DELCATH SYSTEMS, INC.
Form S-1
August 15, 2018
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As filed with the Securities and Exchange Commission on August 15, 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	**3841**	**06-1245881**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

1633 Broadway

Suite 22C

New York, New York 10019

(212) 489-2100

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

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.

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	**Proposed maximum aggregate**	**Amount of registration fee**

	offering price(1)	
Common stock, $.01 par value(2)	$6,000,000	$747.00
Total	$6,000,000	$747.00

(1) Estimated solely for the purpose of calculating the registration fee under Rule 457(o) of the Securities Act.
(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

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.

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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.

Subject to Completion, Dated August 15, 2018

3,298,516 Shares of Common Stock

This prospectus relates to the offer and sale of up to 3,298,516 (based upon a closing price of $1.819 per share on August 10, 2018) shares of common stock of Delcath Systems, Inc., a Delaware corporation, issuable to a certain selling stockholder, upon exercise of certain warrants issued to it at an exercise price of $0.01 per share which warrants were issued and exercise price prepaid pursuant to a Securities Purchase Agreement between the Company (as defined below) and this selling stockholder, dated June 4, 2018.

This prospectus covers any additional shares of common stock that may become issuable by reason of stock splits, stock dividends, and other events described therein.

Unless otherwise noted, the terms the Company, our Company, Delcath, we, us and our refer to Delcath Syst and its subsidiaries.

The selling stockholder may offer its shares from time to time directly or through one or more underwriters, broker-dealers or agents, in the over-the-counter market at market prices prevailing at the time of sale, in one or more privately negotiated transactions at prices acceptable to the selling stockholder, or otherwise, so long as our common stock is trading on the Nasdaq Capital Market or the OTCQB, and if it is not trading on the OTCQB, OTCQX or a listed exchange, sales may only take place at fixed prices.

We are registering these shares of our common stock for resale by the selling stockholder named in this prospectus, or its transferees, pledgees, donees or assigns or other successors-in-interest that receive any of the shares as a gift, distribution, or other non-sale related transfer. We will not receive any proceeds from the sale of shares by the selling stockholder. These shares are being registered to permit the selling stockholder to sell shares from time to time, in amounts, at prices and on terms determined at the time of offering. The selling stockholder may sell this common stock through ordinary brokerage transactions, directly to market makers of our shares or through any other means described in the section entitled PLAN OF DISTRIBUTION beginning of page 87. In connection with any sales of the common stock offered hereunder, the selling stockholder, any underwriters, agents, brokers or dealers participating in such sales may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended (the Securities Act).

We will pay the expenses related to the registration of the shares covered by this prospectus. The selling stockholder will pay any commissions and selling expenses they may incur.

Our common stock trades on the OTCQB under the symbol DCTJ . The closing sale price on the OTCQB on August 10, 2018, was $1.819 per share.

Our principal executive offices are located at 1633 Broadway, Suite 22C, New York, NY 10019. Our telephone number at that address is (212) 489-2100.

Investing in the common stock offered by this prospectus is speculative and involves a high degree of risk. See Risk Factors beginning on page 5.

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

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.

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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.

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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, 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.

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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.

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SUMMARY OF THE OFFERING

Common stock offered by the selling stockholder:	Up to 3,298,516 shares of our common stock, par value $0.01 per share, are being offered by the selling stockholder.
Offering prices:	The shares offered by this prospectus may be offered and sold at prevailing market prices or such other prices as the selling stockholder may determine.
Common stock outstanding:	932,159 shares as of August 10, 2018(*).
OTCQB:	DCTH for common stock.
Use of proceeds:	We are not selling any of the shares of common stock being offered by this prospectus and will receive no proceeds from the sale of the shares by the selling stockholder. All of the proceeds from the sale of common stock offered by this prospectus will go to the selling stockholder at the time it sells its shares.

(*) The total number of shares of our common stock outstanding after this offering is based on 932,158 shares outstanding as of August 10, 2018. Excludes as of that date, the following:
25.2 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.76 per share.

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
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 August 10, 2018:

25.2 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.76 per share

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RISK FACTORS

This offering and an investment in our securities involve a high degree of risk. You should carefully consider the risks described below, together with the financial and other information contained in this prospectus, before you decide to purchase our securities. If any of the following risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that event, the trading price of our common stock and the market value of the securities offered hereby could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Financial Condition

An investment in our securities involve a high degree of risk. You should carefully consider the risks described below, together with the financial and other information contained in this annual report, before you decide to purchase our securities. If any of the following risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that event, the trading price of our common stock and the market value of the securities offered hereby could decline, and you may lose all or part of your investment.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Delcath received a complete response letter from the FDA regarding our Melphalan/HDS Kit system, declining to approve our existing New Drug Application, or NDA, in its current form.

Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky, and it takes several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

In response to our New Drug Application (NDA), which the Company submitted to FDA in August 2012 seeking approval for use of our Melphalan/HDS Kit for the treatment of patients with ocular melanoma of the liver, in September 2013, the FDA denied approval of the NDA in its current form and issued a complete response letter (CRL). A CRL is issued by the FDA when the review of a file is completed, and questions remain that preclude approval of the NDA in its current form. The FDA comments in the CRL included, but were not limited to, a statement that Delcath must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS Kit using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS Kit outweigh its risks. The FDA also required that the additional clinical trial(s) be conducted using the product the company intends to market. Prior to conducting additional clinical trials, Delcath must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. Further, in January 2016 Delcath received agreement on a Special Protocol Assessment (SPA) from the FDA and has initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases.

A SPA is a process whereby a sponsor and FDA reach agreement on clinical trials and protocol elements, as well as planned analyses. While a SPA agreement is not a guarantee that FDA will accept a NDA for filing or that the clinical trial design and results will be adequate to support approval it is hoped that clinical trial quality will be improved.

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In addition, Delcath conducts and participates in numerous clinical trials with a variety of study designs, patient populations and trial endpoints to support additional indications for Melphalan/HDS Kit and HDS with other drug therapies. In 2014, Delcath initiated a Phase 2 clinical trial with Melphalan/HDS Kit for HCC in both the United States and Europe. In 2015, the Phase 2 clinical trial for HCC was expanded to include a cohort of patients with ICC. The trial for this cohort will be conducted at the same centers participating in the Phase 2 HCC trial. Unfavorable or inconsistent clinical data from clinical trials, including the Phase 2 clinical trial for HCC, the market s perception of this clinical data or FDA s perception of this clinical data, may adversely impact our ability to obtain approval, and the financial condition. Additionally, even if the results of our Phase 2 clinical trial for HCC and ICC are positive, there is a substantial risk that it will fail to have positive results in Phase 3 clinical trials with regard to efficacy, safety or other clinical outcomes and may never obtain regulatory approval.

Our former independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our former independent registered public accounting firm issued a report dated March 16, 2018 in connection with the audit of our financial statements as of December 31, 2017, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. In addition, our notes to our financial statements for the year ended December 31, 2017 included a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, Delcath would be forced to delay, reduce or eliminate its research and development programs or any commercialization efforts. The Company s consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If the Company is not able to continue as a going concern, it is likely that holders of its common stock will lose all of their investment.

The Company does not expect to generate significant revenue for the foreseeable future.

Delcath s entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT/Melphalan/HDS and currently has only developed this system for the treatment of cancers in the liver. If CHEMOSAT/Melphalan/HDS for the treatment of cancers in the liver fails as a commercial product, the Company has no other products to sell. In addition, since CHEMOSAT is currently only authorized for marketing in the EEA and limited other jurisdictions, if Delcath is unsuccessful in commercializing the product in the EEA and if Melphalan/HDS is not approved in the United States and elsewhere, there will be no means of generating revenue. In September 2013, the FDA issued a CRL with respect to the Company s NDA for Melphalan/HDS. A CRL is issued by the FDA when the review of a file is completed and questions remain that preclude approval of the NDA in its then current form. Accordingly, Delcath does not expect to realize any revenues from product sales in the United States in the next several years, if at all. As a result, our revenue sources are, and will remain, extremely limited until the Company s product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT/Melphalan/HDS may not be successful in clinical trials, approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all.

Continuing losses may exhaust our capital resources.

As of June 30, 2018, the Company had $1.3 million in cash and cash equivalents. Delcath has had minimal revenue to date, and has a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended December 31, 2017, 2016 and 2015, the Company incurred net losses of approximately $45.1 million, $18.0 million

and $14.7 million, respectively and expects to continue to incur losses in 2018. Management believes its capital resources are adequate to fund operations through July 2018, without giving effect to the offering contemplated hereby. To date, the Company has funded operations through a combination of private placements and public offerings of its securities, including convertible notes. If Delcath continues to

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incur losses, the Company may exhaust its capital resources, and as a result may be unable to complete its clinical trials, product development, regulatory approval process and commercialization of CHEMOSAT/Melphalan/HDS or any other versions of the system. If Delcath is unable to raise capital or generate sufficient revenue, it may not be able to pay its debts when they become due and may have to seek protection from the bankruptcy courts or enter into a receivership.

If the Company cannot raise additional capital, its potential to generate future revenues will be significantly limited since it may not be able to further commercialize CHEMOSAT and Melphalan/HDS, complete its clinical trials or conduct future development and clinical trials.

The Company will require additional financing to complete its clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize its product in the EEA and any other markets where the Company may receive approval for its system. In addition, Delcath is obligated to make payments under long-term research and development obligations and lease agreements. If financing is unavailable to make the required payments under these agreements, the Company could be subject to legal liability and its ability to complete development projects or clinical trials could be impaired. The Company does not know if additional financing will be available when needed at all or on acceptable terms. If unable to obtain additional financing as needed, the Company may not be able to commercialize CHEMOSAT and Melphalan/HDS, obtain regulatory approvals or complete its development projects or clinical trials, which would result in a complete loss of your investment.

Our liquidity and capital requirements will depend on numerous factors, including:

- clinical studies, including a Phase 3 clinical trial to investigate overall survival in ocular melanoma liver metastases and a registration trial in ICC;
- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our commercialization activities, regulatory submissions or ongoing activities for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

CHEMOSAT and Melphalan/HDS is subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to either civil or criminal administrative or judicially-imposed sanctions and/or other penalties.

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In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Melphalan/HDS is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product s primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research has primary jurisdiction over its pre-market development and review.

The Company is not permitted to market Melphalan/HDS in the United States unless and until it obtains regulatory approval from the FDA. To market the product in the United States, Delcath must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and the Company could encounter problems that cause it to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than the Company;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Undesirable side effects caused by any product candidate that Delcath develops could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. In August 2012, the Company submitted the Melphalan/HDS NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA declined to approve the NDA and

issued a CRL. The FDA comments in the CRL included, but were not limited to, a statement that the Company must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market. Prior to conducting additional clinical trials, Delcath must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. However, even if the Company completes its clinical trials and satisfies all the requirements of the CRL, it may not obtain regulatory approval from the FDA. Continued failure to obtain, or additional delays in obtaining, regulatory approvals may:

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adversely affect the commercialization of the current version of CHEMOSAT and Melphalan/HDS or any products that the Company develops in the future;

impose additional costs on Delcath;

diminish any competitive advantages that may be attained; and

adversely affect the Company s ability to generate revenues.

Delcath has obtained the right to affix the CE Mark for the Delcath Hepatic CHEMOSAT Delivery System as a medical device for the delivery of melphalan. Since the Company may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, Delcath s ability to commercialize CHEMOSAT in the EEA will be significantly limited.

In the EEA, CHEMOSAT is regulated as a Class IIb medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan hydrochloride, to the liver with additional extracorporeal filtration of the venous blood return. Delcath s ability to market and promote CHEMOSAT is limited to this approved indication. To the extent that the Company s promotion of CHEMOSAT is found to be outside the scope of its approved indication, Delcath may be subject to fines or other regulatory action, limiting its ability to commercialize CHEMOSAT in the EEA.

The Company is limited to marketing CHEMOSAT in the EEA as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, Delcath s ability to commercialize CHEMOSAT in the EEA will be significantly limited. Delcath s product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference Delcath s product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with Delcath s device may not be within the applicable label with respect to some indications in some Member States of the EEA where the drugs are authorized for marketing. Physicians intending to use CHEMOSAT must obtain melphalan separately for use with CHEMOSAT and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from CHEMOSAT and/or to prescribe the use of melphalan independently, the Company s sales opportunities in the EEA will be significantly impaired.

While the Company has obtained the right to affix the CE Mark, it will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where it receives marketing authorization or approval.

In April 2012, the Company obtained the required certification from its European Notified Body, enabling Delcath to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Generation Two CHEMOSAT system. In order to maintain the right to affix the CE Mark in the EEA, the Company is subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, the Company is subject to ongoing audits by its European Notified Body, and the right to affix the CE Mark to the Generation Two CHEMOSAT system may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that CHEMOSAT or Melphalan/HDS is approved by the FDA or any other regulatory agency, Delcath will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, the Company may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices (GCPs), and good laboratory practices, which are regulations

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and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that the Company conducts post-approval. In addition, post-marketing requirements for CHEMOSAT and Melphalan/HDS may include implementation of a risk evaluation and mitigation strategies (REMS) program to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If the Company is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and may not achieve or sustain profitability, which would have a material adverse effect on the business, results of operations, financial condition and prospects.

The development and approval process in the United States will take many years, require substantial resources and may never lead to the approval of Melphalan/HDS by the FDA for use in the United States.

The Company cannot sell or market Melphalan/HDS with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for Melphalan/HDS. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of

administration of melphalan or other chemotherapeutic agent used in our system. The Company is seeking approval of Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. Delcath must obtain separate regulatory approvals for Melphalan/HDS with melphalan and every other chemotherapeutic agent or other compound used with the system that Delcath intends to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA s satisfaction the product s safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of Melphalan/HDS with melphalan or any other chemotherapeutic agent or compound the Company uses in its system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. Delcath may encounter delays or rejections for various reasons, including its inability to enroll enough patients to complete the clinical trials. Moreover, approval policies or regulations may change. If the Company does not obtain and maintain regulatory approval for its system and the use of melphalan or other chemotherapeutic agents, the value of the Company, results of operations and its ability to raise additional capital will be harmed. In August 2012, Delcath submitted an NDA seeking an indication for ocular

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melanoma liver metastases for our Melphalan/HDS. In September 2013, the FDA issued a CRL. The FDA comments in the CRL included a statement that the Company must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. Failure to obtain FDA approval will have a material adverse effect on Delcath s business, financial condition and results of operations.

