DELCATH SYSTEMS, INC.

Form S-1 June 12, 2018 Table of Contents

As filed with the Securities and Exchange Commission on June 11, 2018

No. 333-

#### **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM S-1

## 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

3841 (Primary Standard Industrial 06-1245881 (I.R.S. Employer

incorporation or organization)

**Classification Code Number**)

**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)

Jennifer K. Simpson

**President and** 

**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)

Copies of all communications, including communications sent to agent for service, should be sent to:

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New York, New York 10019

(516) 222-2230

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#### Approximate date of commencement of proposed sale to the public:

#### As soon as practicable after this Registration Statement becomes effective.

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, 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 of 1933, please 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 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 post-effective amendment filed pursuant to Rule 462(d) 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an 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. (Check One):

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.

#### CALCULATION OF REGISTRATION FEE

| Title of Each Class of                        | Amount<br>to be | Proposed<br>Maximum<br>Offering Price | Proposed<br>Maximum<br>Aggregate | Amount of               |
|---|-----------------|---------------------------------------|----------------------------------|-------------------------|
| Securities to be Registered <sup>(1)</sup>    | Registered      | Per Unit                              | 00 0                             | <b>Registration Fee</b> |
| Subscription Rights to purchase Common Stock, | _               |                                       | _                                | _                       |
| \$0.01 par value per share                    |                 |                                       |                                  | (2)                     |
|   |                 |                                       | \$50,000,000(3)                  | \$6,225(4)              |

Common Stock, \$0.01 par value per share, issuable upon exercise of Subscription Rights

Total \$50,000,000<sup>(3)</sup> \$6,225

- (1) This registration statement relates to (a) non-transferable subscription rights to purchase common stock of the registrant, which subscription rights are to be issued to holders of the registrant s common stock on a pro rata basis without consideration, and (b) the shares of the registrant s common stock issuable upon the exercise of such non-transferable subscription rights.
- (2) The subscription rights are being issued without consideration. Pursuant to Rule 457(g) under the Securities Act of 1933, as amended, no separate registration fee is payable with respect to the subscription rights being offered hereby since the subscription rights are being registered in the same registration statement as the securities to be offered pursuant thereto.
- (3) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act. In no event will the aggregate maximum offering price of all securities issued pursuant to this registration statement exceed \$50,000,000.
- (4) The Company is paying the fee with the filing of this S-1 registration statement.

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, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell 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 an offer to buy these securities in any state where the offer or sale is not permitted.

\$50,000,000 of Rights to Purchase Common Stock

**Subject to Completion, Dated June 11, 2018** 

Subscription Rights to purchase up to shares of common stock at \$[ ] per share and the shares of common stock issuable upon the exercise of such Subscription Rights

We are distributing to holders of our common stock and holders of certain of our instruments convertible and/or exchangeable into our common stock on an as converted basis, at no charge, non-transferable subscription rights to purchase up to the lesser of \$50.0 million or shares of our common stock. We refer to the offering that is the subject of this prospectus as the rights offering. In the rights offering, you will receive, on June , 2018, the record date of the rights offering, [one] subscription right[s] for every share of common stock beneficially owned and settled by 4:00 p.m., Eastern Time, on June , 2018. The subscription rights will not be tradeable. Each subscription right consists of a basic subscription privilege and an over-subscription privilege. We must receive minimum gross proceeds of \$ million from the exercise of the basic subscription privilege and over-subscription privilege in order to complete the offering.

Each basic subscription privilege will entitle you to purchase one share of common stock, which we refer to as the basic subscription right, at a subscription price per share of common stock equal to \$[ ]. In the event that holders exercise subscription rights for in excess of the maximum exercise amount, which is the lesser of \$50.0 million or shares of our common stock (not including the over-subscription privilege), the amount subscribed for by each person will be proportionally reduced, based on the amount subscribed for by each person (not including any over-subscription privilege subscribed for). If you exercise your basic subscription privilege in full, and any portion of the shares of common stock remain available under the rights offering which are unsubscribed, you will be entitled to an over-subscription privilege to purchase a portion of the unsubscribed shares of common stock at the subscription price, subject to proration based on the number of shares of common stock owned and common stock issuable upon full exchange and/or conversion of certain of our instruments convertible and/or exchangeable into our common stock on the record date, which we refer to as the over-subscription privilege.

You may only purchase the number of shares of common stock purchasable upon exercise of the number of basic subscription privilege distributed to you in the rights offering, plus the over-subscription privilege, if any. Accordingly, the number of shares of common stock that you may purchase in the rights offering is limited by the number of shares of our common stock you held or would have held upon full conversion of the shares of certain of our instruments convertible and/or exchangeable into our common stock you held on the record date and by the extent

to which other stockholders exercise their basic subscription privileges and over-subscription privileges, which we cannot determine prior to completion of the rights offering.

