DELCATH SYSTEMS, INC. Form S-3/A November 30, 2018 Table of Contents

As filed with the Securities and Exchange Commission on November 29, 2018

Registration No. 333-227970

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to 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

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:

Jolie Kahn, Esq.

Wexler, Burkhart, Hirschberg & Unger

377 Oak Street

Garden City, NY 11530

(516) 222-2230

Approximate date of commencement of proposed sale to the public:

As soon as practicable after this Registration Statement becomes effective and to be sold.

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

securities to be registered

Amount to be registered/proposed maximum offering price per unit/proposed maximum aggregate offering price

Amount of

registration fee

(1)(2)

Common Stock

Preferred Stock	(1)(2)	
Debt Securities	(1)	
Depositary Shares	(1)	
Warrants	(1)	
Units	(1)	
Total	\$100,000,000 (3)	\$12,120 (4)

- (1) Such indeterminate amount or number of debt securities, shares of preferred stock, shares of common stock, and warrants to purchase any combination of the foregoing securities, as may from time to time be issued at indeterminate prices, with an aggregate initial offering price not to exceed \$8.68, which is calculated pursuant to general instruction 1.B.1. to Form S-3, based upon the last closing sale price of a share of our common stock on the OTCQB on September 19, 2018 multiplied by 8,973,623 shares of common stock beneficially owned by nonaffiliates as of October 17, 2018. If any debt securities are issued at an original issue discount, then the issue price, and not the principal amount of such debt securities shall be used for purposes of calculating the aggregate initial offering price of all securities issued. Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder. The securities also include such indeterminate number of shares of preferred stock, shares of common stock or principal amounts of debt securities as may be issued upon conversion or exchange for debt securities that provide for conversion or exchange, upon exercise of warrants to purchase preferred stock, common stock or debt securities, upon conversion of shares of preferred stock or pursuant to the anti-dilution provisions of any such securities. Includes, but is not limited to, offerings which are underwritten on a firm commitment basis or otherwise, and offerings for which a placement agency agreement exists.
- (2) Includes rights to acquire common stock or preferred stock of the Company under any shareholder rights plan then in effect, if applicable under the terms of any such plan.
- (3) Estimated solely for the purpose of calculating the registration fee. No separate consideration will be received for shares of common stock that are issued upon conversion of debt securities, depositary shares or preferred stock or upon exercise of common stock warrants registered hereunder. The aggregate maximum offering price of all securities issued pursuant to this registration statement will not exceed \$100,000,000.
- (4) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Fee previously paid with initial filing of this registration statement on Form S-3.

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 Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated November 29, 2018.

PROSPECTUS

\$100,000,000

Common Stock

Preferred Stock

Debt Securities

Depositary Shares

Warrants

Units

We may offer and sell up to \$100,000,000 in the aggregate of the securities identified above from time to time in one or more offerings. This prospectus provides you with a general description of the securities.

Each time we offer and sell securities, we will provide a supplement to this prospectus that contains specific information about the offering and the amounts, prices and terms of the securities. The supplement may also add, update or change information contained in this prospectus with respect to that offering. You should carefully read this prospectus and the applicable prospectus supplement before you invest in any of our securities.

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus entitled About this Prospectus and Plan of Distribution for more information. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE THE <u>RISK FACTORS</u> ON PAGE 5 OF THIS PROSPECTUS AND ANY SIMILAR SECTION CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT CONCERNING FACTORS YOU SHOULD CONSIDER BEFORE INVESTING IN OUR SECURITIES.

Our common stock trades on the OTCQB under the symbol DCTH . The closing sale price on the OTCQB on November 21, 2018, was \$0.49 per share.

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 date of this prospectus is , 2018.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or the SEC, using a shelf registration process. By using a shelf registration statement, we may sell securities from time to time and in one or more offerings up to a total dollar amount of \$100,000,000 as described in this prospectus. Each time that we offer and sell securities, we will provide a prospectus supplement to this prospectus that contains specific information about the securities being offered and sold and the specific terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement or free writing prospectus may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement or free writing prospectus, you should rely on the prospectus supplement or free writing prospectus, as applicable. Before purchasing any securities, you should carefully read both this prospectus and the applicable prospectus supplement (and any applicable free writing prospectuses), together with the additional information described under the heading. Where You Can Find More Information; Incorporation by Reference.