Even if the Company obtains regulatory approval for the Melphalan/HDS system in the United States, its ability to market the Melphalan/HDS system would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. If the FDA approves an application for the Melphalan/HDS, our ability to market and promote the Melphalan/HDS would be limited to the approved indication, so even with FDA approval, the Melphalan/HDS system may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, the Company may only market the Melphalan/HDS, if approved by the FDA, for its approved indication and could be subject to enforcement action for off-label marketing. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, Delcath may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

If future clinical trials are unsuccessful, significantly delayed or not completed, the Company may not be able to market Melphalan/HDS for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, the Company concluded a Phase 3 clinical trial of Melphalan/HDS in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase 2 clinical trial of Melphalan/HDS in patients with primary and metastatic melanoma stratified into four arms.

In January 2016 the Company received agreement on a SPA from the FDA and has initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases. In March 2017, Delcath received agreement on a SPA from the FDA for a registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC), a trial the Company expects to initiate when financial resources permit.

It may take several years to complete the testing of Melphalan/HDS for use in the treatment of these indications, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;

pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;

negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause pare-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;

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the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;

Delcath may encounter delays or rejections based on changes in regulatory agency policies during the period in which it is developing a system or the period required for review of any application for regulatory agency approval;

the Company s clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;

the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase 3 trial, relating to the Company s NDA submissions;

the FDA or foreign regulatory authorities may change its approval policies or adopt new regulations that may negatively affect or delay Delcath s ability to bring a system to market or require additional clinical trials; and

a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an application for marketing approval or cause the Company to cease the development of Melphalan/HDS for other indications. If Delcath is unable to develop Melphalan/HDS for other indications the future growth of our business could be negatively impacted. In addition, Delcath has limited clinical data relating to the effectiveness of Melphalan/HDS in certain types of cancer. Such limited data could slow the adoption of CHEMOSAT/ Melphalan/HDS and significantly reduce Delcath s ability to commercialize CHEMOSAT/ Melphalan/HDS.

The Company relies on third parties to conduct certain elements of the clinical trials for CHEMOSAT and Melphalan/HDS, and if they do not perform their obligations to Delcath, the Company may not be able to obtain regulatory approvals for its system.

The Company designs the clinical trials for Melphalan/HDS, but relies on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. Delcath relies heavily on these parties for the execution of its clinical studies and control only certain aspects of their activities. Accordingly, the Company may have less control over the timing and other aspects of these clinical trials than if Delcath conducted them entirely on their own. The Company relies upon third parties to conduct monitoring and data collection of its ongoing and future clinical trials, including its Phase 3 ocular melanoma trial and pivotal ICC trial. Although Delcath relies on these third parties to manage the data from these clinical trials and are responsible for confirming that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require Delcath to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. The Company s reliance on third parties does not relieve it of these responsibilities and requirements, and if Delcath or the third parties upon whom the

Company relies for its clinical trials fail to comply with the applicable GCPs, the data generated in its clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require Delcath to perform additional trials before approving our marketing application. The Company cannot assure you that, upon inspection, the FDA will determine that any of its clinical trials comply or complied with GCPs. In addition, Delcath s clinical trials must be conducted with product that complies with the FDA s cGMP requirements. The Company s failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for Melphalan/HDS if these requirements are not met.

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Purchasers of CHEMOSAT in the EEA may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, Delcath may not be able to successfully commercialize CHEMOSAT in the EEA.

The Company has obtained the right to affix the CE Mark for CHEMOSAT, and Delcath intends to seek third-party or government reimbursement within those countries in the EEA where it expects to market and sell CHEMOSAT. In Germany, the Company has received a ZE diagnostic-related group code, which permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures beginning in 2016. Negotiations on the amount of reimbursement to be received under the code were concluded in 2016 and the procedure is reimbursed under this system in 2017. The ZE system is an annual process and negotiations are underway to set reimbursement levels for 2018. Consequently, reimbursement obtained may not be for the full amount sought. In countries where Delcath is able to obtain reimbursement, local policy could limit the Company s ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until Delcath obtains government reimbursement, it will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that Delcath will qualify for such funding. Even if the Company does qualify, the amount and the duration of this funding may be limited. There are also no assurances that third-party payors or government health agencies of Member States of the EEA will reimburse the product s use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase CHEMOSAT if they do not receive substantial reimbursement for the cost of using the product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

The success of our products may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.

The Company s ability to commercialize its system successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Melphalan/HDS is currently not approved by the FDA. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the use of Melphalan/HDS since the product is currently not approved outside the EEA. Delcath will seek reimbursement by third-party payors of the cost of Melphalan/HDS after its use is approved, but there are no assurances that adequate third-party coverage will be available for Delcath to establish and maintain price levels sufficient for the Company to realize an appropriate return on its investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for healthcare providers.

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT/ Melphalan/HDS and the demand for CHEMOSAT/ Melphalan/HDS. Healthcare providers may respond to such cost-containment pressures by choosing lower cost products or other therapies. In March 2010, the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (ACA) were enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. The President and members of Congress have recently introduced legislative proposals

to significantly alter the ACA. It is uncertain if such proposals will be enacted or what consequences these proposals or the implementation of existing provisions will have on our efforts to commercialize CHEMOSAT and Melphalan/HDS.

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CHEMOSAT/ Melphalan/HDS may not achieve sufficient acceptance by the medical community to sustain our business.

The commercial success of CHEMOSAT and Melphalan/HDS will depend upon its acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Acceptance by the medical community may depend on the extent to which leaders in the scientific and medical communities publish scientific papers in reputable academic journals. If testing and clinical practice do not confirm the safety and efficacy of CHEMOSAT and Melphalan/HDS or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, and CHEMOSAT and Melphalan/HDS as effective and desirable, our efforts to market CHEMOSAT and Melphalan/HDS may fail, which would cause us to cease operation.

Consolidation in the healthcare industry could lead to demands for price concessions.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry. Group purchasing organizations, independent delivery networks and large single accounts in the United States and foreign markets may result in a consolidation of purchasing decisions for potential healthcare provider customers. The Company expects that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the price of CHEMOSAT and Melphalan/HDS and adversely impact our business, financial condition and results of operations.

Further, third-party payors may deny reimbursement if they determine that CHEMOSAT and Melphalan/HDS is not used in accordance with established payor protocols regarding cost effective treatment methods or is used outside its approved indication or for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals and other health care providers will be less likely to purchase CHEMOSAT and Melphalan/HDS, thereby harming our results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of the CHEMOSAT/Melphalan/HDS

There are three third-party manufacturers of melphalan in certain countries of the EEA of which the Company is aware. If any of these manufacturers fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, Delcath may be unable to successfully commercialize our product in the EEA.

Under the current regulatory scheme in the EEA, CHEMOSAT is approved for marketing as a device only, and doctors will separately obtain melphalan for use with CHEMOSAT. Although melphalan has been approved in the EEA for over a decade, the Company is aware that there are currently three approved manufacturers of melphalan in certain countries of the EEA. As a result, there may not be sufficient supply of melphalan for use with its system, and any adverse change in the sole manufacturer s commercial operations or regulatory approval status may seriously impair Delcath s sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where Delcath may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, the Company will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

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If the Company cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents it will be unable to successfully commercialize the Delcath system in the United States or complete its global Phase 3 in ocular melanoma liver metastases, registration trial in ICC, or any future clinical trials.

The Company has entered into a manufacturing and supply agreement with Synerx Pharma, LLC (Synerx) and Bioniche Teoranta (Bioniche) an affiliate of Mylan, Inc., for the supply of its branded melphalan for injection. The agreement with Synerx and Bioniche currently represents Delcath s sole source of branded melphalan in the United States. The Company intends to use the melphalan supplied by Synerx and Bioniche to conduct its global Phase 3 trials for ocular melanoma liver metastases and ICC. Delcath may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that it will use in the future for its clinical trial program and the commercialization of CHEMOSAT and Melphalan/HDS, as well as for labeling and finishing services. The Company may not be able to enter into such arrangements on acceptable terms or at all. To manufacture melphalan or other chemotherapeutic agents on its own, Delcath would first have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent the Company chooses to manufacture for its system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on its revenues and profitability. If Delcath is unable to obtain sufficient melphalan and labeling services on acceptable terms, if it should encounter delays or difficulties in its relationships with current and future suppliers or if current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, Delcath s business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture CHEMOSAT and Melphalan/HDS, our ability to develop and commercialize the system would be impaired.

We manufacture CHEMOSAT and Melphalan/HDS for distribution worldwide in our Queensbury, NY facility. We have a limited manufacturing history and we may not be able to manufacture the system in sufficient commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver CHEMOSAT and Melphalan/HDS to purchasers.

In addition to limiting sales opportunities, delays in manufacturing CHEMOSAT and Melphalan/HDS may adversely affect our ability to obtain regulatory approval in other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture CHEMOSAT and Melphalan/HDS in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

If our Queensbury, NY facility fails to maintain compliance with ISO 13485, a comprehensive management system for the design and manufacture of medical devices, and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble CHEMOSAT and Melphalan/HDS in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

The Company does not have written contracts with all of its suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS.

The Company does not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS. If Delcath is unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, it may not be able to manufacture the system in commercial quantities or in a cost-effective manner, and commercialization of CHEMOSAT and Melphalan/HDS in the EEA may be delayed. In addition, certain components are available from only a limited number of sources.

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Components of CHEMOSAT and Melphalan/HDS are currently manufactured for Delcath in small quantities and may require significantly greater quantities to further commercialize the product. The Company may not be able to find alternate sources of comparable components. If Delcath is unable to obtain adequate supplies of components from existing suppliers or needs to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of CHEMOSAT and Melphalan/HDS may be delayed.

The Company has limited experience in marketing and commercializing its products, and as a result, may not be successful in commercializing CHEMOSAT in the EEA.

The Company has not previously sold, marketed or distributed any products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors. Even though Delcath has obtained the right to affix the CE Mark, it currently has limited sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue the Company s strategy to commercialize CHEMOSAT in the EEA, Delcath must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If Delcath cannot successfully develop the infrastructure to market and commercialize CHEMOSAT, its ability to generate revenues in the EEA may be harmed, and Delcath may not generate sufficient revenue to sustain its business or may be required to enter into strategic alliances to have such activities carried out on its behalf, which may not be on favorable terms.

Competition for sales and marketing personnel is intense, and Delcath may not be successful in attracting or retaining such personnel. The Company s inability to attract and retain skilled sales and marketing personnel or to reach an agreement with a third party could adversely affect its business, financial condition and results of operations. Further, since Delcath s marketing strategy in the EEA includes establishing a network of third-party distributors, the Company must enter into collaborative arrangements with these third-party distributors. The Company may not be able to enter into such arrangements on reasonable terms or at all.

Even if the Company receives FDA or other foreign regulatory approvals, Delcath may be unsuccessful in commercializing CHEMOSAT and Melphalan/HDS in markets outside the EEA, because of inadequate infrastructure or an ineffective commercialization strategy.

Outside the EEA, even if the Company obtains regulatory approval from the FDA or other foreign regulatory agencies, its ability to commercialize CHEMOSAT and Melphalan/HDS may be limited due to Delcath s inexperience in developing a sales, marketing and distribution infrastructure. If the Company is unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market its products in the United States or foreign countries, particularly in Asia, Delcath s efforts to commercialize CHEMOSAT and Melphalan/HDS or any other product outside of the EEA may be less successful.

Even if the Company is successful in commercializing CHEMOSAT and Melphalan/HDS in the EEA, Delcath may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so the Company s EEA strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, Delcath s efforts to promote and market CHEMOSAT in each of its target markets may fail in any or all of those markets.

The Company s plan to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and Melphalan/HDS may not be successful.

The Company may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, Delcath may face competition in its search for alliances. As a result, the Company may not be able to enter into any additional

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alliances on acceptable terms, if at all. The Company s collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and Melphalan/HDS or any other product. The success of any collaboration will depend upon Delcath s ability to perform its obligations under any agreements as well as factors beyond its control, such as the commitment of its collaborators and the timely performance of their obligations. The terms of any such collaboration may permit Delcath s collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with the Company s expectations or its collaborators may breach their agreements with the Company. In addition, any third parties with which the Company collaborates may have significant control over important aspects of the development and commercialization of its products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. Delcath is not able to control or influence the amount and timing of resources that any collaborator may devote to the Company s research and development programs or the commercialization, marketing or distribution of its products. The Company may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with CHEMOSAT and Melphalan/HDS or the withdrawal of their support for its products. The failure of any such collaboration could have a material adverse effect on its business.

If the Company fails to overcome the challenges inherent in international operations, its business and results of operations may be materially adversely affected.

Currently the Company has only received authorization to market CHEMOSAT in the EEA, and intends to seek similar authorization or approvals in other foreign countries. As a result, Delcath expects international sales of its products to account for a significant portion of its revenue, which exposes Delcath to risks inherent in international operations. To accommodate the Company s international sales, Delcath will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of its customers. Accordingly, Delcath will face additional risks resulting from its international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to satisfy foreign regulatory requirements to market its products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that the Company establishes with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;

- the possibility that foreign countries may impose additional withholding taxes or otherwise tax its foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If the Company fails to overcome the challenges it encounters in its international operations, Delcath s business and results of operations may be materially adversely affected.

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CHEMOSAT has been used a limited number of times in a clinical setting in the EEA, so market acceptance of CHEMOSAT will depend on EEA healthcare professionals efforts to learn about the product.