The subscription rights will expire if they are not exercised by 5:00 p.m., Eastern time, on July , 2018, unless the rights offering is extended or earlier terminated by us. If we elect to extend the rights offering, we will issue a press release announcing the extension no later than 9:00 a.m., Eastern time, on the next business day after the most recently announced expiration date of the rights offering. We may extend the rights offering for a period not to exceed 30 days in our sole discretion. Once made, all exercises of subscription rights are irrevocable. However, it is a condition of this rights offering that, as described elsewhere in this prospectus, on or before the expiration of this rights offering or its earlier termination, we receive subscriptions or over-subscriptions or a combination thereof for an aggregate of

\$\[ \] If this condition is not satisfied on or before the expiration of this rights offering or its earlier termination, we will cancel the rights offering and all exercises of subscriptions will not be completed and all funds advanced in connection with such exercises will be promptly refunded by the subscription agent. All subscription payments will be deposited into an escrow account maintained by the subscription agent for the benefit of the holders exercising their subscriptions under the rights offering, and if the rights offering is not completed for any reason all funds will be promptly returned to such subscribers in the amounts advanced in connection with their respective exercises.

We have engaged Advisory Group Equity Services, Ltd. doing business as RHK Capital (RHK Capital) as the dealer-manager for this rights offering. If the rights offering is not fully subscribed following expiration of the rights offering, RHK Capital has additionally agreed to use its commercially reasonable efforts to place any unsubscribed shares at the subscription price for an additional period of up to 45 days. The number of shares that may be sold by us during this period will depend upon the number of shares that are subscribed for pursuant to the exercise of subscription rights by our stockholders.

We are conducting the rights offering to raise capital that we intend to use for general corporate purposes. Our former independent registered public accounting firm in its report on our December 31, 2017 financial statements raised substantial doubt about our ability to continue as a going concern. We had cash and cash equivalents in the amount of \$2.0 million as of March 31, 2018. We estimate that the current funds on hand and funds raised through this rights offering, if fully subscribed, will be sufficient to continue operations through at least December 31, 2019.

You should carefully consider whether to exercise your subscription rights prior to the expiration of the rights offering. All exercises of subscription rights are irrevocable, even if the rights offering is extended by our board of directors for a period of 30 days.

If we amend the rights offering to allow for an extension of the rights offering for a period of more than 30 days or make a fundamental change to the terms of the rights offering set forth in this prospectus, you may cancel your subscription and receive a prompt refund of any money you have advanced. Our board of directors may cancel the rights offering at any time prior to the expiration of the rights offering for any reason. In the event the rights offering is canceled, all subscription payments received by the subscription agent will be promptly returned, without interest.

In the event that the exercise by a stockholder of the basic subscription privilege or the over-subscription privilege could, as determined in our sole discretion, potentially result in a limitation on our ability to use net operating losses, tax credits and other tax attributes, under the Internal Revenue Code of 1986, as amended, and rules promulgated by the Internal Revenue Service, we may, but are under no obligation to, reduce the exercise by such stockholder of the basic subscription privilege or the over-subscription privilege to such number of shares of common stock as in our sole discretion determine to be advisable in order to preserve our ability to use the tax attributes.

Our board of directors is making no recommendation regarding your exercise of the subscription rights. The subscription rights may not be sold, transferred or assigned and will not be listed for trading on any stock exchange or

market. Shares of our common stock are traded on the OTC Market Group s OTCQB marketplace under the symbol DCTH . On June 4, 2018, the closing sales price for our common stock was \$3.23 per share. The shares of common stock issued in the rights offering will also be traded on the OTCQB under the same symbol.

On May 2, 2018, we effected a 1-for-500 reverse stock split of our outstanding shares of common stock. All share and per share information in this prospectus have been retroactively adjusted to give effect to the reverse stock split, including the financial statements and notes thereto.

|              |                         |              | <b>Underwriting Discounts</b> |       | Discounts  | Proceeds, Before |              |
|--------------|-------------------------|--------------|-------------------------------|-------|------------|------------------|--------------|
|              | <b>Subscription Fee</b> |              | and Commissions(1)            |       |            | Expense, to us   |              |
|              | Min                     | Max          | Min                           |       | Max        | Min              | Max          |
| Per share of |                         |              |                               |       |            |                  |              |
| common stock | \$<br>[]:               | \$ [         | ] \$                          | []\$  | []\$       | []               | \$ []        |
| Total        | \$<br>,000,000          | \$50,000,000 | \$                            | \$ 4, | 000,000 \$ |                  | \$46,000,000 |