We have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus and the applicable prospectus supplement to this prospectus is accurate only as of the date on its respective cover, that the information appearing in any applicable free writing prospectus is accurate only as of the date of that free writing prospectus, and that any information incorporated by reference is accurate only as of the date of the document incorporated by reference, unless we indicate otherwise. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus incorporates by reference, and any prospectus supplement or free writing prospectus may contain and incorporate by reference, market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included or incorporated by reference in this prospectus, any prospectus supplement or any applicable free writing prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading Risk Factors contained in this prospectus, the applicable prospectus supplement and any applicable free writing prospectus, and under similar headings in other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

When we refer to Delcath, we, our, us and the Company in this prospectus, we mean Delcath Systems, Inc., and consolidated subsidiaries, unless otherwise specified. When we refer to you, we mean the potential holders of the applicable series of securities.

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

Available Information

Our web site address is http://www.delcath.com/. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus.

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This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be obtained from us, as provided below. Forms of the indenture and other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement or documents incorporated by reference in the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters.

Incorporation by Reference

The SEC s rules allow us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or a subsequently filed document incorporated by reference modifies or replaces that statement.

This prospectus and any accompanying prospectus supplement incorporate by reference the documents set forth below that have previously been filed with the SEC:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 16, 2018 and our Amendment No. 1 to Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on April 30, 2018 (amended to include Part III information);

Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018, filed with the SEC on May 10, 2018, our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, filed with the SEC on August 14, 2018, and our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, filed with the SEC on November 13, 2018;

Our Current Reports on Form 8-K filed with the SEC on January 26, 2018, February 12, 2018, March 13 and 26, 2018, April 9 and 26, 2018, June 8, 2018, July 26 and 30, 2018, September 7, 10 (8-K/A), 24, 27 and 28, 2018, October 17 and 24, 2018 and November 7, 2018; and

A description of our common stock contained in our Registration Statement on Form 8-A filed on September 22, 2000, including all amendments and reports filed for the purpose of updating such description.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, which we refer to as the Exchange Act in this prospectus, prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

You may request a free copy of any of the documents incorporated by reference in this prospectus by writing or telephoning us at the following address:

DELCATH SYSTEMS, INC.

Attn: Corporate Secretary

1633 Broadway, Suite 22C

New York, New York 10019

(212) 489-2100

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus or any accompanying prospectus supplement.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information contained in this prospectus, any applicable prospectus supplement or documents incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities.

We file reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements or other information filed by us at the SEC s Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at (800) SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Delcath Systems, Inc. The address of the SEC website is http://www.sec.gov.

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THE COMPANY

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 (CDP) for Melphalan/HDS is comprised of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (The FOCUS Trial), a Global Phase 3 clinical trial that is investigating objective response rate in mOM, and The ALIGN Trial, a registration trial for intrahepatic cholangiocarcinoma (ICC). Our CDP also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs).

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.

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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, suchas 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%.

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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.

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.

RISK FACTORS

Investment in any securities offered pursuant to this prospectus and the applicable prospectus supplement involves risks. You should carefully consider the risk factors incorporated by reference to our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K we file after the date of this prospectus, and all other information contained or incorporated by reference into this prospectus, as updated by our subsequent filings under the Exchange Act, and the risk factors and other information contained in the applicable prospectus supplement and any applicable free writing prospectus before acquiring any of such securities. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

USE OF PROCEEDS

We intend to use the net proceeds from offerings under this prospectus pursuant to prospectus supplements for:

the clinical and regulatory development of clinical studies, including the Phase 3 Ocular Melanoma liver metastases trial, a registration trial for intrahepatic cholangiocarcinoma, investigator initiated trials, and European Union Commercial Registry;

commercialization of our products,

obtaining regulatory approvals;

capital expenditures;

working capital; and

the balance, if any, for other general corporate purposes.

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We expect that the proceeds of these offerings will be sufficient to allow us to continue our ongoing clinical trial programs, however, we are subject to substantial risks that could require us to obtain additional funding in order to achieve these objectives. See Risk Factors. We may need substantial additional capital in the future, which could cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights, and if additional capital is not available, we may have to delay, reduce or cease operations.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our certificate of incorporation, which has been publicly filed with the SEC. See Where You Can Find More Information; Incorporation by Reference.

DESCRIPTION OF CAPITAL STOCK AND RECENT TRANSACTIONS

The following description of our common stock and preferred stock summarizes the material terms and provisions of our common stock and preferred stock. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated By-Laws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. We refer in this section to our Amended and Restated Certificate of Incorporation, as amended, as our certificate of incorporation, and we refer to our

Amended and Restated By-Laws as our by-laws. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 1,000,000,000 shares of our common stock, \$0.01 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.01 par value per share. As of November 21, 2018, we had 9,022,952 shares of common stock outstanding and 85 shares of preferred stock outstanding. As of November 21, 2018, we had 66.9 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$2.99 per share,

Common Stock

Voting

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Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

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Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Other Rights and Restrictions

Our common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such stock. Our common stock is not subject to redemption by us. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the stockholder s shares of common stock. If we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Listing

Our common stock is quoted on the OTCQB under the symbol DCTH.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

Preferred Stock

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, none of which are outstanding. Our board of directors may issue preferred stock in one or more series and has the authority to fix the designation and powers, rights and preferences and the qualifications, limitations, or restrictions with respect to each class or series of such class without further vote or action by the stockholders. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management.