Since all of the Company s prior clinical studies were conducted in the United States and CHEMOSAT has had limited use in a clinical setting in the EEA, physicians in the EEA have limited clinical experience with the product. As a result, CHEMOSAT may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors in the EEA until healthcare professionals are properly educated about the procedure. Market acceptance of CHEMOSAT in the EEA will depend upon a variety of factors including:

- whether future clinical trials demonstrate significantly improved patient outcomes;
- the Company s ability to educate and train physicians to perform the procedure and drive acceptance of the use of CHEMOSAT;
- Delcath s ability to obtain adequate reimbursement and convince healthcare payors that use of CHEMOSAT results in reduced treatment costs and improved outcomes for patients;
- whether CHEMOSAT replaces and/or complements treatment methods in which many hospitals have made a significant investment; and
- whether doctors and hospitals are willing to replace their existing technology with a new medical technology until the new technology s value has been demonstrated.

The Company intends to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in the EEA, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop. Without effort from healthcare professionals to become educated about Delcath s product, the market may not accept CHEMOSAT and its efforts to commercialize CHEMOSAT in the EEA may be unsuccessful.

Similar considerations apply in any other market where the Company receives approval. Successful commercialization of CHEMOSAT in these markets will depend on market acceptance by healthcare professionals.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect the Company s ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. CHEMOSAT and Melphalan/HDS competes with all forms of liver cancer treatments that are alternatives to the gold standard treatment of surgical resection. Many of the Company s competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, Delcath s revenues or profitability will be substantially reduced.

The Company s ability to develop CHEMOSAT and Melphalan/HDS for other indications could affect its orphan drug exclusivity. Delcath has the following six designations:

- two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma (November 2008)
- orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors (May 2009)
- orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer (August 2009)
- orphan drug designation of the drug melphalan for the treatment of HCC (October 2013)
- orphan drug designation of the drug melphalan or the treatment of ICC (July 2015)

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If CHEMOSAT and Melphalan/HDS are approved for an indication different than the indications for which Delcath has received orphan drug designations, the Company will not obtain orphan drug exclusivity, which could increase its competition. If another company has orphan drug designations for these same indications and receives marketing approval before Delcath does, then the Company will be blocked from marketing approval for seven years from the date of its approval for the same indication of use.

The loss of key personnel could adversely affect the Company s business.

The loss of a member of the Company s senior executive staff could harm its business. Competition for experienced personnel is intense. If Delcath cannot retain its current personnel or attract additional experienced personnel, Delcath s ability to compete could be adversely affected.

We have had a legal proceeding filed against us, and it is premature to assess what the potential outcome of the proceeding will be, and what impact, if any, the outcome could have on our business.

On July 27, 2018, Hudson Bay Master Fund Ltd. filed a summons and complaint against the Company in the New York State Supreme Court, New York County (the Suit). The Suit alleges breaches by the Company of Hudson Bay s rights of participation in future Company offerings granted in the September 2017 Securities Purchase Agreement between the Company and Hudson Bay and in the February 2018 Securities Purchase Agreement among, inter alia, the Company and Hudson Bay. In terms of relief sought, Hudson Bay claims both monetary damages (which it claims to be in excess of $1 million) and specific performance. While the Company denies any liability with respect to the claims set forth in the Suit, it is premature to assess the outcome of this proceeding, and what, if any, impact any potential outcome could have on our business operations or financial condition.

The Backstop Agreement (as defined below) entered into on June 4, 2018 does not obligate the backstop investors to invest the full balance of the $50,000,000 not subscribed to under our current rights offering unless certain conditions are met as described in this prospectus, so we cannot be assured that we will receive the entire $50,000,000 rights offering amount.

On June 4, 2018, we entered into a Backstop Commitment Purchase Agreement with the selling stockholder, and on July 20, 2018 Discover Growth Fund, LLC entered into the same form of agreement with us (the Backstop Agreement). Pursuant to the Backstop Agreement, the investors have agreed, subject to customary conditions outside of its control, to purchase from us, on a fully committed basis, shares of common stock that would have been delivered to our stockholders upon exercise of rights that are not duly exercised prior to the expiration date of the rights offering. Such shares will be purchased for an aggregate amount equal to the aggregate subscription price and otherwise on the same terms as the shares offered to stockholders in the rights offering. Within two business days following the satisfaction of the closing conditions contained in the Backstop Agreement, and each successive 15 business day period thereafter during the term of the Backstop Agreement, the investors have agreed to purchase from us up to such number of shares equal to the lesser of (i) $1,000,000 worth of shares or (ii) 20% of the dollar trading volume of our common stock on the five trading days immediately preceding the purchase date. Therefore, if our dollar trading volume is limited as the result of either low volume in the market for our common stock, or as a result of a decrease in the market price of our common stock, we may not be able to cause the investors to purchase the full amount of the backstop commitment on or before the termination date of the Backstop Agreement, which is on or before June 30, 2019, nor may we be able to register the shares of common stock to be sold pursuant to the Backstop Agreement in full or part or at all. Any failure to receive the full $50,000,000 (inclusive of the proceeds from this rights offering) may cause a material adverse effect on our ability to fund our operations and complete our clinical trials.

We rely on the proper function, availability and security of information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations.

We rely on information technology systems to process, transmit, and store electronic information in our day-to-day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Any of these event may cause us to have difficulty preventing, detecting, and controlling fraud, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Intellectual Property

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

Our success depends significantly on our ability to maintain and protect our proprietary rights in the technologies and inventions used in or embodied by our product. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality, license and other contractual restrictions in our manufacturing, consulting, employment and other third party agreements. These legal means may afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We have not and may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product and technologies in any or all countries throughout the world could be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from copying our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection that covers the commercial products to develop their own competing products that are the same or substantially the same as our commercial product and, further, may export otherwise infringing products to territories where we have patent protection, but judicial systems do not adequately enforce patents to cause infringing activities to be ceased.

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We do not have patent rights in certain foreign countries in which a market exists or may exist in the future. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our product.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Moreover, the United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies.

Our success depends in part on our ability to obtain patents, which can be an expensive, time consuming, and uncertain process, and the value of the patents is dependent in part on the breadth of coverage and the relationship between the coverage and the commercial product.

The patent position of medical drug and device companies is generally highly uncertain. The degree of patent protection we require may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us sufficient exclusivity, or to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file patent applications on the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or license from others in the future may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;

any patents we obtain or license from others in the future may not be valid or enforceable; and

we may not develop additional proprietary technologies that are patentable

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in the CHEMOSAT/Melphalan/HDS methods and/or devices that cause

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such methods and/or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us.

Our success depends in part on our ability to commercialize CHEMOSAT/Melphalan/HDS prior to the expiration of our patent protection.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our CHEMOSAT/Melphalan/HDS methods and devices, we may be open to competition from generic versions of such methods and devices.

We may in the future become involved in lawsuits to protect or enforce our intellectual property, or to defend our products against assertion of intellectual property by a third party, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To stop any such infringement or unauthorized use, litigation may be necessary. Our intellectual property has not been tested in litigation. There is no assurance that any of our issued patents will be upheld if later challenged or will provide significant protection or commercial advantage. A court may declare our patents invalid or unenforceable, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, or may interpret the claims of our patents narrowly, thereby substantially narrowing the scope of patent protection they afford. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

In addition, third parties may initiate legal or administrative proceedings against us to challenge the validity or scope of our intellectual property rights, or may allege an ownership right in our patents, as a result of their past employment or consultancy with us. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor s patents, we could be prevented from marketing our product in one or more foreign countries.

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third-party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third-party patents, it is possible that CHEMOSAT/Melphalan/HDS could be found to infringe these patents. It is also possible that our competitors or

potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, import or export our product. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product.

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Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor s patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others patent rights, which may not be possible or could require substantial funds or time.

Litigation related to infringement and other intellectual property claims such as trade secrets, with or without merit, is unpredictable, can be expensive and time-consuming, and can divert management s attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages, and attorneys fees, and could prohibit us from using technologies essential to our product, any of which would have a material adverse effect on our business, results of operations, and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our product unless we can obtain licenses to use technology or ideas covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline.

If others have filed patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference or derivation proceedings declared by the USPTO to determine priority of invention, which could also be costly and could divert our attention from our business. If the USPTO declares an interference and determines that our patent or application is not entitled to a priority date earlier than that of the other patent application, our ability to maintain or obtain those patent rights will be curtailed. Similarly, if the USPTO declares a derivation proceeding and determines that the invention covered by our patent application was derived from another, we will not be able to obtain patent coverage of that invention.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT/Melphalan/HDS or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our United States patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications,

have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

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We maintain a patent license arrangement with a third party, and our future business may depend, in part, upon the maintenance of that arrangement.

Certain aspects of our next generation products may be covered by United States patents and United States patent applications owned by a third party and exclusively licensed to us. If we breach the terms of the license agreement, the license may be terminated by the licensor. If we do not meet certain commercialization obligations by 2019, the license may be converted to a non-exclusive license by the licensor. We cannot guarantee that the license will not be terminated or converted in the future. Without the patent license we will not be able to prevent others from practicing the technology covered by the licensed patent. Moreover, without the patent license, we may be subject to allegations of patent infringement by the patent owner. We cannot guarantee that the third party will fulfill its responsibilities under the license arrangement.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product and our technologies.

Legislation introduced earlier this decade increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the United States patent system from a first-to-invent system to a first-to-file system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. As case law continues to develop in response to this legislation, it is not yet clear what the full impact of the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future.

Our trademarks may be infringed or successfully challenged, resulting in harm to our business.

We rely on our trademarks as one means to distinguish our product from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand

recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement.

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We may rely primarily on trade secret protection for important proprietary technologies in the European Economic Area.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Specifically in the European Economic Area (EEA), we rely on design patent and trade secret protection for CHEMOSAT/Melphalan/HDS. Without utility patent protection in the EEA covering the current version of CHEMOSAT/Melphalan/HDS, CHEMOSAT/Melphalan/HDS will only be covered by design patent and trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to CHEMOSAT/Melphalan/HDS will significantly impair our ability to commercialize CHEMOSAT in the EEA, and our value and results of operations will be harmed. In particular, we rely on trade secret protection for the filter media, which is a key component of our system.

Similar considerations apply in other foreign countries not mentioned above in the Intellectual Property and Other Rights section where we receive approval. Since we do not have issued patents for the current version of CHEMOSAT/Melphalan/HDS in these countries, our ability to successfully commercialize CHEMOSAT/Melphalan/HDS will depend on our ability to maintain trade secret protection in these markets.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information,know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other

proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to

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paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

Risks Related to Products Liability

The Company may be the subject of product liability claims or product recalls, and it may be unable to maintain insurance adequate to cover potential liabilities.

The Company s business exposes Delcath to potential liability risks that may arise from clinical trials and the testing, manufacture, marketing, sale and use of CHEMOSAT/Melphalan/HDS. In addition, because CHEMOSAT/Melphalan/HDS is intended for use in patients with cancer, there is an increased risk of death among the patients treated with Delcath s system which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. The Company may be subject to claims against it even if the injury is due to the actions of others. For example, if the medical personnel that use Delcath s system on patients are not properly trained or are negligent in the use of the system, the patient may be injured, which may subject Delcath to claims. Were such a claim asserted, the Company would likely incur substantial legal and related expenses even if Delcath prevails on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit the Company s ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for Delcath to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on Delcath s business, financial condition and results of operations. The Company currently carries product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to Delcath s Common Stock

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

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

- fluctuations in quarterly operating results or the operating results of competitors;

variance in financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of its markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;

failure of its products to achieve or maintain market acceptance or commercial success;

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conditions and trends in the markets served;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of competitors;

changes in pricing policies or the pricing policies of competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by the Company or its competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving Delcath, its general industry or both;

recruitment or departure of key personnel;

changes in capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or expected sales of common stock by stockholders; and

the trading volume of Delcath s common stock.

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

The exercise price and number of certain outstanding warrants may be adjusted in future offerings.

The 1.0 million warrants issued in the Company s February 2015, July 2015 and October 2016 offerings, and in a transaction signed in November 2017 are subject to an exercise price adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting Delcath s common stock, and adjusted as a result of the June 2018

private placement, pursuant to which the exercise price as readjusted to $0.01. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. In addition to the potential dilutive effect of this provision, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of Delcath s common stock.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

The Company is not restricted from issuing additional shares of common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of August 10, 2018, the Company had an aggregate of 1 billion shares of common stock authorized and of that 999.1 million not issued or outstanding, including 25.2 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of $7.76. The Company may issue all of these shares without any action or approval by its shareholders. Delcath may expand its business through complementary or strategic business combinations or acquisitions of other companies and assets, and may issue shares of common stock in connection with those transactions. The market price of Delcath s common stock could decline as a result of the issuance of a large number of shares of common stock, particularly if the per share consideration received for the stock issued is less than the per share book value of Delcath s common stock or if the Company is not expected to be able to

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generate earnings with the proceeds of the issuance that are as great as the earnings per share generated before the issuance of the additional shares. In addition, any shares issued in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by investors. The Company cannot predict the size of future issuances or the effect, if any, that they may have on the market price of its common stock.

The Company has a history of reverse splits, which have severely impacted its common stock price.

Since Delcath s initial public offering in 2000, it has executed four reverse stock splits, for a cumulative ratio since its IPO of 1:44,800,000. Each such reverse split (except for the most recent reverse stock split effected on May 2, 2018) has resulted in an effective decline in the price of Delcath s common stock. For example, the most recent reverse split of 1:350 was effected on November 6, 2017, resulting in an opening price of $10.50. By November 30, 2017, Delcath s common stock closed at $0.09 and has continued to decline. On May 2, 2018, Delcath effected a 1:500 reverse split of its common stock, resulting in an opening price of $2.50. Although as of the close of the trading day on August 10, 2018, the price was $1.819, there can be no assurance that such reverse split will not result in a further significant diminution of the value of Delcath s common stock.

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

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

providing for a staggered board; and

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

The Company is subject to the risks relating to penny stocks.

Trading in the Company s common stock is subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

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The Company has never declared or paid any dividends to the holders of its common stock and does not expect to pay cash dividends in the foreseeable future.

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

If the Company engages in acquisitions, reorganizations or business combinations, it will incur a variety of risks that could adversely affect its business operations or its stockholders.