- (1) In connection with the rights offering, we have agreed to pay RHK Capital a cash fee up to 6.0% of the gross proceeds of this offering in cash, a non-accountable expense allowance up to 1.8% of the gross proceeds of this offering, and an out-of-pocket accountable expense allowance of 0.2%. For any unsubscribed shares placed by RHK Capital during the 45-day placement period following the expiration of the rights offering, we have agreed to pay RHK Capital a placement fee equal to, and in lieu of, the dealer-manager fee, with such placement fee and expenses not to exceed the aggregate amounts that would have otherwise been received by RHK Capital if the offering were to have been fully subscribed. See Plan of Distribution on page 118 of this prospectus for a description of the fees and expenses to be paid to RHK Capital for services performed in connection with this rights offering.
- (2) Assumes that the rights offering is fully subscribed and that the maximum offering amount in the aggregate of \$50.0 million is subscribed.

The exercise of your subscription rights for shares of our common stock involves risks. See <u>Risk Factors</u> beginning on page 15 of this prospectus, as well as the risk factors and other information in any documents we incorporate by reference into this prospectus, to read about important factors you should consider before exercising your subscription rights.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The distribution of this prospectus and the offering of the securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus in any jurisdiction in which it would be unlawful for us to make such an offer or solicitation.

If you have any questions or need further information about this rights offering, please call agent for the rights offering, at .1 , our information .1

The date of this prospectus is , 2018

<sup>&</sup>lt;sup>1</sup> To be added by amendment.

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## **ABOUT THIS PROSPECTUS**

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this document, regardless of the time of delivery of this prospectus or the time of issuance or sale of any securities. Our business, financial condition, results of operations and prospects may have changed since that date. You should read this prospectus in its entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the section of this prospectus entitled Where You Can Find More Information.

For investors outside of the United States, neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.

#### **Industry and Market Data**

This prospectus includes industry data and forecasts that we obtained from industry publications and surveys, public filings and internal company sources. Industry publications and surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of the included information. Statements as to our market position and market estimates are based on independent industry publications, government publications, third party forecasts, management s estimates and assumptions about our markets and our internal research. While we are not aware of any misstatements regarding the market, industry or similar data presented herein, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed under the headings Risk Factors and Cautionary Statement Concerning Forward-Looking Statements in this prospectus.

#### PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It does not contain all the information you need to consider in making your investment decision. Before making an investment decision, you should read this entire prospectus carefully and should consider, among other things, the matters set forth under Risk Factors and our financial statements and related notes thereto appearing elsewhere in this prospectus. In this prospectus, except as otherwise indicated, Delcath, Delcath Systems, we, our, and us refer to Delcath Systems, Inc., a Delaware corporation and its subsidiaries. Delcath is our registered United States trademark.

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, our system is in commercial development under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT®), where it has been used at major medical centers to treat a wide range of cancers of the liver.

Our primary research focus is on ocular melanoma liver metastases (mOM) and intrahepatic cholangiocarcinoma (ICC), a type of primary liver cancer, and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

In the United States, Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the FDA. Although the Melphalan/HDS Kit has not been approved in the U.S., FDA has granted us six orphan drug designations, which apply to the orphan indication for the drug component even though approved as a drug/device, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma (HCC) and ICC. Melphalan/HDS has not been approved for sale in the United States. There are also orphan drug designations for melphalan for neurodendocrine tumors, cutaneous melanoma, and ocular tumors, as well as for the use of doxorubicin for HCC.

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (EU) where the prospect of securing adequate reimbursement for the procedure is strongest. In 2015 national reimbursement coverage for CHEMOSAT procedures was awarded in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are expected to be renegotiated annually.

Our clinical development program for CHEMOSAT and Melphalan/HDS is comprised, in part, of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (The FOCUS Trial), a Global Phase 3 clinical trial that is investigating overall survival in mOM. We have also initiated a separate clinical trial that also uses Melphalan/HDS Kit for intrahepatic cholangiocarcinoma (ICC). Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

The direction and focus of our CDP for CHEMOSAT and Melphalan/HDS is informed by prior clinical development conducted between 2004 and 2010, non-clinical, commercial CHEMOSAT cases performed on patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European commercial and United States regulatory activity has led to the implementation of several safety improvements to our product and the associated medical procedure.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT and Melphalan/HDS represents a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver. We believe that CHEMOSAT and Melphalan/HDS is uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

## Cancers in the Liver A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to the American Cancer Society s (ACS) *Cancer Facts & Figures 2017* report, cancer is the second leading cause of death in the United States, with an estimated 600,920 deaths and 1,688,780 new cases expected to be diagnosed in 2017. Cancer is one of the leading causes of death worldwide, accounting for approximately 8.2 million deaths and 14.1 million new cases in 2012 according to GLOBOCAN. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the U.S. in 2014 was \$87.8 billion. The liver is often the life-limiting organ for cancer patients and one of the leading causes of cancer death. Patient prognosis is generally poor once cancer has spread to the liver.