As of the date of this prospectus, we have designated the following series of preferred stock: Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock. None of the shares of the Series A, Series B or Series C Preferred Stock are issued and outstanding. 85 shares of Series D Preferred Stock are issued and outstanding as of November 21, 2018. None of the shares of preferred stock in any of Series A, Series B, Series C or Series D is to be registered under this prospectus.

Anti-Takeover Effects of Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period

of three years following the time that this stockholder became an interested stockholder unless:

prior to this time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

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at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a business combination includes:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we may include in any applicable prospectus supplement and in any related free writing prospectuses, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms summarized below will apply generally to any debt securities that we may offer, we will describe the particular terms of any debt securities in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below.

We may issue debt securities from time to time in one or more distinct series. The debt securities may be senior debt securities or subordinated debt securities. Senior debt securities may be issued under a senior indenture, which form of indenture is filed herewith as Exhibit 4.1. If we issue debt securities pursuant to an indenture, in the applicable prospectus supplement we will specify the trustee under such indenture. We will include in a supplement to this prospectus the specific terms of debt securities being offered, including the terms, if any, on which debt securities may be convertible into or exchangeable for common stock, preferred stock or other debt securities. The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of debt securities and any indentures are summaries of these provisions, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the debt securities and the indentures (including any amendments or supplements we may enter into from time to time which are permitted under the debt securities or an indenture).

Unless otherwise specified in a prospectus supplement, the debt securities will be direct unsecured obligations of the Company. Any debt securities designated as senior will rank equally with any of our other senior and unsubordinated debt. Any debt securities designated as subordinated will be subordinate and junior in right of payment to any senior indebtedness. There may be subordinated debt securities that are senior or junior to other series of subordinated debt securities.

The applicable prospectus supplement will set forth the terms of the debt securities or any series thereof, including, if applicable:

the title of the debt securities and whether the debt securities will be senior debt securities or subordinated debt securities;

any limit upon the aggregate principal amount of the debt securities;

whether the debt securities will be issued as registered securities, bearer securities or both, and any restrictions on the exchange of one form of debt securities for another and on the offer, sale and delivery of the debt securities in either form:

the date or dates on which the principal amount of the debt securities will mature;

if the debt securities bear interest, the rate or rates at which the debt securities bear interest, or the method for determining the interest rate, and the date or dates from which interest will accrue;

if the debt securities bear interest, the dates on which interest will be payable, or the method for determining such dates, and the regular record dates for interest payments;

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the place or places where the payment of principal, any premium and interest will be made, where the debt securities may be surrendered for transfer or exchange and where notices or demands to or upon us may be served;

any optional redemption provisions, which would allow us to redeem the debt securities in whole or in part;

any sinking fund or other provisions that would obligate us to redeem, repay or purchase the debt securities;

if the currency in which the debt securities will be issuable is United States dollars, the denominations in which any registered securities will be issuable, if other than denominations of \$1,000 and any integral multiple thereof, and the denominations in which any bearer securities will be issuable, if other than the denomination of \$5,000;

if other than the entire principal amount, the portion of the principal amount of debt securities which will be payable upon a declaration of acceleration of the maturity of the debt securities;

the events of default and covenants relevant to the debt securities, including, the inapplicability of any event of default or covenant set forth in the indenture relating to the debt securities, or the applicability of any other events of defaults or covenants in addition to the events of default or covenants set forth in the indenture relating to the debt securities;

the name and location of the corporate trust office of the applicable trustee under the indenture for such series of notes;

if other than United States dollars, the currency in which the debt securities will be paid or denominated;

if the debt securities are to be payable, at our election or the election of a holder of the debt securities, in a currency other than that in which the debt securities are denominated or stated to be payable, the terms and conditions upon which that election may be made, and the time and manner of determining the exchange rate between the currency in which the debt securities are denominated or stated to be payable and the currency in which the debt securities are to be so payable;

the designation of the original currency determination agent, if any;

if the debt securities are issuable as indexed securities, the manner in which the amount of payments of principal, any premium and interest will be determined;