The Company may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If Delcath does pursue such a strategy, the Company could, among other things:

- issue equity securities that would dilute current stockholders percentage ownership;
- incur substantial debt that may place strains on its operations;
- spend substantial operational, financial and management resources in integrating new businesses, personnel intellectual property, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize its programs and even cease development and commercialization of CHEMOSAT/Melphalan/HDS;
- suffer the loss of key personnel, or
- merge with, or otherwise enter into a business combination with, another company in which Delcath stockholders would receive cash or shares of the other company or a combination of both on terms that certain of the Company s stockholders may not deem desirable.

Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

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

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

Failure of our products to achieve or maintain market acceptance or commercial success;

fluctuations in our quarterly operating results or the operating results of our competitors;

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variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt or the prospect of future reverse stock splits;

actual or expected sales of our common stock by our stockholders; and

the trading volume of our common stock.

In addition, the stock markets, in general, and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in

our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management s attention and resources, which could further materially harm our financial condition and results of operations.

Our warrants contain anti-dilution provisions that, if triggered, could cause dilution to our existing stockholders.

The 1.0 million warrants issued in our February 2015, July 2015 and October 2016 offerings, and in a transaction signed in November 2017 are subject to an exercise price adjustment as a result of the June 2018 private placement, pursuant to which the exercise price as readjusted to $0.01. In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

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

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

providing for a staggered board; and

authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

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

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

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

If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

We may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

issue equity securities that would dilute our current stockholders percentage ownership;

incur substantial debt that may place strains on our operations;

spend substantial operational, financial and management resources in integrating new businesses, personnel intellectual property, technologies and products;

assume substantial actual or contingent liabilities;

reprioritize our programs and even cease development and commercialization of CHEMOSAT and Melphalan/HDS;

suffer the loss of key personnel, or

merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our

stockholders may not deem desirable.

Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of August 10, 2018, we had an aggregate of 1 billion shares of common stock authorized and of that 999.1 million not issued or outstanding, including 25.2 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of $7.76. We may issue all of these shares without any action or approval by our shareholders. We may expand our business through complementary or strategic business combinations or

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acquisitions of other companies and assets, and we may issue shares of common stock in connection with those transactions. The market price of our common stock could decline as a result of our issuance of a large number of shares of common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, will, may, can, continue, potential, should, and the negative of these terms or other comparable terminology identify forward-looking statements. Statements in this prospectus that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 in Item 1A under Risk Factors as well as in Item 7A Quantitative and Qualitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and System;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and Melphalan/HDS;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this

prospectus. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after such applicable date or to reflect the occurrence of unanticipated events.

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USE OF PROCEEDS

We are not selling any of the shares of common stock being offered by this prospectus and will receive no proceeds from the sale of the shares by the selling stockholder. All of the proceeds from the sale of common stock offered by this prospectus will go to the selling stockholder at the time they offer and sell such shares. We will bear all costs associated with registering the shares of common stock offered by this prospectus.

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PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is quoted on the OTCQB under the symbol DCTH. The table below sets forth, for the periods indicated, the quarterly high and low sale prices per share of our common stock since 2015. The information in the table below reflects a one-for-three hundred fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse split effected on May 2, 2018.

	High	Low
2015:		
First Quarter	$ 4,368,250	$ 2,688,000
Second Quarter	4,032,000	2,268,000
Third Quarter	2,576,000	1,120,000
Fourth Quarter	1,736,000	1,092,000
2016:		
First Quarter	$ 1,512,000	$ 700,000
Second Quarter	997,500	644,000
Third Quarter	806,750	434,000
Fourth Quarter	479,500	157,500
2017:		
First Quarter	$ 152,250	$ 14,000
Second Quarter	47,250	3,500
Third Quarter	36,265	9,615
Fourth Quarter	25,175	15
2018:		
First Quarter	$ 26	$ 5
Second Quarter	6	1

The last reported trading price of our common stock on August 10, 2018 was $1.819. As ofAugust 10, 2018, we had approximately 100 holders of record of our common stock.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.

Equity Compensation Plans

Summary equity compensation plan data

The following table sets forth information, as of December 31, 2017, about our equity compensation plans (including the potential effect of debt instruments convertible into common stock) in effect as of that date:

Plan category	(a) Number of securities	(b) Weighted-average exercise	(c) Number of securities

	to be issued upon exercise of outstanding options, warrants and rights[1][2]	price of outstanding options[1]	remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))[1]
Equity compensation plans approved by security holders		$	
Equity compensation plans not approved by security holders			
Totals		$	

(1) Reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse split effected on May 2, 2018.
(2) Net of equity instruments forfeited, exercised or expired.

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OUR BUSINESS

Unless the context otherwise requires, all references in this Prospectus to the Company , Delcath , Delcath Systems , w our , and us refers to Delcath Systems, Inc., a Delaware corporation, incorporated in August 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100.

About Delcath

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 commercially available 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.

Our clinical development program for CHEMOSAT and 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 overall survival in mOM, and a registration trial for intrahepatic cholangiocarcinoma (ICC) which was initiated in May 2018. 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, commercialCHEMOSAT 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.

In the United States, Melphalan/HDS is considered a combination drug and device product and is regulated as a drug by the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, HCC and ICC. Melphalan/HDS has not been approved for sale in the United States.

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 reimbursement coverage 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. In 2017, Dutch health authorities added CHEMOSAT to their treatment guidelines for patients with ocular melanoma metastatic to the liver, an important step toward eventual reimbursement in the Dutch market.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT and Melphalan/HDS represent a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver and are 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, 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 we commissioned 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. Based on the research conducted in 2016, 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

CHEMOSAT and Melphalan/HDS administer 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 settings are permitted up to six treatments. In non-clinical commercial settings patients have received up to eight treatments. In the United States, melphalan hydrochloride for injection will be included with the system. 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 associated with the CHEMOSAT and Melphalan/HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT and Melphalan/HDS is associated with toxic side effects and certain risks, some of which are potentially life threatening. An integrated safety population comprised of patients treated during our prior clinical development using early versions of the Melphalan/HDS showed these risks to include grade 3 or 4 bone marrow suppression and febrile neutropenia, as well as risks of hepatic injury, severe hemorrhage, gastrointestinal perforation, stroke, and myocardial infarction in the setting of an incomplete cardiac risk assessment. Deaths due to certain adverse reactions within this integrated safety population were not observed to occur again during the clinical trials following the adoption of related protocol amendments.

Procedure and Product Refinements

The trials that comprised this integrated safety population used early versions of the device and procedure. As a consequence of these identified risks and experience gained in non-clinical, commercial usage in Europe, we have continued to develop and refine both the CHEMOSAT and Melphalan/HDS and the PHP procedure. The procedure refinements have included modifications to the pre, peri and post procedure patient management and monitoring, as well as the use of the following: prophylactic administration of proton pump inhibitors, prophylactic platelet transfusions, prophylactic hydration at key pre-treatment intervals, use of vasopressor agents coupled with continuous monitoring for maintenance of blood pressure and prophylactic administration of growth factors to reduce risk of serious myelosuppression. In addition, in 2012 we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other product enhancements.

Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2017, physicians in Europe and the United States also presented the results of research that signaled an improved safety profile as well as efficacy in multiple tumor types at several major medical conferences.

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Phase 3 Melanoma Metastases Trial

In February 2010, we concluded a randomized Phase 3 multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive PHP treatments with melphalan using the Melphalan/HDS, or to a control group providing best alternative care (BAC). Patients assigned to the PHP arm were eligible to receive up to six cycles of treatment at approximately four to eight week intervals. Patients randomized to the BAC arm were permitted to cross-over into the PHP arm at radiographic documentation of hepatic disease progression. A majority of the BAC patients did in fact cross over to the PHP arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, we announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melphalan/HDS for patients with unresectable metastatic ocular and cutaneous melanoma in the liver had successfully achieved the study s primary endpoint of extended hepatic progression-free survival (hPFS). An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization and the European Society of Medical Oncology in September 2011. Data submitted in October 2012 to the FDA in Delcath s New Drug Application (NDA) comparing treatment with the PHP with melphalan (the treatment group) to BAC (the control group), showed that patients in the PHP arm had a statistically significant longer median hPFS of 7.0 months compared to 1.7 months in the BAC control group, according to the Independent Review Committee (IRC) assessment. This reflects a 4-fold increase of hPFS over that of the BAC arm, with 50% reduction in the risk of progression and/or death in the PHP treatment arm compared to the BAC control arm. Results of this study were published in Annals of Surgical Oncology, in December 2015.

Phase 2 Multi-Histology, Unresectable Hepatic Tumor Trial

Also, in 2010, we concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using an early version of the Melphalan/HDS in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), ocular or cutaneous melanoma, metastatic colorectal adenocarcinoma (mCRC), and HCC. In the metastatic neuroendocrine (mNET) cohort (n=24), the objective tumor response rate was 42%, with 66% of patients achieving hepatic tumor shrinkage and durable disease stabilization. In the mCRC cohort, there was inconclusive efficacy possibly due to advanced disease status of the patients. Similar safety profiles were seen across all tumor types studied in the trial.

Phase 2 Multi-Histology Clinical Trial HCC Cohort

In the HCC cohort (n=8) of our Phase 2 Multi-Histology trial, a positive signal in hepatic malignancies was observed in 5 patients. Among these patients, one patient received four treatments, achieved a partial response lasting 12.22 months, and survived 20.47 months. Three other patients with stable disease received 3-4 treatments, with hPFS ranging 3.45 to 8.15 months, and overall survival (OS) ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. The observed duration of hPFS and OS in this limited number of patients exceeded that generally associated with this patient population.

Prior United States Regulatory Experience

Based on the results from our prior clinical development in August 2012, we submitted an NDA under Section 505(b)(2) of the Federal Food Drug Cosmetic Act (FFDCA) seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, and subsequently amended the indication to ocular melanoma metastatic to the liver. Data submitted to the Food and

Drug Administration (FDA) used the early clinical trial versions of the system along with early clinical procedure techniques. Our NDA was accepted for filing by the FDA on October 15, 2012 and was designated for standard review with an initial Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013.

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On May 2, 2013 we announced that an *Oncologic Drug Advisory Committee* (ODAC) panel convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of Melphalan/HDS did not outweigh the risks associated with the procedure. A significant portion of FDA s presentation to the ODAC panel was focused on the FDA s assessment of treatment related risks, including the analysis of treatment-related deaths that occurred during clinical trials. The FDA also expressed concerns about hypotension (low blood pressure) during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression. We believe that the protocol amendments and other procedure refinements instituted during clinical trials and subsequently in commercial, non-clinical usage in Europe, including changes to the way blood pressure is managed and monitored, may help address these procedure related risks. Collection of adequate safety data on all aspects of the procedure is a major focus of the clinical trials in our current CDP.

Briefing materials presented to the 2013 ODAC panel by both the FDA and Delcath are available on our website at http://delcath.com/clinical-bibliography.

2013 Complete Response Letter

In September 2013 the FDA issued a complete response letter (CRL) in response to our NDA. The FDA issues a CRL after the review of a file has been completed and questions remain that preclude approval of the NDA in its current form. The FDA comments included, but were not limited to, a statement that Delcath must perform another well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure, and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. The FDA also required that the additional clinical trial(s) be conducted using the product the Company intends to market, and that certain clinical, clinical pharmacology, human factors and product quality elements of the CRL be addressed.

In January 2016, we announced the conclusion of a Special Protocol Assessment (SPA) with the FDA on the design of a new Phase 3 clinical trial of Melphalan/HDS to treat patients with hepatic dominant ocular melanoma. This SPA provides agreement that our new Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the entire data in the application. The SPA agreement also represents the satisfactory resolution of a substantial number of the FDA s CRL non-clinical trial related requirements in that without these successful resolutions, the SPA request would not have been permitted to be filed.

Current Clinical Development Program

The focus of our current CDP is to generate clinical data for the CHEMOSAT and Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment procedure. We believe that the improvements we have made to CHEMOSAT and Melphalan/HDS and to the PHP procedure have addressed the severe toxicity and procedure-related risks observed during the previous Phase 2 and 3 clinical trials. The CDP is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory approvals in various jurisdictions, including the United States.

(the FOCUS Trial) - NCT02678572

In January 2016, we initiated a new pivotal Phase 3 clinical trial officially entitled *A Randomized, Controlled, Phase 3 Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma*. Called the FOCUS Trial, this new global Phase 3 trial will evaluate the safety,

efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with hepatic dominant OM. The primary endpoint is a comparison of overall survival between the two study arms. Secondary and exploratory endpoints include progression-free survival, overall response rate and Quality of Life (QoL) measures. In the FOCUS trial s treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years.

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The FOCUS Trial is being conducted at leading cancer centers in the United States and Europe. The Moffitt Cancer Center in Tampa, Florida was activated as a participating center in January 2016 with Jonathan Zager, M.D., FACS, Professor of Surgery in the Cutaneous Oncology and Sarcoma Departments and a Senior Member at Moffitt Cancer Center, serving as the trial s lead investigator. In October 2016 we announced the addition of several prestigious cancer centers in the United States and Europe. We intend to include approximately 40 leading cancer centers in the United States and Europe in the FOCUS Trial.

The FOCUS Trial is being conducted under a SPA we negotiated with the FDA in January 2016, and the first patient was enrolled in February 2016. In 2017, enrollment in this trial proceeded more slowly than anticipated, and cash constraints during the second half of the year limited our ability to take steps to accelerate enrollment In January 2018 we announced a SPA modification agreement with the FDA to revise the patient eligibility criteria to permit a greater extent of extra-hepatic disease by removing the size restriction, number and location of extra-hepatic lesions, in conjunction with a treatment plan for the extra-hepatic metastases. We hope that once approved by the institutional review boards of our participating clinical trial sites, this modification will help accelerate enrollment in this registrational trial. Any impact on enrollment of the SPA modification is not expected to be immediate, and it is unlikely that enrollment for this trial will be completed in time to submit an NDA to FDA in 2019.

Under the terms of the SPA, the FOCUS Trial is the only Phase 3 trial required for submission of an NDA. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the totality of data in the application.

There currently is no SOC for the treatment of hepatic dominant ocular melanoma. Melphalan hydrochloride has been granted orphan drug status by FDA for treatment of patients with ocular melanoma. Based on the strength of the efficacy data in this disease observed in our prior Phase 3 clinical trial and the reports of an improved safety profile observed in non-clinical trial experience in Europe, we are confident that this program can address the concerns raised by the FDA in its CRL. We believe that ocular melanoma liver metastases represent a significant unmet medical need, and that pursuit of an indication in this disease state represents the fastest path to potential marketing approval of the Melphalan/HDS in the United States.