## **Liver Cancers Incidence and Mortality**

There are two types of liver cancers: primary liver cancer and metastatic liver disease. Primary liver cancer (hepatocellular carcinoma or HCC, including intrahepatic bile duct cancers or ICC) originates in the liver or biliary tissue and is particularly prevalent in populations where the primary risk factors for the disease, such as hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Metastatic liver disease, also called liver metastasis, or secondary liver cancer, is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer.

#### Ocular Melanoma

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. Based on third party research conducted in 2016, we estimate that up to 4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, we estimate that approximately 90% of patients will develop liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care (SOC) for patients with ocular melanoma liver metastases. According to our 2016 research, we estimate that approximately 2,000 patients with ocular melanoma liver metastases in the United States and Europe may be eligible for treatment with the Melphalan/HDS.

## **Intrahepatic Cholangiocarcinoma**

Hepatobiliary cancers include hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC), and are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new

cases of hepatobiliary cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 40,710 new cases of these cancers were expected to be diagnosed in the United States in 2017.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of hepatobiliary cases diagnosed in the United States and Europe annually. We believe that 90% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. We estimate that approximately 9,300 ICC patients in the United States and Europe annually could be candidates for treatment with Melphalan/HDS, which we believe represents a significant market opportunity.

According to the ACS, the overall five-year survival rate for hepatobiliary cancers in the United States is approximately 18%. For patient diagnosed with a localized stage of disease, the ACS estimates 5-year survival at 31%. The ACS estimates that 5-year survival for all cancers is 68%.

## About CHEMOSAT and Melphalan/HDS Kit

CHEMOSAT and Melphalan/HDS administers concentrated regional chemotherapy to the liver. This whole organ therapy is performed by isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (PHP® therapy), three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body s circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters absorb chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug and related toxic side effects, before the filtered blood is returned to the patient s circulatory system.

PHP therapy is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT and Melphalan/HDS is repeatable, and a new disposable CHEMOSAT and Melphalan/HDS is used for each treatment. Patients treated in clinical trial settings are permitted up to six treatments. In non-clinical commercial settings patients have received up to eight treatments. In the United States, if we receive FDA approval, melphalan hydrochloride for injection will be included with the system and marketed as the drug/device melphalan/HDS Kit. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

#### Risks of Investing

Investing in our securities involves substantial risks. Potential investors are urged to read and consider the risk factors relating to an investment in the common stock set forth under Risk Factors in this prospectus as well as other information we include in this prospectus.

## **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 our website is not a part of this prospectus.

## **SUMMARY OF THE OFFERING**

The following summary describes the principal terms of the rights offering, but is not intended to be complete. See the information under the heading The Rights Offering in this prospectus for a more detailed description of the terms and conditions of the rights offering.

#### **Securities Offered**

We are distributing, at no charge, to holders of our common stock, and holders of certain of our instruments convertible or exchangeable into our common stock, on an as converted basis, non-transferrable subscription rights to purchase up to an aggregate of shares of our common stock. Holders of our common stock will receive one subscription right for each share of common stock owned and holders of certain of our instruments convertible or exchangeable into our common stock will receive one subscription right for each share of common stock they would own upon full conversion of certain of our instruments convertible or exchangeable into our common stock owned and settled by, 4:00 p.m., New York City time, on June , 2018; provided, that, the rights may only be exercised for a maximum of the lesser of shares or \$50.0 million of subscription proceeds.

## **Basic Subscription Privilege**

The basic subscription privilege of each subscription right will entitle you to purchase one share of our common stock at a subscription price of \$ per share.

## **Over-Subscription Privilege**

If you fully exercise your basic subscription privilege and basic subscription rights are exercised for an amount less than \$, you may also exercise an over-subscription right to purchase additional shares of common stock that remain unsubscribed at the expiration of the rights offering, subject to the availability and pro rata allocation of shares among stockholders exercising this over-subscription right.

## **Conditions to Closing**

The completion of the Rights Offering is conditioned upon the minimum offering amount of at least \$ million of common stock.

#### Minimum Offering Amount from exercise of subscription rights

We will not complete the rights offering unless we receive aggregate subscriptions of at least \$ million.

#### **Record Date**

June , 2018.

## **Expiration Date of the Rights Offering**

5:00 p.m., Eastern time, on July , 2018.

#### **Subscription Price**

\$ per share, payable in cash. To be effective, any payment related to the exercise of a right must clear prior to the expiration of the rights offering.