if the debt securities do not bear interest, the dates on which we will furnish to the applicable trustee the names and addresses of the holders of the debt securities;

if other than as set forth in an indenture, provisions for the satisfaction and discharge or defeasance or covenant defeasance of that indenture with respect to the debt securities issued under that indenture;

the date as of which any bearer securities and any global security will be dated if other than the date of original issuance of the first debt security of a particular series to be issued;

whether and under what circumstances we will pay additional amounts to non-United States holders in respect of any tax assessment or government charge;

whether the debt securities will be issued in whole or in part in the form of a global security or securities and, in that case, any depositary and global exchange agent for the global security or securities, whether the global form shall be permanent or temporary and, if applicable, the exchange date;

if debt securities are to be issuable initially in the form of a temporary global security, the circumstances under which the temporary global security can be exchanged for definitive debt securities and whether the definitive debt securities will be registered securities, bearer securities or will be in global form and provisions relating to the payment of interest in respect of any portion of a global security payable in respect of an interest payment date prior to the exchange date;

the extent and manner to which payment on or in respect of debt securities will be subordinated to the prior payment of our other liabilities and obligations;

whether payment of any amount due under the debt securities will be guaranteed by one or more guarantors, including one or more of our subsidiaries;

whether the debt securities will be convertible and the terms of any conversion provisions;

the forms of the debt securities; and

any other terms of the debt securities, which terms shall not be inconsistent with the requirements of the Trust Indenture Act of 1939, as amended.

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This prospectus is part of a registration statement that does not limit the aggregate principal amount of debt securities that we may issue and provides that we may issue debt securities from time to time in one or more series under one or more indentures, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities.

We intend to disclose any restrictive covenants for any issuance or series of debt securities in the applicable prospectus supplement.

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DESCRIPTION OF DEPOSITARY SHARES

We may, at our option, elect to offer depositary shares rather than full shares of preferred stock. Each depositary share will represent ownership of and entitlement to all rights and preferences of a fraction of a share of preferred stock of a specified series (including dividend, voting, redemption and liquidation rights). The applicable fraction will be specified in a prospectus supplement. The shares of preferred stock represented by the depositary shares will be deposited with a depositary named in the applicable prospectus supplement, under a deposit agreement among us, the depositary and the holders of the certificates evidencing depositary shares, or depositary receipts. Depositary receipts will be delivered to those persons purchasing depositary shares in the offering. The depositary will be the transfer agent, registrar and dividend disbursing agent for the depositary shares. Holders of depositary receipts agree to be bound by the deposit agreement, which requires holders to take certain actions such as filing proof of residence and paying certain charges.

The summary of the terms of the depositary shares contained in this prospectus does not purport to be complete and is subject to, and qualified in its entirety by, the provisions of the deposit agreement and our certificate of incorporation and the certificate of designation that are, or will be, filed with the SEC for the applicable series of preferred stock.

Dividends

The depositary will distribute all cash dividends or other cash distributions received in respect of the series of preferred stock represented by the depositary shares to the record holders of depositary receipts in proportion to the number of depositary shares owned by such holders on the relevant record date, which will be the same date as the record date fixed by us for the applicable series of preferred stock. The depositary, however, will distribute only such amount as can be distributed without attributing to any depositary share a fraction of one cent, and any balance not so distributed will be added to and treated as part of the next sum received by the depositary for distribution to record holders of depositary receipts then outstanding.

In the event of a distribution other than in cash, the depositary will distribute property received by it to the record holders of depositary receipts entitled thereto, in proportion, as nearly as may be practicable, to the number of depositary shares owned by such holders on the relevant record date, unless the depositary determines (after consultation with us) that it is not feasible to make such distribution, in which case the depositary may (with our approval) adopt any other method for such distribution as it deems equitable and appropriate, including the sale of such property (at such place or places and upon such terms as it may deem equitable and appropriate) and distribution of the net proceeds from such sale to such holders.

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Liquidation Preference

In the event of the liquidation, dissolution or winding up of the affairs of Delcath, whether voluntary or involuntary, the holders of each depositary share will be entitled to the fraction of the liquidation preference accorded each share of the applicable series of preferred stock as set forth in the applicable prospectus supplement.

Redemption

If the series of preferred stock represented by the applicable series of depositary shares is redeemable, such depositary shares will be redeemed from the proceeds received by the depositary resulting from the redemption, in whole or in part, of the preferred stock held by the depositary. Whenever we redeem any preferred stock held by the depositary, the depositary will redeem as of the same redemption date the number of depositary shares representing the shares of preferred stock so redeemed. The depositary will mail the notice of redemption promptly upon receipt of such notice from us and not less than 30 nor more than 60 days prior to the date fixed for redemption of the preferred stock and the depositary shares to the record holders of the depositary receipts.