Percutaneous Hepatic Perfusion (PHP) vs. Cisplatin/Gemcitabine in Patients with Intrahepatic Cholangiocarcinoma (The ALIGN Trial) - NCT03086993

In March 2017 we announced another SPA agreement with the FDA for the design of a new pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma (ICC) titled *A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma (The ALIGN Trial)*. Under the SPA, the Pivotal ICC Trial will enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint is overall survival (OS) and secondary and exploratory endpoints include safety, progression-free survival (PFS), overall response rate (ORR) and quality-of-life measures. This trial opened for patient enrollment in May of 2018. The SPA agreement for this trial indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS in ICC. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the totality of data in the application.

Phase 2 Hepatocellular Carcinoma (HCC) & Intrahepatic Cholangiocarcinoma (ICC) Program

In 2014 we initiated a Phase 2 clinical trial program in Europe and the United States, with the goal of obtaining an efficacy and safety signal for Melphalan/HDS in the treatment of HCC and ICC. Due to differences in treatment practice patterns between Europe and the United States, we established separate European and United States trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria:

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Protocol 201 NCT02406508 - Conducted in the United States, this trial is intended to assess the safety and efficacy of Melphalan/HDS followed by sorafenib. The trial will evaluate overall response rate via modified Response Evaluation Criteria in Solid Tumors (mRECIST), progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life. This trial is now closed to enrollment.

Protocol 202 NCT02415036 - Conducted in Europe, this trial is intended to assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial will also evaluate overall response rate via mRECIST criteria, progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life. This trial is now closed to enrollment.

ICC Cohort - In 2015 we expanded *Protocol 202* to include a cohort of patients with ICC. The trial for this cohort is being conducted at the same centers participating in the Phase 2 HCC trial. This trial has completed enrollment and data collection for the ICC cohort is ongoing. We will announce results for this cohort once the data are fully mature.

ICC Retrospective Data Collection - The original goal to obtain an efficacy signal for the Phase 2 ICC cohort has been satisfied by the result of multicenter patient outcomes identified in the retrospective data collection of our commercial ICC cases conducted by our European investigators. These promising outcomes and observations were discussed with Key Opinion Leaders (KOL) at a Delcath-organized medical advisory panel meeting and led to the agreement that PHP® therapy does, indeed, demonstrate an efficacy signal in ICC and is worthy of full clinical investigation. Data from this retrospective data collection provided important scientific support during our negotiations with the FDA for our SPA for the Pivotal ICC Trial. Data for the retrospective data collection are being submitted for publication by the European investigators, and details of these findings will be announced when publicly available.

With the objectives of identifying an efficacy signal worthy of further clinical investigation now met, we have terminated enrollment in our Phase 2 program and will close the Phase 2 trials in order to focus available resources on the FOCUS Trial and the Pivotal ICC Trial.

Clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy. A substantial portion of the Company s operating expenses consist of research and development expenses incurred in connection with its clinical trials. See the Company s Consolidated Financial included in Item 8 of this Annual Report on Form 10-K.

European Investigator Initiated Trials

In addition to the clinical trials in our CDP, we are supporting data generation in other areas. We are currently conducting one Investigator Initiated Trial (IIT) in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in the Netherlands. We are planning two additional IITs one for colorectal carcinoma metastatic to the liver at Heidelberg University in Heidelberg, Germany and one for pancreatic carcinoma metastatic to the liver at Spire Hospital in Southampton, England. We continue to evaluate other IITs as suitable opportunities present in Europe. We believe IITs will serve to build clinical experience at key cancer centers and will help support efforts to obtain full reimbursement in Europe.

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European Clinical Data Generation

On April 2, 2015, we announced the activation of our prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry will gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. A prospective registry is an organized system that uses observational study methods to collect defined clinical data under normal conditions of use to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Registry data is non-randomized, and as such cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable supportive data repository from a commercial setting that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe.

Recent Data Presentations

In March 2018, we announced that a comparative summary of research was presented by Dr. Jonathan Zager of Moffitt Cancer Center in Tampa, FL, at the Society of Surgical Oncology (SSO) annual meeting. In a presentation entitled Percutaneous Hepatic Perfusion (PHP) in Hepatic Liver Metastases, Dr. Zager compared the results from the Company s prior Phase 3 study, published by Hughes, et al (Annals of Surgical Oncology, 2015) with more recent results published by Karydis, et al (Journal of Surgical Oncology, 2017) and Abbott, et al (American Journal of Clinical Oncology, 2017). The Hughes study was conducted from 2005 to 2010, and used an earlier generation of the Melphalan/HDS system, whereas the Karydis and Abbott studies evaluated patients primarily treated with the Generation Two version of the Melphalan/HDS system along with other refinements to the peri- and post-procedure management of patients.

In his presentation, Dr. Zager highlighted that in all three studies results with PHP provided evidence of improved efficacy, with Hughes showing a 5x increase in hPFS over the study control arm (PHP 245 days vs BAC 49 days), and Abbott showing significantly longer hPFS for PHP than treatment with chemoembolization (CE) and Yttrium-90 beads (Y90) (PHP 310 days, CE 80 days, Y-90 54 days). Karydis showed an overall response rate with PHP of 47%, a >84% disease control rate and hPFS of 9.1 months. Regarding safety, Dr. Zager compared select safety data in the Hughes study conducted with the generation one system with data from the Karydis study conducted primarily in patients treated with the generation two system. The Hughes study was characterized by high percentages of hematologic side effects ranging from 60%-86% (anemia, thrombocytopenia, neutropenia). In the Karydis study, Grade 3 and 4 hematologic side effects (anemia, neutropenia, thrombocytopenia) were seen in approximately 30% of patients treated with PHP. Dr. Zager attributed this improvement in the safety profile to improvements in filtration with the generation two system, improved peri- and post-procedure management of patients, and greater experience in the treating centers. Dr. Zager concluded that PHP Therapy can be administered safely in high-volume cancer centers.

In January 2018, we announced the publication of a multi-center retrospective analysis of Delcath s PHP® Therapy published in the peer-reviewed Journal of Surgical Oncology. The study, *Percutaneous Hepatic Perfusion with Melphalan in Uveal Melanoma: A Safe and Effective Treatment Modality in an Orphan Disease* , was conducted by researchers from Moffitt Cancer Center (Moffitt) in Tampa, FL and the University Hospital Southampton (UHS) in the United Kingdom. The retrospective analysis of outcomes in 51 patients with liver metastases from ocular melanoma represents the largest data set compilation on the use of PHP Therapy in this tumor type outside of a clinical trial setting.

Patients in the study were treated at the two centers between December 2008 and October 2016. Patients received up to four PHP treatments at UHS and up to six PHP treatments at Moffitt. All patients received at least one PHP treatment, the median number of treatments per patient was two, and a total of 134 PHP treatments had been

administered. Results showed that of the 51 treated patients, 22 (43.1%) showed a partial response, 3 (5.9%) showed a complete response, and 17 (33.3%) had stable disease. The six-month overall and hepatic disease control rates were 64.7% and 70.6% respectively. Survival analysis showed median overall survival of 15.3 months at the time of data cut off. One year overall survival was 64.6%.

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Safety analysis showed that 19 patients (37.5%) had Grade 3 or 4 non-hematologic toxicity. Cardiovascular toxicity was seen in 17.6% of patients, a rate comparable to the company s prior Phase 3 study. Further to implementation of the Gen 2 filter along with prophylactic use of growth factors, severe neutropenia was seen in 16 (31.3%) patients as opposed to 60 (85.7%) patients in the prior Phase 3 trial. Most significantly, as compared to the prior Phase 3, there were no treatment related deaths. Researchers stated that PHP Therapy can be safely employed in appropriately selected ocular melanoma patients in institutions with appropriate expertise.

The study authors further concluded that results clearly demonstrate that PHP Therapy appears to be an effective means of obtaining rapid intrahepatic disease control and is a sensible option in patients with predominant liver disease. Researchers said their results support the use of PHP Therapy in an integrated approach to the management of metastatic ocular melanoma and looked to the company s Phase 3 FOCUS Trial to further quantify the benefit and optimize treatment strategies for these patients.

In September 2017, we announced that results of a single institution study were presented at the Cardiology and Interventional Radiology of Europe (CIRSE) annual meeting, held in Copenhagen, Denmark on September 16-20, 2017.

The study, *Prospective Clinical and Pharmacological Evaluation of the Delcath System s Second Generation (GEN2) Hemofiltration System in Patients Undergoing Percutaneous Hepatic Perfusion (PHP) with Melphalan,* was conducted by a team at the Leiden University Medical Center (LUMC) in Leiden, The Netherlands and presented by T.S. Meijer, MD. The study prospectively evaluated filtration efficiency and hematologic side effects in seven patients who received a total of ten PHP procedures with the GEN2 CHEMOSAT system. Pharmacokinetic sampling was conducted at several points during the PHP procedure, and filtration efficiency was calculated at several discrete points. Blood tests were conducted following each procedure to determine hematologic side effect Grade Levels until the blood values normalized.

Results of the study showed the GEN2 CHEMOSAT system had an overall efficiency of 86%, with efficiency highest at the time of highest concentration of melphalan in the blood and declining as melphalan blood concentration declined. Peak efficiency was 95.4% in samples taken after 10 minutes of filtration, 85.9% at the end of the drug infusion period, and 77.5% at the end of the saline washout period. Researchers noted these results were superior to and more consistent than prior experience published with the first generation CHEMOSAT system. Hematologic side effects were mainly Grade 1 and 2 with some Grade 3 and 4 side effects emerging post-procedure, including 40% of treatment cycles showing Grade 4 thrombocytopenia, 80% showing Grade 3 or 4 leucopenia, and 70% showing lymphocytopenia. All patients were asymptomatic and all lab results normalized in three weeks. Other adverse events were managed, and there was no mortality, no severe bleeding complications, and no hypotensive cardiac or cerebral events. Researchers concluded that the GEN2 CHEMOSAT system appears to have higher melphalan filter efficiency, more consistent performance, and appears safe but needs further validation.

In July 2017, the *Journal of Cancer Research and Clinical Oncology* published an analysis of clinical findings from 29 Hannover Medical School patients who were treated with percutaneous hepatic perfusion (PHP®) therapy with Melphalan/HDS as last-line therapy for primary and secondary liver tumors. Hannover Medical School physicians treated 29 patients with a total of 54 PHP procedures. Patients received as many as five treatments each, with an average of two per patient. Nineteen patients were diagnosed with unresectable liver metastases that arose from solid tumors, including 11 cases of ocular melanoma, and the remaining 10 patients had hepatocellular or cholangiocarcinoma.

Across all patients, the overall response rate (ORR) was 19.2 percent, with ocular melanoma patients experiencing the highest ORR (33.3 percent). As has been published previously, high tumor volumes negatively impact overall survival

(OS). Median OS was 261 days for the entire patient group. Two patients with cholangiocarcinoma and one patient with ocular melanoma had the longest survival with 566, 465, and 477 days respectively. Overall, PHP with Melphalan/HDS was well tolerated. Complications including thrombocytopenia, cardiovascular events, ulcerous bleeding, and edema were reported. These results are summarized in the Journal of Cancer Research and Clinical Oncology article, *Safety and Efficacy of Chemosaturation in Patients with Primary and Secondary Liver Tumors.*

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In February 2017, we announced that the *American Journal of Clinical Oncology* published a single-center retrospective review, in which authors found that investigational PHP with Melphalan/HDS offers promising results with a doubling of overall survival and significantly longer progression-free survival (PFS) and hPFS than other targeted therapies. The review, *Hepatic Progression-free and Overall Survival After Regional Therapy to the Liver for Metastatic Melanoma,* was written by a team from the Moffitt Cancer Center who analyzed clinical outcomes of three different non-randomized approaches used to treat 30 patients with liver metastases primarily resulting from ocular melanoma and skin melanoma. A third of the patients received PHP using melphalan delivered via the Delcath Hepatic Delivery System (Melphalan/HDS), 12 received chemoembolization (CE) and six received radioembolization with yttrium-90 (Y90). Two patients crossed over once their cancer progressed one from PHP to Y90 and one from CE to PHP.

The paper s authors concluded that patients who received PHP with Melphalan/HDS had significantly longer median hPFS at 361 days compared to 54 days for Y90 and 80 days for CE, as well as a longer median PFS at 245 days compared to 54 days for Y90 and 52 days for CE. Median overall survival was also longest for PHP at 608 days compared to 295 days for Y90 and 265 days for CE. The authors noted that further studies, including a randomized controlled trial, would be needed to confirm whether clinically superior outcomes can be achieved with PHP compared to other liver-targeted treatments.

Side effects following all treatments were similar, with most complications recorded as anorexia, abdominal pain, fatigue and nausea. Laboratory irregularities, such as thrombocytopenia and abnormal liver function tests, were seen immediately after treatment in some patients, but returned to baseline within a few days.

Market Access and Commercial Clinical Adoption

Europe

Our market access and clinical adoptions efforts are focused on the key target markets of Germany, United Kingdom and the Netherlands, which represent a majority of the total potential liver cancer market (primary and metastatic) in Europe and where progress in securing reimbursement for CHEMOSAT treatments offers the best near-term opportunities. We also continue to support clinical adoption of CHEMOSAT in Spain, France and Italy. We employ a combination of direct and indirect sales channels to market and sell CHEMOSAT in these markets. Our European Headquarters is in Galway, Ireland.