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#### **Placement Period**

If the rights offering is not fully subscribed following expiration of the rights offering, RHK Capital has agreed to use its commercially reasonable efforts to place any unsubscribed shares at the subscription price for an additional period of up to 45 days. The number of shares that may be sold by us during this period will depend upon the number of shares that are subscribed for pursuant to the exercise of subscription rights by our common stockholders. No assurance can be given that any unsubscribed shares will be sold during this period.

#### **Use of Proceeds**

We are conducting the Rights Offering for general corporate purposes. See Use of Proceeds for a more detailed description of the intended use of proceeds from the Rights Offering.

#### **Non-Transferability of Rights**

The Subscription Rights granted to you may be exercised only by you, and, therefore, you may not sell, transfer or assign your Subscription Rights to anyone else.

#### **Shares Outstanding Before the Rights Offering**

932,169 shares of our common stock, as of June 4, 2018.

## **Shares Outstanding After the Rights Offering**

Assuming 28,571,429 shares of our common stock are issued in the rights offering through the exercise of subscription rights, we anticipate that 29,503,598 shares of our common stock will be outstanding following the completion of the rights offering.

#### **Risk Factors**

Since our inception, we have incurred substantial losses. We will need the funding sought under this prospectus to remain a going concern, maintain operations, and to activate our business plan, which includes, among other things, advertising, retaining channels of distribution, retaining supplier relationships and recruiting experienced personnel. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should carefully consider all of the risks which are discussed more fully in Risk Factors beginning on page 15 of this prospectus.

## **Reverse Stock Split**

On May 2, 2018, we effected a 1-for-500 reverse stock split of our outstanding shares of common stock.

## **Dividend policy**

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 currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.

OTCQB symbol for common stock DCTH

**Risk factors** See Risk Factors and other information included in this prospectus for a

discussion of the factors you should carefully consider before deciding to

invest in our securities

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**Transfer agent and registrar** American Stock Transfer and Trust Company, LLC The number of shares of our common stock outstanding prior to and immediately after this offering, as set forth above, excludes the following potentially dilutive securities as of June 4, 2018:

1.0 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$184.88 per share

## **Questions and Answers About the Rights Offering**

The following are examples of what we anticipate will be common questions about the rights offering. The answers are based on selected information included elsewhere in this prospectus. The following questions and answers do not contain all of the information that may be important to you and may not address all of the questions that you may have about the rights offering. This prospectus and the documents incorporated by reference into this prospectus contain more detailed descriptions of the terms and conditions of the rights offering and provide additional information about us and our business, including potential risks related to the rights offering, the shares of common stock offered hereby, and our business. We urge you to read this entire prospectus and the documents incorporated by reference into this prospectus.

## Why are we conducting the rights offering?

We are conducting the offering to raise capital that we intend to use to provide working capital to expand growth in India and for general corporate purposes.

## What is the rights offering?

We are distributing to holders of our common stock, \$0.01 par value, and holders of certain of our instruments convertible or exchangeable into our common stock, on an as converted basis, at no charge, non-transferable subscription rights to purchase shares of common stock. On the record date, June \_\_\_\_, 2018, you will receive one subscription right for each whole share of common stock owned and one subscription right for every share of common stock you would own upon full exchange or conversion of the certain of our instruments convertible or exchangeable into our common stock owned and settled by 4:00 p.m., Eastern Time, on July \_\_\_, 2018. Each subscription right will entitle the holder to a basic subscription privilege and an over-subscription privilege.

## What are the basic subscription privilege?

A basic subscription privilege will entitle you to purchase one shares of common stock, at the subscription price, for each share of common stock held by you on 4:00 p.m., Eastern Time, on June , 2018, the Record Date. For example, if you owned 100 shares of common stock on the record date, you will receive subscription rights. You may exercise all or a portion of your basic subscription privilege or you may choose not to exercise any basic subscription privilege at all.

If you are a record holder, the number of common shares you may purchase pursuant to your basic subscription privilege is indicated on the subscription rights certificate. If you hold your shares in the name of a broker, dealer, bank, or other nominee who uses the services of the Depository Trust Company, or DTC, you will not receive a subscription rights statement. Instead, DTC will issue one subscription right to your nominee record holder for each share of our common stock that you own or would own upon full conversion of certain of our instruments convertible or exchangeable into our common stock that you own as of the record date. If you are not contacted by your nominee,

you should contact your nominee as soon as possible.

If sufficient shares of common stock are available, we will seek to honor your basic subscription request in full. In the event that holders exercise subscription rights for in excess of the lesser of \$50.0 million or

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28,571,429 shares of common stock (not including the over- subscription privilege), the amount subscribed for by each person will be proportionally reduced, based on the amount subscribed for by each person (not including any over-subscription privilege subscribed for).

