of the date above upon exercise of Common Stock warrants with an exercise price of \$10.00 per share. 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
- (6) Consists of 125,864 shares of Common Stock and 416,748 shares of Common Stock that may be acquired through the exercise of options that are exercisable as of, or will become exercisable within, 60 days of the date above. The Selling Stockholder’s address is 39 Lawrence St., Cambridge, MA, 02139.
- (7) Consists of 546,000 shares of Common Stock. The Selling Stockholder’s address is 461 South Maya Palm Drive, Boca Raton, FL33432.

Relationship with Selling Stockholders

On April 8, 2020, we entered into a Board Appointment Agreement, dated as of April 8, 2020, with Rosalind Opportunities Fund I L.P. and Rosalind Maser Fund L.P. (“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. Mitchell Robbins, Bigger Capital Fund, LP and District 2 Capital Fund LP have not held any position or office with us or any of our predecessors or affiliates within the last three years and have not had a material relationship with us or any of our predecessors or affiliates within the past three years.

PLAN OF DISTRIBUTION

Each Selling Stockholder, or the Selling Stockholders, of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities 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 securities:

- 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 Stockholder 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 Stockholder 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 Stockholder 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.

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We are required to pay certain fees and expenses that we incur incident to the registration of the securities. 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 resale securities 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 Stockholder under this prospectus will be passed upon for us by Cooley LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements as of December 31, 2021 and 2020 and for each of the two years in the period ended December 31, 2021 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, 2021, filed with the SEC on March 31, 2022, including those portions of the Form 10-K incorporated by reference from our [definitive proxy statement](#) filed with the SEC on April 4, 2022;
- Our Quarterly Reports on Form 10-Q for the periods ended (i) March 31, 2022, filed with the SEC on [May 11, 2022](#) and (ii) June 30, 2022, filed with the SEC on [August 8, 2022](#);
- Our Current Reports on Form 8-K, filed with the SEC on [May 6, 2022](#), [June 7, 2022](#), [July 20, 2022](#); and
- The description of our Common Stock contained in our registration on [Form 8-A12B](#) (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.

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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 1,257,705 Shares of
Common Stock Offered by the Selling Stockholders**

PROSPECTUS

, 2022

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You must not rely on any unauthorized information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not offer to sell any securities in any jurisdiction where it is unlawful. Neither the delivery of this prospectus, nor any sale made hereunder, shall create any implication that the information in this prospectus is correct after the date hereof.

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 | \$ 485 |
| Accountants' fees and expenses | 10,300 |
| Legal fees and expenses | 50,000 |
| Miscellaneous | — |
| Total: | <u>\$ 60,785</u> |

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, or 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 has actually and reasonably incurred.

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.

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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.

| <u>Exhibit Number</u> | <u>Exhibit Description</u> | <u>Schedule / Form</u> | <u>File Number</u> | <u>Exhibit</u> | <u>File Date</u> |
|-----------------------|--|------------------------|--------------------|----------------|--------------------|
| 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 | 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) | | | | |

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| <u>Exhibit Number</u> | <u>Exhibit Description</u> | <u>Schedule / Form</u> | <u>File Number</u> | <u>Exhibit</u> | <u>File Date</u> |
|-----------------------|--|------------------------|--------------------|----------------|------------------|
| 4.1 | Form of Pre-Funded Warrant | Form 8-K | 001-16133 | 4.1 | July 20, 2022 |
| 10.1 | Form of Form of Registration Rights Agreement, dated July 18, 2022, by and among Delcath Systems, Inc. and the persons party thereto | Form 8-K | 001-16133 | 10.2 | July 20, 2022 |
| 5.1 | Opinion of Cooley LLP | | | | Filed Herewith |
| 23.1 | Consent of Marcum LLP, independent registered public accounting firm | | | | 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

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(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)(1)(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.

(d) The undersigned registrant hereby undertakes that: (1) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and (2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus 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.

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 September 7, 2022.

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

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|-------------------|
| <u>/s/ Gerard Michel</u> Gerard Michel | Chief Executive Officer and Director <i>(Principal Executive Officer)</i> | September 7, 2022 |
| <u>/s/ Anthony Dias</u> Anthony Dias | Chief Financial Officer <i>(Principal Accounting Officer)</i> | September 7, 2022 |
| <u>/s/ Roger G. Stoll, Ph.D.</u> Roger G. Stoll, Ph.D. | Chairman of the Board | September 7, 2022 |
| <u>/s/ Elizabeth Czerepak</u> Elizabeth Czerepak | Director | September 7, 2022 |
| <u>/s/ Steven Salamon</u> Steven Salamon | Director | September 7, 2022 |
| <u>/s/ John R. Sylvester</u> John R. Sylvester | Director | September 7, 2022 |
| <u>/s/ Gilad Aharon</u> Gilad Aharon | Director | September 7, 2022 |



Nicolas H.R. Dumont
+1 212 479 6446
ndumont@cooley.com

September 7, 2022

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, covering the resale by certain selling stockholders (the “**Selling Stockholders**”) of up to 1,257,705 shares of the Company’s common stock, par value \$0.01 per share (“**Common Stock**”), consisting of (i) 690,954 outstanding shares of Common Stock (the “**Shares**”) and (ii) up to 566,751 shares of Common Stock (the “**Warrant Shares**”) issuable upon the exercise of outstanding pre-funded warrants to purchase shares of Common Stock (the “**Warrants**”). The Shares and the Warrants were issued pursuant to a Securities Purchase Agreement, dated July 18, 2022, by and among the Company and the purchasers named therein (the “**Securities Purchase Agreement**”).

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 Securities Purchase Agreement, 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.

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, we express no opinion to the extent that future issuances of securities of the Company, including the Warrant Shares, adjustments to outstanding securities of the Company, including the Warrants, and/or other matters cause the Warrants to be exercisable for more shares of Common Stock than the number that remain available for issuance. 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.

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Delcath Systems, Inc.
September 7, 2022
Page Two

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares are validly issued, fully paid, and nonassessable and that the Warrant Shares, when issued in accordance with the terms of the 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.

Very truly yours,

COOLEY LLP

By: /s/ Nicolas H.R. Dumont
Nicolas H.R. Dumont

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INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in this Registration Statement of Delcath Systems, Inc. on Form S-3 of our report dated March 30, 2022, which includes an explanatory paragraph as to 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, 2021 and 2020 and for the years ended December 31, 2021 and 2020 appearing in the Annual Report on Form 10-K of Delcath Systems, Inc. for the year ended December 31, 2021. 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
September 7, 2022

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(1) | Fee Rate | Amount of Registration Fee(2) |
|-----------------|----------------------------|--|---------------------------------------|-----------------------|--|-------------------------------------|-----------|-------------------------------|
| Fees to Be Paid | Equity | Common stock, par value \$0.01 per share | Rule 457(c) | 1,257,705 (2) | — | \$5,232,052.80 | 0.0000927 | \$485.02 |
| | Total Offering Amounts | | | | | \$5,232,052.80 | | \$485.02 |
| | Total Fees Previously Paid | | | | | | | — |
| | Total Fee Offsets | | | | | | | — |
| | Net Fee Due | | | | | | | \$485.02 |

- (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 stockholder pursuant to the prospectus 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 1,257,705 shares of the Registrant’s common stock, including 566,751 shares of common stock issuable upon the exercise of pre-funded 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 September 1, 2022, as reported on the Nasdaq Global Market.