Since launching CHEMOSAT in Europe, over 500 treatments have been performed at over 25 leading European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, and other tumor types, including cutaneous melanoma, hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, pancreatic and neuroendocrine. In 2017, SPIRE Southampton Hospital in the U.K. and the Medical University of Hannover in Germany each surpassed 100 treatments with CHEMOSAT since initiating procedures. In 2017, we announced our first patient to receive eight CHEMOSAT treatments, and have seen the average number of repeat treatments performed on a per patient basis consistently increase.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. Medical devices are typically reimbursed under Diagnosis Related Groups (DRG) as part of a procedure. Prior to obtaining permanent DRG reimbursement

codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

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Germany

In October 2015, we announced that the Institut für das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a national Zusatzentgeld (ZE) reimbursement code for procedures performed with CHEMOSAT in Germany. The ZE diagnostic-related group (DRG) code is a national reimbursement code that augments existing DRG codes until a specific new DRG code can be created, and will replace the previous Neue Untersuchungs und Behandlungsmethoden (NUB) procedure that required patients in Germany to apply individually for reimbursement of their CHEMOSAT treatment. With the establishment of a ZE code for CHEMOSAT, the procedure is now permanently represented in the DRG catalog in Germany. Coverage levels under this process are negotiated between hospitals in Germany and regional sickness funds, with coverage levels renegotiated annually.

In May 2018 we announced that the German Guidelines Program in Oncology (GGPO) included treatment with Delcath s CHEMOSAT® in the German national treatment guidelines for liver metastases from melanoma. This inclusion of treatment with CHEMOSAT is in the S3 Guidelines, which represents the highest level within the classification of the guidelines indicating that it is based on evidence and consensus within the German clinical community.

The GGPO s update was based on its evaluation of published data on treatment with CHEMOSAT as a loco-regional treatment for melanoma liver metastases. Following this evaluation, and after soliciting additional feedback from the oncology community in Germany, treatment with CHEMOSAT was classified with Evidence Level 1B, indicating the second highest level of evidence. Treatment with CHEMOSAT is the sole therapy classified with this top designation. Other loco-regional therapies previously included in the guidelines have been designated with Evidence Level 4, indicating an absence of clinical trial supporting evidence.

United Kingdom

In May 2014, NICE, a non-departmental public body that provides guidance and advice to improve health and social care in the UK, completed a clinical review of CHEMOSAT. The NICE review indicated that as the current body of evidence on the safety and efficacy of PHP with CHEMOSAT for primary or metastatic liver cancer is limited, the procedure should be performed within the context of research by clinicians with specific training in its use and techniques. Delcath expects to consult again with the Interventional Procedures Advisory Committee at the National Institute for Clinical Excellence (NICE) in England, to provide recent clinical evidence with a view to moving existing Interventional Procedural Guidance from research to specialist status. This would enable greater scope for commercialization because it would allow more use by NHS clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement with the NHS.

In the short term, public patients will continue to be treated in the UK through clinical trials. Private patients will continue to be treated through the established private treatment pathway such as private insurance coverage or self-pay.

Netherlands

In the Netherlands CHEMOSAT has been performed at the Netherlands Cancer Institute in 2013 and at Leiden University Medical Centre since 2014. In June 2017 the Medical Oncology National Treatment Guidelines for Uveal Melanoma were updated and now include recommendations to consider CHEMOSAT in the treatment of liver metastases. We are hopeful that inclusion in the national guidelines and the support of clinicians treating patients with CHEMOSAT will support an application for reimbursement in this market.

Spain

In April 2016, we announced that the General and Digestive Surgery team at HM Sanchinarro University Hospital had activated the hospital s CHEMOSAT program. The Sanchinarro team successfully performed three procedures with CHEMOSAT, using the procedure to treat patients with peripheral cholangiocarcinoma and neuroendocrine tumors liver metastases. HM Sanchinarro University Hospital is the second center in Spain to offer CHEMOSAT treatments.

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Turkey

In April 2016 we announced the activation of the Hacettepe University Clinic in Ankara, Turkey as a CHEMOSAT treatment center. Hacettepe University Clinic successfully completed its first CHEMOSAT treatments in March 2016, and the center represents the first CHEMOSAT commercial location to be activated outside of the European Union. We believe that Hacettepe University can serve as an important hub for CHEMOSAT treatment to patients in Turkey and throughout the region.

Distribution Partners

As a result of the Company s strategy to prioritize resources on the key direct markets of Germany, the Netherlands and the United Kingdom, the Company expects that its distribution strategy will play a lesser role in its current commercial activities. In Spain, the Company has determined that there was no benefit to continuing with an indirect model and therefore terminated its relationship with its distributor in Spain and is now represented in Spain through a sales agency. The Company is represented in Turkey through a distribution partner.

Regulatory Status

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, has primary jurisdiction over its pre-market development and review.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;

completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;

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performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;

submission to the FDA of an NDA after completion of all pivotal clinical trials;

a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and

FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the European Economic Area (EEA) and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.

Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

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Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor s agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins.

Prior to initiating our currently ongoing Phase 3 clinical trial(s), we submitted a proposal for the design, execution and analysis under a SPA.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA s goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. For new oncology products, the FDA will often solicit an opinion from an ODAC, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a Complete Response Letter (CRL) if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy (REMS) that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

There are three primary regulatory pathways for a New Drug Application under Section 505 of the FFDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) application is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA s findings of safety and effectiveness for previously approved products. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

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Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

The FDA has granted Delcath six orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. In October 2013, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of HCC. In July 2015, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of cholangiocarcinoma, which includes ICC.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process that requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted at all or on a timely basis.

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds rights in eight U.S. utility patents, one U.S. design patent, five pending U.S. utility patent applications, six issued foreign counterpart utility patents (including the validation of a European patent directed to our filter apparatus in eight European countries, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications. In July 2017, a patent directed to our chemotherapy filtration system was issued by the U.S. Patent and Trademark Office.

When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT and Melphalan/HDS that will enable us to expand our patent portfolio around advances to our current systems, technology, and methods for our current applications as well as beyond the treatment of cancers in the liver.

There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

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To maintain our proprietary position, we also rely on trade secrets and proprietary technological experience to protect proprietary manufacturing processes, technology, and know-how relating to our business. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

In certain circumstances, United States patent law allows for the extension of a patent s duration for a period of up to five years after FDA approval. The Company intends to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted Delcath five orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, the Company believes that it will provide us with added protection once commercialization of an orphan drug designated product begins.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against Delcath, the Company may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, Delcath plans to enforce its intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
7,022,097	Method For Treating Glandular Diseases and Malignancies	4/4/2006	Owned	6/24/2023
9,707,331	Apparatus For Removing Chemotherapy Compounds from Blood	7/18/2017	Owned	9/17/2034
D708749	Dual Filter	7/8/2014	Owned	7/8/2028
9,314,561	Filter and Frame Apparatus and Method of Use	4/19/2016	Owned	2/7/2034
9,541,544	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	1/10/2017	Owned	8/28/2033
8,679,057	Recovery Catheter Assembly	3/25/2014	Licensed	3/4/2031
9,265,914	Recovery Catheter Assembly	2/23/2016	Licensed	4/5/2031
9,108,029	Recovery Catheter Assembly and Method	8/18/2015	Licensed	2/9/2034
9,814,823	Recovery Catheter Assembly and Method	10/9/2017	Licensed	7/27/2032

Patent Applications in the United States

Application No.	Application Title	Filing	Owned or

		Date	Licensed
15/651,141	Apparatus For Removing Chemotherapy Compounds from Blood	7/17/2017	Owned
15/071,896	Filter and Frame Apparatus and Method of Use	3/16/2016	Owned
15/346,239	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	11/8/2016	Owned
14/995,677	Recovery Catheter Assembly	1/14/2016	Licensed
14/797,108	Recovery Catheter Assembly and Method	7/11/2015	Licensed
15/728,296	Recovery Catheter Assembly and Method	10/9/2017	Licensed

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Foreign Patents

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
84.098	Dual Filter (Argentina)	6/29/2012	Owned	6/29/2027
343454	Dual Filter (Australia)	7/23/2012	Owned	6/25/2022
146201	Dual Filter (Canada)	5/15/2013	Owned	5/15/2023
ZL 201230277905.5	Dual Filter (China)	3/20/2013	Owned	6/22/2022
1333173	Dual Filter (Europe)	6/27/2012	Owned	6/25/2037
1456186	Dual Filter Cartridge for Fluid Filtration (Japan)	10/26/2012	Owned	10/26/2032
2797644	Filter and Frame Apparatus and Method of Use (Belgium)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (France)	4/12/2017	Owned	12/29/2032
602012031191.6	Filter and Frame Apparatus and Method of Use (Germany)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Great Britain)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Ireland)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Italy)	4/12/2017	Owned	12/29/2032
2797644	Filter and Frame Apparatus and Method of Use (Luxembourg)	4/12/2017	Owned	12/29/2032

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain

that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there

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are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers communications regarding off-label use.

European Regulatory Environment

In the EEA, the CHEMOSAT system is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the CHEMOSAT system is governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT system on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments.

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product s design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical

Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the

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manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body s assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer s behalf with regard to the manufacturer s obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the EU must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer s investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action (FSCA). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT system and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can

result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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The European Commission recently reviewed the Medical Device Directive legislative framework and promulgated REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. This new Medical Device Regulation became effective on May 25, 2017, marking the start of a 3-year transition period for manufacturers selling medical device in Europe to comply with the new medical device regulation (MDR) which governs all facets of medical devices. The transition task is highly complex and touches every aspect of product development, manufacturing production, distribution and post marketing evaluation.

Effectively addressing these changes will require a complete review of our device operations to determine what is necessary to comply. We do not believe the MDR regulatory changes will impact our business at this time, though implementation of the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

Other International Regulations

The CHEMOSAT device has received registrations in the following countries: Australia, New Zealand, Argentina, Taiwan, and Singapore. With limited resources and our attention focused on European commercial and clinical adoption efforts, pursuing other markets at this time is not practical. We will continue to evaluate commercial opportunities in these and other markets when resources are available and at an appropriate time.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors. We also believe that the current global economic conditions and new healthcare reforms could put competitive pressure on us, including reduced selling prices and potential reimbursement rates, and overall procedure rates. Certain markets in Europe are experiencing the effects of continued economic weakness, which is affecting healthcare budgets and reimbursement.

The CHEMOSAT and Melphalan/HDS competes with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In the disease states we are targeting there are also numerous clinical trials sponsored by third-parties, which can compete for potential patients in the near term and may ultimately lead to new competitive therapies.

For ocular melanoma liver metastases, there are currently no approved or effective treatment options, and patients are generally treated with a variety of local and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Covidian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others.

For ICC, gemcitabine plus cisplatin remains the standard of care for the treatment of ICC in patients who are not candidates for surgery.

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar , GlaxoSmithKline), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib

in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST , GlaxoSmithKline) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K

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mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy , Bristol Myers Squibb) and the B-RAF targeted drug vemurafenib (Zelboraf , Genentech) may also make up the competitive landscape for the treatment of metastatic liver disease. Many of these treatments are approved in Europe and other global markets.

Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. In addition, some of our competitors have considerable experience in conducting clinical trials, regulatory, manufacturing and commercialization capabilities. Our competitors may develop alternative treatment methods, or achieve earlier product development, in which case the likelihood of us achieving meaningful revenues or profitability will be substantially reduced.

Manufacturing and Quality Assurance

We manufacture certain components including our proprietary filter media, and assemble and package the CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and distribution facility in Galway, Ireland where we intend to conduct final manufacturing and assembly in the future. Delcath currently utilizes third-parties to manufacture some components of the CHEMOSAT and Melphalan/HDS. The CHEMOSAT and Melphalan/HDS and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and Delcath relies on third-party vendors to perform the sterilization process.

We are committed to providing high quality products to our customers. To honor this commitment, Delcath has implemented updated quality systems throughout our organization. Delcath s quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. These systems are designed to enable us to satisfy the various international quality system regulations including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization (ISO) with respect to products sold in the EEA. The Company is required to maintain ISO 13485 certification for medical devices to be sold in the EEA, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. On February 17, 2011, we announced that we had achieved ISO 13485 certification for our Queensbury manufacturing facility. On December 28, 2011, we announced that we had achieved ISO 13485 certification for our Galway, Ireland facility. All Delcath facilities are presently ISO 13485:2016 certified.

Employees

During 2017, Delcath added 7 employees to support clinical trial implementations in the EU and United States and to meet the demands of commercial sales. As of December 31, 2017, Delcath had 46 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

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Directors, Executive Officers, and Corporate Governance.

Information About Directors. The following table sets forth certain information about our director who successfully stood for re-election and about our directors whose terms will continue after the Annual Meeting.

Name	Age	Position with Delcath	Director Since
Class I Directors Term expiring at the 2019 Annual Meeting			
William D. Rueckert	65	Director	2014
Marco Taglietti, M.D.	58	Director	2014
Class III Directors Terms expiring at the 2018 Annual Meeting			
Simon Pedder, Ph.D.	57	Director	2017
Roger G. Stoll, Ph.D.	74	Chairman	2008
Jennifer K. Simpson, Ph.D.	49	Director	2015

Simon Pedder, PhD. Dr. Pedder currently serves as Chief Business and Strategy Officer at Athenex, Inc., a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer, a company with which he has been an officer since February 2016. During his long career in drug development, Dr. Pedder has held several leadership positions including President and CEO of Cellectar Biosciences from April 2014 to June 2015, President and CEO of Chelsea Therapeutics from May 2004 to July 2012 and previously, Executive Officer and Vice President of Oncology Pharma Business at Hoffmann-LaRoche, Life Cycle Leader and Global Project Leader of Pegasys/IFN and Head of the Hepatitis Franchise at Hoffmann-LaRoche.

Dr. Pedder led the late stage development and commercial launch of multiple proprietary pharmaceutical products, including Pegasys®, Copegus® and Northera®, which will benefit Delcath as it moves through its phase III clinical trials and NDA submission for the Ocular Melanoma and Intrahepatic Cholangiocarcinoma indications. The Board of Delcath has determined that Dr. Pedder is a key addition due to his expertise in late stage drug development.