See The Rights Offering Limitation on the Purchase of Shares of Common Stock for a description of certain limitations on purchase.

## What is the over-subscription privilege?

If you exercise your basic subscription privilege in full, you may also choose to exercise your over-subscription privilege to purchase shares of common stock that the other record holders do not purchase through the exercise of their basic subscription privilege. You should indicate on your subscription rights certificate, or the form provided by your nominee if your shares are held in the name of a nominee, the aggregate amount you would like to apply to purchase shares of common stock pursuant to your over-subscription privilege.

If sufficient shares of common stock are available, we will seek to honor your over-subscription request in full. If over- subscription requests exceed the number of shares of common stock available, however, we will allocate the available shares of common stock pro-rata among the record holders exercising the over-subscription privilege in proportion to the number of shares of our common stock each of those record holders owned on the record date, relative to the number of shares owned on the record date by all record holders exercising the over-subscription privilege. If this pro-rata allocation results in any record holders receiving a greater number of shares of common stock than the record holder subscribed for pursuant to the exercise of the over-subscription privilege, then such record holder will be allocated only that number of shares of common stock for which the record holder oversubscribed, and the remaining shares of common stock will be allocated among all other record holders exercising the over-subscription privilege on the same pro rata basis described above. The proration process will be repeated until all shares of common stock have been allocated. See The Rights Offering Limitation on the Purchase of Shares of Common Stock for a description of certain limitations on purchase.

To properly exercise your over-subscription privilege, you must deliver to the subscription agent the subscription payment related to your over-subscription privilege before the rights offering expires. See The Rights Offering The Subscription Rights Over-Subscription Privilege. To the extent you properly exercise your over-subscription privilege for a number of shares of common stock that exceeds the number of unsubscribed shares of common stock available to you, any excess subscription payments will be returned to you as soon as practicable after the expiration of the rights offering, without interest or penalty.

Our subscription agent for the rights offering, will determine the over-subscription allocation based on the formula described above.

#### Will fractional shares be issued upon exercise of subscription rights?

No. We will not issue fractional shares of common stock in the rights offering. Any excess subscription payments received by the subscription agent will be returned as soon as practicable after expiration of the rights offering, without interest or penalty.

## What effect will the rights offering have on our outstanding common stock?

On June 4, 2018, 932,169 shares of our common stock were outstanding. Based on the foregoing, and assuming no other transactions by us involving our common stock prior to the expiration of the rights offering, is fully subscribed

for the maximum number of shares of common stock available, approximately 29,503,598

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shares of our common stock will be issued and outstanding. The exact number of shares of common stock that we will issue in this rights offering will depend on subscription price and the number of shares of common stock that are subscribed for in the Rights Offering.

#### How was the subscription price formula determined?

Our board of directors determined the subscription price taking into consideration, among other things, the following factors:

the current and historical trading prices of our common stock on the OTCQB and Nasdaq;

the price at which stockholders might be willing to participate in the rights offering;

our need for additional capital and liquidity;

the cost of capital from other sources; and

comparable precedent transactions, including the percentage of shares offered, the terms of the subscription rights being offered, the subscription price and the discount that the subscription price represented to the immediately prevailing closing prices for those offerings.

In conjunction with the review of these factors, our board of directors reviewed our history and prospects, including our past and present earnings and cash requirements, our prospects for the future, the outlook for our industry and our current financial condition. Our board of directors believes that the subscription price should be designed to provide an incentive to our current stockholders to participate in the rights offering and exercise their basic subscription privilege and their over-subscription privilege.

The subscription price does not necessarily bear any relationship to any established criteria for value. You should not consider the subscription price as an indication of actual value of the Company or our common stock. We cannot assure you that the market price of our common stock will not decline during or after the rights offering. You should obtain a current price quote for our common stock before exercising your subscription rights and make your own assessment of our business and financial condition, our prospects for the future, and the terms of this rights offering. Once made, all exercises of subscription rights are irrevocable.

#### Am I required to exercise all of the basic subscription privilege I receive in the rights offering?

No. You may exercise any number of your basic subscription rights, or you may choose not to exercise any basic subscription privilege. If you do not exercise any basic subscription privilege, the number of shares of our common stock you own will not change. However, if you choose not to exercise your basic subscription privilege in full, your proportionate ownership interest in the Company will decrease. If you do not exercise your basic subscription privilege in full, you will not be entitled to exercise your over-subscription privilege.