Voting

Promptly upon receipt of notice of any meeting at which the holders of the series of preferred stock represented by the applicable series of depositary shares are entitled to vote, the depositary will mail the information contained in such notice of meeting to the record holders of the depositary receipts as of the record date for such meeting. Each such record holder of depositary receipts will be entitled to instruct the depositary as to the exercise of the voting rights pertaining to the number of shares of preferred stock represented by such record holder s depositary shares. The depositary will endeavor, insofar as practicable, to vote such preferred stock represented by such depositary shares in accordance with such instructions, and we will agree to take all action which may be deemed necessary by the depositary in order to enable the depositary to do so. The depositary will abstain from voting any of the preferred stock to the extent that it does not receive specific instructions from the holders of depositary receipts.

Withdrawal of Preferred Stock

Upon surrender of depositary receipts at the principal office of the depositary and payment of any unpaid amount due the depositary, and subject to the terms of the deposit agreement, the owner of the depositary shares evidenced thereby is entitled to delivery of the number of whole shares of preferred stock and all money and other property, if any, represented by such depositary shares. Partial shares of preferred stock will not be issued. If the depositary receipts delivered by the holder evidence a number of depositary shares in excess of the number of depositary shares representing the number of whole shares of preferred stock to be withdrawn, the depositary will deliver to such holder at the same time a new depositary receipt evidencing such excess number of depositary shares. Holders of preferred stock thus withdrawn will not thereafter be entitled to deposit such shares under the deposit agreement or to receive depositary receipts evidencing depositary shares therefor.

Amendment and Termination of Deposit Agreement

The form of depositary receipt evidencing the depositary shares and any provision of the deposit agreement may at any time and from time to time be amended by agreement between us and the depositary. However, any amendment which materially and adversely alters the rights of the holders (other than any change in fees) of depositary shares will not be effective unless such amendment has been approved by at least a majority of the depositary shares then outstanding. No such amendment may impair the right, subject to the terms of the deposit agreement, of any owner of any depositary shares to surrender the depositary receipt evidencing such depositary shares with instructions to the

depositary to deliver to the holder of the preferred stock and all money and other property, if any, represented thereby, except in order to comply with mandatory provisions of applicable law.

The deposit agreement will be permitted to be terminated by us upon not less than 30 days prior written notice to the applicable depositary if a majority of each series of preferred stock affected by such termination consents to such termination, whereupon such depositary will be required to deliver or make available to each holder of depositary receipts, upon surrender of the depositary receipts held by such holder, such number of whole or fractional shares of preferred stock as are represented by the depositary shares evidenced by such depositary receipts together with any other property held by such depositary with respect to such depositary receipts. In addition, the

deposit agreement will automatically terminate if (a) all outstanding depositary shares thereunder shall have been redeemed, (b) there shall have been a final distribution in respect of the related preferred stock in connection with any liquidation, dissolution or winding-up of Delcath and such distribution shall have been distributed to the holders of depositary receipts evidencing the depositary shares representing such preferred stock or (c) each share of the related preferred stock shall have been converted into stock of Delcath not so represented by depositary shares.

Charges of Depositary

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangements. We will pay charges of the depositary in connection with the initial deposit of the preferred stock and initial issuance of the depositary shares, and redemption of the preferred stock and all withdrawals of preferred stock by owners of depositary shares. Holders of depositary receipts will pay transfer, income and other taxes and governmental charges and certain other charges as are provided in the deposit agreement to be for their accounts. In certain circumstances, the depositary may refuse to transfer depositary shares, may withhold dividends and distributions and sell the depositary shares evidenced by such depositary receipt if such charges are not paid. The applicable prospectus supplement will include information with respect to fees and charges, if any, in connection with the deposit or substitution of the underlying securities, the receipt and distribution of dividends, the sale or exercise of rights, the withdrawal of the underlying security, and the transferring, splitting or grouping of receipts. The applicable prospectus supplement will also include information with respect to the right to collect the fees and charges, if any, against dividends received and deposited securities.

Miscellaneous

The depositary will forward to the holders of depositary receipts all notices, reports and proxy soliciting material from us which are delivered to the depositary and which we are required to furnish to the holders of the preferred stock. In addition, the depositary will make available for inspection by holders of depositary receipts at the principal office of the depositary, and at such other places as it may from time to time deem advisable, any notices, reports and proxy soliciting material received from us which are received by the depositary as the holder of preferred stock. The applicable prospectus supplement will include information