Dr. Pedder received his Ph.D. in Pharmacology from the College of Medicine at the University of Saskatchewan in Canada, where he was a faculty member in the Department of Pharmacology at the College of Medicine. Dr. Simon earned a Master of Science in Toxicology from Concordia University in Montreal, Canada, a Bachelor of Science in Environmental Studies from the University of Waterloo in Canada and completed the Roche-sponsored Pharmaceutical Executive Management Program at Columbia Business School in New York City

William D. Rueckert was appointed as a Director in December 2014. Mr. Rueckert has served on many public and private corporate boards in both the life science and banking industries. He is currently President of Oyster Management Group, LLC, an investment partnership specializing in community banking. From 2007 until 2012 he served on the board of Novogen Ltd. (ASX, NASDAQ) a biotechnology company based in Sydney, Australia. He acted as Chairman from 2010 until 2012, and as acting CEO led the restructuring of the company, spinning off its major subsidiary, Marshall Edwards, Inc. (now MEI Pharma, Inc. NASDAQ.) He is currently a director of MEI Pharma, Inc. (NASDAQ), a San Diego based company that is developing novel oncology therapies. Until its sale to H. Lundbeck A/S, he was a director of Chelsea Therapeutics International, Ltd. (NASDAQ) whose drug candidate, Northera, was approved by the FDA in 2014. He has also served on the boards of several banks including Westport Bank and Trust, Lafayette American Bank and Hudson United Bank (all NASDAQ.) He currently serves on the board of Fairfield County Bank, a mutually owned, community bank based in Ridgefield, Connecticut, and Bleachers, Inc., a privately held company that streams live and archived sports and entertainment events from independent schools. Among his civic associations, Mr. Rueckert is a Director and President of the Cleveland H. Dodge Foundation,

Co-Chairman of the Board of Trustees of Teachers College, Columbia University, a Director of the Y Retirement Fund, a Trustee of International House, an Emeritus Director of the YMCA of Greater New York, a Trustee of the American University of Beirut and a

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Director of Wave Hill, Inc. He earned a BA in Spanish in 1977 from the University of New Hampshire. The Nominating Committee considered Mr. Rueckert s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Mr. Rueckert should serve as director of Delcath.

Roger G. Stoll, Ph.D. was appointed as a Director in December 2008, Executive Chairman in September 2014 and has served as our Chairman since October 1, 2015. From 2002 to 2008, he served as Chairman, Chief Executive Officer and President of Cortex Pharmaceuticals, Inc. (OTCBB: CORX). In August 2008, he was appointed Executive Chairman of its board. He retired from Cortex Pharmaceuticals in August, 2012. From 2001 to 2002, he was a consultant to several east coast venture capital firms and startup ventures. From 1998 to 2001, he was Executive Vice President of Fresenius Medical Care-North America, in charge of the dialysis products division and the diagnostic systems business units, which included hemodialysis machines and dialysis filters equipment. From 1991 to 1998, Dr. Stoll was Chief Executive of Ohmeda, a global leader in anesthetic agents, critical care drugs and related operating room equipment and devices. He also served on the boards of directors of St. Jude Medical and the BOC Group, plc. From 1986 to 1991, Dr. Stoll held several executive management positions at Bayer, AG, including Executive Vice-President and General Manager for its worldwide Diagnostic Business Group. Prior to that, Dr. Stoll worked for American Hospital Supply Corp., where he rose from Director of Clinical Pharmacology to President of its American Critical Care Division. He began his pharmaceutical career at the Upjohn Company in 1972. Dr. Stoll obtained his B.S. in Pharmacy from Ferris State University, obtained a Ph.D. in Biopharmaceutics and Drug Metabolism at the University of Connecticut and was a post-doctoral fellow for two years at the University of Michigan. From 2008 and until its sale to H. Lundbeck A/S, Dr. Stoll served on the board of directors of Chelsea Therapeutics (NASDAQ: CHTP) and was a member of that board s audit and compensation committees. Dr. Stoll in the past also served on the boards of Questcor and Agensys, HIMA and PMA (now PhRMA). Dr. Stoll also serves on the School of Pharmacy Advisory Board of the University of Connecticut. The Nominating Committee considered Dr. Stoll s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical and medical device experience, as well as the overall composition of the Board, in making the determination that Dr. Stoll should serve as director of Delcath.

Dr. Marco Taglietti, M.D. was appointed as a Director in December 2014. Dr. Taglietti serves as CEO and on the Board of Directors of NASDAQ-listed SCYNEXIS, Inc., a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives. Prior to its acquisition in February 2014, Dr. Taglietti served as Executive Vice President, Research and Development, and Chief Medical Officer of Forest Laboratories. He also served as President of the Forest Research Institute. Prior to joining Forest Labs in 2007, Dr. Taglietti held the position of Senior Vice President, Head of Global Research and Development, at Stiefel Laboratories, Inc. for three years. He joined Stiefel after 12 years at Schering-Plough Corporation where he last held the position of Vice President, Worldwide Clinical Research for Anti-Infectives, Oncology, CNS, Endocrinology and Dermatology. Dr. Taglietti began his career at Marion Merrell Dow Research Institute. He received his medical degree and board certifications from the University of Pavia in Italy. The Nominating Committee considered Dr. Taglietti s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Dr. Taglietti should serve as director of Delcath.

In addition, information concerning Jennifer K. Simpson, one of our Directors and our President and Chief Executive Officer, is provided under Information About Executive Officers.

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Information About our Executive Officers

The following table provides information concerning the current executive officers of Delcath.

Name	Age	Office Currently Held
Jennifer K. Simpson, Ph.D.	48	President and Chief Executive Officer
Barbra C. Keck, M.B.A.	39	Chief Financial Officer and Secretary
John Purpura	55	Executive Vice President, Global Head of Operations

The following is a brief description of the business experience of the following officers:

Jennifer K. Simpson was appointed as a Director in October 2015. Dr. Simpson joined Delcath as Executive Vice President, Global Marketing in March 2012 and was promoted to Executive Vice President, Global Head of Business Operations in April 2013 and Interim Co-President and Co-Chief Executive Officer, Executive Vice President, Global Head of Business Operations in September 2013. In September 2014, Dr. Simpson was named Interim President and Chief Executive Officer and named President and Chief Executive Officer in October 2015. From May 2011 to March 2012, Dr. Simpson served as the Vice President, Global Marketing, Oncology Brand Lead at ImClone Systems, Inc. (a wholly owned subsidiary of Eli Lilly and Company), where she was responsible for all product commercialization activities and launch preparation for one of the late-stage assets. From June 2009 to May 2011, Dr. Simpson served as the Vice President, Product Champion and from 2008 to 2009 as the Associate Vice President, Product Champion for ImClone s product Ramucirumab. From 2006 to 2008, Dr. Simpson served as Product Director, Oncology Therapeutics Marketing at Ortho Biotech (now Janssen Biotech), a Pennsylvania-based biotech company that focuses on innovative solutions in immunology, oncology and nephrology. Earlier in her career, Dr. Simpson spent over a decade as a hematology/oncology nurse practitioner and educator. Dr. Simpson earned a Ph.D. in Epidemiology from the University of Pittsburgh, an M.S. in Nursing from the University of Rochester, and a B.S. in Nursing from the State University of New York at Buffalo.

Barbra C. Keck joined Delcath as Controller in January 2009, was promoted to Vice President in October 2009, to Senior Vice President in March 2015 and to Chief Financial Officer in February 2017. Prior to joining Delcath, she was an audit assistant with Deloitte & Touche, LLP from August 2008 to December 2008. From June 2006 to August 2008, Ms. Keck was the Assistant to the Vice President and Dean of Baruch College, Zicklin School of Business, and from September 2005 to May 2006 she was the Donor Relations and Communications Manager for Young Audiences New York. From 2002 to 2005, Ms. Keck was the Manager, UD Arts Series at the University of Dayton, where she also served as the Manager, Arts and Cultural Events from 1999 to 2002. Between those positions, from 2002 to 2003, she was the Director of Teacher Programs at the Muse Machine. Ms. Keck served as the General Manager of Dayton Bach Society and the Manager of UD Arts Series from 1999 to 2002. She earned her M.B.A. in Accountancy from Baruch College and Bachelor of Music in Music Education from the University of Dayton.

John Purpura joined Delcath as Executive Vice President, Regulatory Affairs and Quality Assurance in November 2009 and was promoted to Executive Vice President, Global Head of Operations on July 19, 2016. Prior to joining Delcath, he was with Bracco Diagnostics (formerly E-Z-EM, Inc.) as Vice President and then Executive Director of International Regulatory Affairs from 2007 to 2008 and Head of Regulatory Affairs for North America and Latin America from 2008 to 2009. Prior to E-Z-EM, Inc., Mr. Purpura had an 11-year career with Sanofi-Aventis, ultimately serving as Associate Vice President for Regulatory CMC from 2005 to 2007. From 1985 to 1995, he had various quality and regulatory management roles with Bolar Pharmaceuticals, Luitpold Pharmaceuticals and Eon Labs Manufacturing. He earned his M.S. in Management & Policy and B.S. degrees in Chemistry and Biology at the State

University of New York at Stony Brook.

Board of Directors. We currently have five directors serving on the Board of Directors. The Board of Directors oversees the business affairs of the Company and monitors the performance of management. In accordance with our corporate governance principles, our Board does not involve itself in day-to-day operations.

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The directors keep themselves informed through discussions with the Chairman of the Board, Roger G. Stoll, Jennifer K. Simpson, in her capacity as Director and Chief Executive Officer, or CEO, and other key executives, and by reading the reports and other materials that management sends them and by participating in Board and committee meetings. Our directors hold office until their successors have been elected and qualified unless the director resigns or is removed or by reason of death or other cause is unable to serve in the capacity of director.

Board Independence. The Board has determined that four of our five directors (each of Simon Pedder, Roger Stoll, William D. Rueckert and Marco Taglietti) are independent directors within the meaning of the NASDAQ listing rules.

Attendance. The Board of Directors met 12 times in 2017 (including regularly scheduled and annual meetings). During 2017, each director attended at least 75% of the aggregate of: (i) the total number of meetings of the Board (held during the period for which he or she served as a director) and (ii) the total number of meetings held by all committees of the Board of Directors on which he or she served (held during the period that he or she served). It is Delcath s policy that, absent unusual or unforeseen circumstances, all directors are expected to attend annual meetings of stockholders, and all of our then directors attended our 2017 Annual Meeting.

Board Leadership Structure. Roger G. Stoll, Ph.D. was appointed Executive Chairman effective September 2014 and designated Chairman in connection with the appointment of Dr. Simpson as director effective October 2015. Dr. Stoll has been a member of the Board of Directors since 2008.

It is our policy to separate the Chairman and Chief Executive Officer roles. We believe this structure is appropriate for Delcath because it allows our President and CEO to concentrate on Delcath s day-to-day operations, while providing for effective oversight by the Chairman, who is involved in strategic and key matters, such as business strategy, major transactions and the broader business of Delcath. For a company like Delcath that is focused on the development, approval and commercialization of a specialized product in an extremely technical, highly regulated and intensely competitive industry, we believe our President and CEO is in the best position to lead our management team, in part because of the depth of her experience in conducting clinical trials in oncology, and to respond to the current pressures and needs of a company the stage of growth and development of Delcath, with assistance from our Chairman who also focuses the Board s attention on the broader issues of corporate business strategy and corporate governance. We believe that splitting the roles between Chairman, on the one hand, and President and CEO, on the other hand, minimizes any potential conflicts that may result from combining the roles of CEO, President and Chairman, and maximizes the effectiveness of our management and governance processes to the benefit of our stockholders. Our President and CEO and Chairman regularly consult with each other as part of this structure.

Board s Role in Risk Oversight. The Board as a whole is responsible for risk oversight, with reviews in certain areas being conducted by the relevant Board committees. Each of the Board s committees oversees the management of risks associated with their respective areas of responsibility. In performing this oversight function, the committees are assisted by management which provides visibility about the identification, assessment and monitoring of potential risks and management s strategy to mitigate such risks. Key members of management responsible for a particular area report directly to the Board committee charged with oversight of the associated function and, if the circumstances require, the whole Board. The Board committees review various risk exposures with the full Board and otherwise keep the full Board abreast of the committees risk oversight activities throughout the year, as necessary or appropriate.

Risk Assessment of Compensation Programs. Our Compensation and Stock Option Committee annually evaluates whether our compensation programs encourage excessive risk-taking by employees at the expense of long-term Company value. Based upon its assessment, including a review of the overall annual award limitations and individual annual limitations in the Delcath 2009 Stock Incentive Plan and the Compensation Committee s role in the consideration and approval of certain awards, the Compensation and Stock Option Committee does not believe that

our compensation programs encourage excessive or inappropriate risk-taking, motivate imprudent risk-taking or create risks that are reasonably likely to have a material adverse effect on the Company.

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Director Continuing Education. We require our directors to attend, at least annually, educational programs provided by various universities, stock exchanges and other regulatory agencies to assist our directors in maintaining or enhancing their skills and abilities as directors and to update their knowledge and understanding of the pharmaceutical, medical device and biopharma industries and the regulatory environment in which Delcath operates and to which it is subject.

Board Committees. Our Board has three standing committees: an Audit Committee, a Compensation and Stock Option Committee and a Nominating and Corporate Governance Committee. No individual director is the chairman of more than one committee.

Audit Committee. The Audit Committee provides assistance to the Board in fulfilling its oversight responsibilities with respect to the Company s financial statements, the Company s system of internal accounting and financial controls and the independent audit of the Company s financial statements. Functions of the Audit Committee include:

- the selection, evaluation and, where appropriate, replacement of our outside auditors;
- an annual review and evaluation of the qualifications, performance and independence of our outside auditors;
- the approval of all auditing services and permitted non-audit services provided by our outside auditors;
- the review of the adequacy and effectiveness of our accounting and internal controls over financial reporting; and
- the review and discussion with management and with our outside auditors of the Company s financial statements to be filed with the Securities and Exchange Commission (the SEC).