## How soon must I act to exercise my subscription rights?

If you received a subscription rights certificate and elect to exercise any or all of your subscription rights, the subscription agent must receive your completed and signed subscription rights certificate and payment for both your basic subscription privilege and any over-subscription privilege you elect to exercise before the rights offering expires on July 3018, at 5:00 PM Eastern Time. If you hold your shares in the name of a broker, dealer, custodian bank, or other nominee, your nominee may establish a deadline before the expiration of the rights offering by which you must provide it with your instructions to exercise your subscription rights, along with the required subscription payment.

#### May I transfer my subscription rights?

No. The subscription rights may be exercised only by the stockholders to whom they are distributed, and they may not be sold, transferred, assigned or given away to anyone else, other than by operation of law. As a result, a subscription rights certificate may be completed only by the stockholder who receives the statement. The subscription rights will not be listed for trading on any stock exchange or market.

# Is there any back-stop or standby commitment in place to purchase rights that are not purchased in the offering?

Yes, there is a back-stop commitment in place to purchase rights that are not exercised in the offering.

## Is there a minimum subscription required to complete the rights offering?

There is no individual minimum purchase requirement in the rights offering. However, we will not complete the rights offering unless we receive aggregate subscriptions of at least \$ million of common stock in the rights offering.

## Are there any conditions to completing the rights offering?

There are no other conditions to completion.

## If the rights offering is not completed, will my subscription payment be refunded to me?

Yes. The subscription agent will hold all funds it receives in escrow until completion of the rights offering. If the rights offering is not completed, the subscription agent will return promptly, without interest, all subscription payments. We reserve the right to terminate the offering at any time if, due to market conditions or otherwise, the Board of Directors deems it advisable not to proceed with the rights offering.

#### Will our directors and executive officers participate in the rights offering?

To the extent they hold common stock as of the record date, our directors and executive officers will be entitled to participate in the rights offering on the same terms and conditions applicable to other rights holders. None of our directors or executive officers has entered into any binding commitment or agreement to exercise subscription rights received in the rights offering.

## Has the board of directors made a recommendation to stockholders regarding the rights offering?

No. Our board of directors is not making a recommendation regarding your exercise of the subscription rights. Stockholders who exercise subscription rights will incur investment risk on new money invested. We cannot predict the price at which our shares of common stock will trade after the rights offering. On June 4, 2018 the closing price of our common stock was \$3.23 per share. The market price for our common stock may be above the subscription price or may be below the subscription price. If you exercise your subscription rights, you may not be able to sell the underlying shares of our common stock in the future at the same price or a higher price. You should make your decision based on your assessment of our business and financial condition, our prospects for the future, the terms of the rights offering and the information contained in this prospectus. See Risk Factors for discussion of some of the risks involved in investing in our securities.

## How do I exercise my subscription Rights?

If you are a stockholder of record (meaning you hold your shares of our common stock or certain of our instruments convertible or exchangeable into shares of our common stock in your name and not through a broker, dealer, bank, or other nominee) and you wish to participate in the rights offering, you must deliver a properly

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completed and signed subscription rights certificate, together with payment of the subscription price for both your basic subscription privilege and any over-subscription privilege you elect to exercise, to the subscription agent before 5:00 PM Eastern Time, on June 7, 2018. If you are exercising your subscription rights through your broker, dealer, bank, or other nominee, you should promptly contact your broker, dealer, bank, or other nominee and submit your subscription documents and payment for the shares of common stock subscribed for in accordance with the instructions and within the time period provided by your broker, dealer, bank or other nominee.

## What if my shares are held in street name?

If you hold your shares of our common stock in the name of a broker, dealer, bank, or other nominee, then your broker, dealer, bank, or other nominee is the record holder of the shares you own. The record holder must exercise the subscription rights on your behalf. Therefore, you will need to have your record holder act for you.

If you wish to participate in this rights offering and purchase shares of common stock, please promptly contact the record holder of your shares. We will ask the record holder of your shares, who may be your broker, dealer, bank, or other nominee, to notify you of this rights offering.

## What form of payment is required?

You must timely pay the full subscription price pursuant to the exercise of subscription rights by delivering to the subscription agent a cashier scheck drawn on a U.S. bank; or wire transfer.

## When will I receive my new shares of common stock?

The subscription agent will arrange for the issuance of the common stock as soon as practicable after the expiration of the rights offering, payment for the shares of common stock subscribed for has cleared, and all prorating calculations and reductions contemplated by the terms of the rights offering have been effected. All shares that you purchase in the rights offering will be issued in book-entry, or uncertificated, form meaning that you will receive a direct registration (DRS) account statement from our transfer agent reflecting ownership of these securities if you are a holder of record of shares. If you hold your shares in the name of a broker, dealer, bank, or other nominee, DTC will credit your account with your nominee with the securities you purchase in the rights offering.

# After I send in my payment and subscription rights certificate to the Subscription Agent, may I cancel my exercise of Subscription Rights?

No. Exercises of subscription rights are irrevocable unless the rights offering is terminated, even if you later learn information that you consider to be unfavorable to the exercise of your subscription rights. You should not exercise your subscription rights unless you are certain that you wish to participate in the rights offering.

## How much will the Company receive from the rights offering?

Assuming the rights offering is fully subscribed for the \$50.0 million maximum amount, including any over-subscription privilege, we estimate that the net proceeds from the rights offering will be approximately \$ million, after deducting fees and expenses payable to the dealer-manager, and after deducting other expenses payable by us.

## What are the limitations on the exercise of the basic subscription privilege and over-subscription privilege?

In the event that the exercise by a stockholder of the basic subscription privilege or the over-subscription privilege could, as determined by the Company in its sole discretion, potentially result in a limitation on the Company s ability to use net operating losses, tax credits and other tax attributes, which we refer to as the Tax Attributes, under the Internal Revenue Code of 1986, as amended, which we refer to as the Code, and rules promulgated by the Internal Revenue Service, the Company may, but is under no obligation to, reduce the exercise by such stockholder of the basic subscription privilege or the over-subscription privilege to such number of shares of common stock as the Company in its sole discretion shall determine to be advisable in order to preserve the Company s ability to use the Tax Attributes.

#### Are there risks in exercising my subscription rights?

Yes. The exercise of your subscription rights involves risks. Exercising your subscription rights involves the purchase of additional shares of our common stock and you should consider this investment as carefully as you would consider any other investment. We cannot assure you that the market price of our common stock will exceed the subscription price, nor can we assure you that the market price of our common stock will not further decline after the rights offering. We also cannot assure you that you will be able to sell shares of our common stock purchased in the rights offering at a price equal to or greater than the subscription price. In addition, you should carefully consider the risks described under the heading Risk Factors for discussion of some of the risks involved in investing in our securities.

## Can the board of directors terminate or extend the rights offering?

Yes. Our board of directors may decide to terminate the rights offering at any time and for any reason before the expiration of the rights offering. We also have the right to extend the rights offering for period not to exceed 30 days. We do not presently intend to extend the rights offering. We will notify stockholders if the rights offering is terminated or extended by issuing a press release.

## If the rights offering is not completed or is terminated, will my subscription payment be refunded to me?

Yes. The subscription agent will hold all funds it receives in a segregated bank account until completion of the rights offering. If we will cancel the offering, you will receive a refund of the money you have advanced, without interest. If you own shares in street name, it may take longer for you to receive your subscription payment because the subscription agent will return payments through the record holder of your shares.

## How do I exercise my subscription rights if I live outside the United States?

The subscription agent will hold subscription rights certificates for stockholders having addresses outside the United States. To exercise subscription rights, foreign stockholders must notify the subscription agent and timely follow other procedures described in the section entitled The Rights Offering Foreign Stockholders.

#### What fees or charges apply if I purchase shares of our common stock?

We are not charging any fee or sales commission to issue subscription rights to you or to issue shares to you if you exercise your subscription rights. If you exercise your subscription rights through the record holder of your shares, you are responsible for paying any fees your record holder may charge you.

## What are the U.S. federal income tax consequences of exercising subscription rights?

The U.S. federal income tax consequences of the Rights Offering to shareholders will depend on whether the Rights Offering is part of a disproportionate distribution. We intend to take the reporting position that the

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Subscription Rights issued to common shareholders pursuant to the Rights Offering (a) are not part of a disproportionate distribution and (b) will not be a taxable distribution with respect to your existing securities. The disproportionate distribution rules are complicated, however, and their application is uncertain, and thus our tax counsel is not rendering a definitive opinion regarding the application of such rules. The position we are taking is not binding on the Internal Revenue Service (IRS) or the courts and it is possible that the IRS could successfully challenge our reporting position and assert that the Rights Offering is a taxable distribution. You should consult your tax advisor as to the tax consequences of the rights offering in light of your particular circumstances. For a more detailed discussion, see Certain U.S. Federal Income Tax Consequences on page 107.

## To whom should I send my forms and payment?

If your shares are held in the name of a broker, dealer or other nominee, then you should send your subscription documents, rights certificate, notices of guaranteed delivery and subscription payment to that record holder. If you are the record holder, then you should send your subscription documents, rights certificate, notices of guaranteed delivery and subscription payment by hand delivery, first class mail or courier service to:

American Stock Transfer

6201 15th Ave

Brooklyn, NY 11219

You are solely responsible for completing delivery to the subscription agent of your subscription documents, rights certificate and payment. We urge you to al