The Board has determined that each member of the Audit Committee, William D. Rueckert (Chair), and Simon Pedder and Roger Stoll qualifies as an audit committee financial expert as defined by SEC rules. During 2017, the Audit Committee met four times. Each member of the Audit Committee is independent within the meaning of the NASDAQ listing rules and otherwise meets the financial statement proficiency requirements of the NASDAQ listing rules. The Audit Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

Compensation and Stock Option Committee. The Compensation and Stock Option Committee (the Compensation Committee) assists the Board of Directors in the discharge of the Board s responsibilities with respect to the compensation of Delcath s directors, executive officers, and other key employees and consultants. The Compensation Committee establishes our overall compensation philosophy and is authorized to approve the compensation payable to our executive officers, including our named executive officers, and other key employees, including all perquisites, equity incentive awards, cash bonuses, and severance packages. The Compensation Committee also administers certain of our employee benefit plans, including its equity incentive plans, and is responsible for assessing the independence of compensation consultants and legal advisors. The Compensation Committee has concluded that each of Wexler, Burkhart, Hirschberg & Unger, LLP, outside legal counsel to the Compensation Committee and the Company, as well as Pearl Meyer & Partners, compensation consultant to the Compensation Committee, qualified as

independent. The Compensation Committee exercises sole power to retain compensation consultants and advisors and to determine the scope of the associated engagements. The current members of the Compensation and Stock Option Committee are Marco Taglietti (Chair) and William D. Rueckert, Simon Pedder and Roger Stoll, each of whom is independent within the meaning of the NASDAQ listing rules. During 2017, the Compensation and Stock Option Committee met nine times. The Compensation and Stock Option Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

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Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee (the Nominating Committee) is responsible for identifying individuals qualified to become Board members, and recommends to the Board the director nominees to be proposed by the Board for election by the stockholders (as well as any director nominees to be appointed by the Board to fill interim vacancies). The Nominating Committee also recommends the directors to be selected for membership on each Board committee.

The Nominating Committee is also responsible for developing and recommending to the Board appropriate corporate governance guidelines and policies, and for leading the Board in its annual review of the Board s performance.

The current members of the Nominating Committee are Roger Stoll (Chairman), William D. Rueckert and Marco Taglietti, each of whom is independent, within the meaning of the NASDAQ listing rules. During 2017, the Nominating Committee met one time. The Nominating Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

The Nominating Committee, with, when it deems it necessary, the assistance of a third-party search firm, identifies candidates for director nominees. In considering candidates for the Board, the Nominating Committee considers each candidate s credentials as a whole, including, but not necessarily limited to, outstanding achievement in a candidate s personal career, broad and relevant experience, integrity, sound and independent judgment, experience and knowledge of the business environment and markets in which the Company operates, business acumen, and willingness and ability to devote adequate time to Board duties. The Nominating Committee considers the diversity of its members in the context of the Board as a whole, including the personal characteristics, experience and background of directors and nominees to facilitate Board deliberations that reflect a broad range of perspectives.

Recommendations by Stockholders of Director Nominees. The Nominating Committee will consider any recommendation by a stockholder of a candidate for nomination as a director. If a stockholder wants to recommend a director candidate for consideration by the Nominating Committee, the stockholder should submit the name of the proposed nominee, together with the reasons why the stockholder believes the election of the candidate would be beneficial to the Company and its stockholders and the information about the nominee that would be required in a proxy statement requesting proxies to vote in favor of the candidate. The stockholder s submission must be accompanied by the written consent of the proposed nominee to being nominated by the Board and the candidate s agreement to serve if nominated and elected. Any such submission should be directed to the Nominating Committee at Delcath s principal office, 1633 Broadway, Suite 22C, New York, New York 10019. If a stockholder intends to nominate a person for election to the Board of Directors at an annual meeting, the stockholder must provide Delcath with written notice of his or her intention no later than the deadline for receiving a stockholder proposal for inclusion in Delcath s proxy statement for such meeting (as described below under the heading Stockholder Proposals For the 2018 Annual Meeting) and must otherwise comply with our amended and restated certificate of incorporation. Copies of any recommendation received in accordance with these procedures will be distributed to each member of the Nominating Committee. One or more members of the Nominating Committee may contact the proposed candidate to request additional information.

Stockholder Communications with the Board of Directors. Any stockholder wishing to communicate with the Board or with any specified director should address his or her communication to the Board of Directors or to the particular director(s) in care of the Corporate Secretary, Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019. All such written communication, other than items determined by our legal counsel to be inappropriate for submission to the intended recipient(s), will be submitted to the Board or to the particular director(s). Any stockholder communication not so delivered, will be made available upon request to any director. Examples of stockholder communications that would be considered inappropriate for submission include, without limitation, customer complaints, business solicitations, product promotions, job inquiries, junk mail and mass mailings, as well as

material that is unduly hostile, threatening, illegal or similarly unsuitable.

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Code of Ethics. We maintain a Code of Business Conduct and Ethics (Code) that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including our independent directors, who are not employees of the Company, with regard to their Delcath-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates our expectations of our employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the Code incorporates guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of our Code is published on our web site at http://delcath.com/investors/governance. We intend to disclose future amendments to certain provisions of our Code, or waivers of such provisions granted to our principal executive officer, principal financial officer or principal accounting officer and persons performing similar functions on our web site.

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REPORT OF THE AUDIT COMMITTEE

The Audit Committee reviewed and discussed the Company s audited financial statements for the fiscal year ended December 31, 2017, with management and Grant Thornton, the Company s independent registered public accounting firm for the fiscal year ended December 31, 2017. The Audit Committee also discussed with Grant Thornton the matters required to be discussed by the Statement on Auditing Standards No. 16, as amended, as adopted by the Public Company Accounting Oversight Board in Rule 3200T regarding Communication with Audit Committees. The Audit Committee has received and reviewed the written disclosures and the letter from Grant Thornton required by applicable requirements of the Public Company Accounting Oversight Board regarding Grant Thornton s communications with the Audit Committee concerning independence, and has discussed with Grant Thornton its independence from the Company.

Based on the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company s audited financial statements be included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, for filing with the Securities and Exchange Commission.

Submitted by the Audit Committee of the Board of Directors,

William Rueckert (Chair)

March 16, 2018

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SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who are beneficial owners of more than 10% of our common stock to file with the Securities and Exchange Commission reports of holdings and changes in beneficial ownership of Delcath s equity securities. Based on a review of copies of reports furnished to Delcath or written representations that no reports were required, we believe that all reports were timely filed in 2017.

Delcath maintains a Code of Business Conduct and Ethics (Code) that applies to all employees, including its principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including its independent directors, who are not employees of the Company, with regard to their Delcath-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates Delcath s expectations of its employees that enable the Company to provide accurate and timely disclosure in its filings with the SEC and other public communications. In addition, the Code incorporates guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of the Company s Code is published on its web site at http://delcath.com/investors/governance and is incorporated by reference herein. The Company intends to disclose future amendments to certain provisions of its Code, or waivers of such provisions granted to its principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions on its web site. Except as expressly stated herein, the information contained on Delcath s website does not constitute a part of this Annual Report on Form 10-K and is not incorporated by reference herein.

Executive Compensation.

Our Compensation and Stock Option Committee is responsible for formulating and establishing our overall compensation philosophy with respect to our executive officers. The Company believes that a strong executive management team comprised of talented individuals in key positions at the Company is critical to the development and growth of our business and to increasing stockholder value. Accordingly, a key objective of executive compensation is to attract and retain talented and experienced individuals, while motivating them to perform and make decisions consistent with the Company s business objectives, goals and culture. We emphasize pay-for-performance by linking executive compensation to Company performance. For each executive, the amount of pay that is actually realized is primarily driven by the Company s performance and each executive s contribution to that performance.

Our Compensation Committee engaged an independent compensation consulting firm, Pearl Meyer, to assist with the formulation of our executive compensation programs for 2017.

Our Compensation Committee considers the input it receives from our stockholders when designing and evaluating our executive compensation practices. *Compensation Components*. The three primary components of executive compensation are base salary, annual incentive cash awards and long-term equity incentive awards:

Base Salary. We pay our executive officers a base salary, which our Compensation Committee reviews and determines annually. Base salaries are used to compensate our executive officers for performing the core responsibilities of their positions and to provide them with a level of security with respect to a portion of their total compensation. Base salaries are set in part based on the executive s unique skills, experience and expected contribution to the Company, as well as individual performance, including the impact of such

performance on our business results, and the period of the executive s performance. Decisions regarding base salary increases take into account the executive s current base salary, third-party benchmark and survey data, and the salary compensation paid to executive officers within and outside the Company, as well as the Company s overall performance, its ability to afford such increases, its success in achieving its operational and strategic goals and objectives, and the executive officer s contribution to Company performance.

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Annual Incentive Cash Awards. Annual incentive compensation is intended to establish a direct correlation between annual cash awards and the performance of the Company. The Company s Annual Incentive Plan (AIP) is an annual incentive cash bonus plan designed to align the interests of participants with the interests of the Company and its stockholders. The AIP is designed to strengthen the link between a participant s pay and his or her overall performance and the Company s performance, focus participants on critical individual and corporate objectives, offer a competitive cash incentive, and encourage and reward performance and competencies critical to the Company s success.

Long-Term Incentive Compensation. In addition to using base salaries and annual incentive cash bonuses, which our Compensation and Stock Option Committee views as short-term compensation, a portion of our executive compensation is in the form of long-term equity compensation. Our Long-Term Incentive Plan (LTIP) is an annual equity-based incentive plan designed to align participants interests with those of the Company and its stockholders by rewarding participants for their contributions to the long-term success of the Company. The LTIP is designed to incentivize Company leaders to focus on the long-term performance of the Company, offer participants competitive, market-based long-term incentive award opportunities, and strengthen the link between a participant s compensation and his or her overall performance and the Company s overall long-term performance. We believe the LTIP assists us in achieving an appropriate balance between our short- and long-term.

Interface of Executive Officers with Compensation Committee in Determining Compensation. The Compensation Committee, based on input from the Company s Chief Executive Officer and Chairman, determines the compensation of our executive officers. The CEO and Chairman assist the Compensation Committee by providing performance assessments and compensation recommendations for each of the Company s executive officers, including the named executive officers (other than the CEO). The final decisions regarding the compensation for the named executive officers is then independently assessed and approved by the Compensation Committee. Other than completing a self-evaluation performance review, and submitting it to the Compensation Committee, the CEO does not participate in the formulation or discussion of her compensation. The Chairman provides the performance review for the CEO and submits that review to the Compensation Committee for its consideration. The Chairman also has discussions with the full committee related to all the performance items submitted for the named executive officers. Upon completion of these reviews, final decisions related to the compensation of the CEO require approval of the full Board of Directors after recommendations are made by the Compensation Committee.

Role of Compensation Consultants. The Compensation Committee retained PM&P as its independent compensation consultant to assist the Compensation Committee in evaluating executive compensation programs. PM&P reports directly to the Compensation Committee, and is not permitted to perform services for management unless approved by the Compensation Committee.

Inputs to Committee Decision Making.

Performance Evaluation Process. The Company utilizes a formal annual performance review program to evaluate our executives competencies, as well as individual performance objectives. The competencies in the program include: commitment to quality, integrity and ethics, as well as results oriented, teamwork, dependability, job knowledge and productivity. Each executive performs a self-evaluation and also is rated by the CEO on his or her competencies at year end and a final average total rating is calculated. Corporate performance objectives, which are set at the beginning of the year, are linked to the Company s overall performance and attainment of these objectives. Following completion of the performance year, the CEO submits performance evaluations and recommendations for each executive to the Executive Chairman who after review with the CEO then submits information to the Compensation Committee. The Committee reviews the completed individual performance evaluation forms for our executive officers

including the CEO and assesses the Company s overall performance relative to the achievement of corporate objectives. The information gathered as part of this evaluation process was used by our Compensation Committee to assist it in making compensation decisions.

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While the Company conducts its performance evaluations annually, the 2017 AIP was based solely on the achievement of corporate performance goals.

Peer Group Review. The Compensation Committee, with the assistance of PM&P, generally reviews the peer group on a regular basis. Due to the unique nature of the Company s business, we continually face challenges as we strive to develop the most appropriate mix of companies to comprise our peer group. The challenges we face include:

- We are an early commercial stage company with limited product revenues ($1.1M in 2014). As a result, a typical revenue range for peer selection purposes is more challenging due to our relatively small size.

- We are a medical device company and specialty pharmaceutical company. Our proprietary technology is designed to administer high-dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Our CHEMOSAT System for Melphalan is classified as a class IIb medical device and has been approved in Europe. In the United States, we are considered a drug device combination product regulated under a 505(b)(2) new drug application which is not currently approved yet. (As previously discussed, we received a complete response letter from the U.S. FDA to our NDA.) Because our product is regulated as both a device and a drug in the U.S. only, we have to recruit executive talent who have background and skill sets from both industries and who have experience in both device and drug development from larger, more established companies.

- There are very few peers across the medical device and pharmaceutical industries with a similar combination product which is considered a drug in certain regions and classified as a device in other regions, and so exact peers for us are difficult to identify.

Generally, the Compensation Committee considers each of the above challenges as well as the following selection criteria to select its peer group:

- We focused on companies with industry/product similarity Drug Delivery Systems/Medical Device companies with a focus on cancer/oncology and Pharmaceuticals/Biopharmaceuticals/Biotherapeutics companies with a cancer focused drug. As a result, multiple GICS sub-industries were reviewed and considered.

- We used a range of revenue from $0 $100M to develop a pool of potential firms to consider.

- We then narrowed the pool of potential companies based on market capitalization and other secondary factors (R&D expenses, number of employees, further test of business model and product similarity, etc.).

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Due to the changes in the Company s size and market capitalization, the Compensation Committee believed that a re-assessment of the peer group was warranted in 2014. The Compensation Committee, the Chairman, and management worked with PM&P to revise the peer group to reflect the smaller size of Delcath and the increased intensity in the clinical development activities. The following table reflects the new peer group which was reviewed and approved by the Compensation Committee and the full board of Delcath before being implemented:

Company	Industry[1]	Revenue[2]	Market Capitalization[3]
Accurexa Inc.	Healthcare Equipment	$ 0	$ 17
Adamis Pharmaceuticals Corporation	Pharmaceuticals	$ 0	$ 49
Aethlon Medical, Inc.	Healthcare Equipment	$ 1	$ 33
Arno Therapeutics, Inc.	Biotechnology	$ 0	$ 27
ArQule Inc.	Biotechnology	$ 11	$ 71
BSD Medical Corp.	Healthcare Equipment	$ 5	$ 23
Celator Pharmaceuticals, Inc.	Biotechnology	$ 0	$ 65
Cellectar Biosciences, Inc.	Biotechnology	$ 0	$ 16
Celsion Corp.	Biotechnology	$ 1	$ 59