DELCATH SYSTEMS, INC.
Form 424B4
August 06, 2018
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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-225567

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

Subscription Rights to purchase up to 28,571,429 shares of common stock at $1.75 per share and the shares of common stock issuable upon the exercise of such Subscription Rights

We are distributing to holders of our common stock and holders of certain of our instruments exercisable into our common stock on an as converted basis, at no charge, non-transferable subscription rights to purchase up to the lesser of $50.0 million or 28,571,429 shares of our common stock. We refer to the offering that is the subject of this prospectus as the rights offering. In the rights offering, you will receive, on August 3, 2018, the record date of the rights offering, one subscription right for every share of common stock beneficially owned and settled by 4:00 p.m., Eastern Time, on August 1, 2018. The subscription rights will not be tradeable. Each subscription right consists of a basic subscription privilege and an over-subscription privilege.

Each basic subscription privilege will entitle you to purchase five hundred shares of common stock, which we refer to as the basic subscription right, at a subscription price per share of common stock equal to $1.75. In the event that holders exercise subscription rights for in excess of the maximum exercise amount, which is the lesser of $50.0 million or 28,571,429 shares of our common stock (not including the over-subscription privilege), the amount subscribed for by each person will be proportionally reduced, based on the amount subscribed for by each person (not including any over-subscription privilege subscribed for). If you exercise your basic subscription privilege in full, and any portion of the shares of common stock remain available under the rights offering which are unsubscribed, you will be entitled to an over-subscription privilege to purchase a portion of the unsubscribed shares of common stock at the subscription price, subject to proration based on the number of shares of common stock owned and common stock issuable upon full exchange and/or conversion of certain of our instruments convertible and/or exchangeable into our common stock on the record date, which we refer to as the over-subscription privilege.

You may only purchase the number of shares of common stock purchasable upon exercise of the number of basic subscription privilege distributed to you in the rights offering, plus the over-subscription privilege, if any. Accordingly, the number of shares of common stock that you may purchase in the rights offering is limited by the number of shares of our common stock you held or would have held upon full conversion of the shares of certain of our instruments convertible and/or exchangeable into our common stock you held on the record date and by the extent to which other stockholders exercise their basic subscription privileges and over-subscription privileges, which we cannot determine prior to completion of the rights offering.

The subscription rights will expire if they are not exercised by 5:00 p.m., Eastern time, on August 27, 2018, unless the rights offering is extended or earlier terminated by us. If we elect to extend the rights offering, we will issue a press release announcing the extension no later than 9:00 a.m., Eastern time, on the next business day after the most recently announced expiration date of the rights offering. We may extend the rights offering for a period not to exceed 30 days in our sole discretion. Once made, all exercises of subscription rights are irrevocable. All subscription payments will

be deposited into an escrow account maintained by the subscription agent for the benefit of the holders exercising their subscriptions under the rights offering, and if the rights offering is not completed for any reason all funds will be promptly returned to such subscribers in the amounts advanced in connection with their respective exercises.

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

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

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

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

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

Our board of directors is making no recommendation regarding your exercise of the subscription rights. The subscription rights may not be sold, transferred or assigned and will not be listed for trading on any stock exchange or market. Shares of our common stock are traded on the OTC Market Group s OTCQB marketplace under the symbol DCTH . On July 27, 2018, the closing sales price for our common stock was $2.49 per share. The shares of common stock issued in the rights offering will also be traded on the OTCQB under the same symbol.

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

	Subscription Fee	Underwriting Discounts and Commissions(1)	Proceeds, Before Expense, to us

Per share of common stock	$ 1.75	$ .14	$ 1.61
Total	$ 50,000,000	$ 4,000,000	$ 46,000,000

(1) In connection with the rights offering, we have agreed to pay RHK Capital a cash fee up to 6.0% of the gross proceeds of this offering in cash, a non-accountable expense allowance up to 1.8% of the gross proceeds of this offering, and an out-of-pocket accountable expense allowance of 0.2%. For any unsubscribed shares placed by RHK Capital including through the backstop agreement described herein, we have agreed to pay RHK Capital a placement fee equal to, and in lieu of, the dealer-manager fee, with such placement fee and expenses not to exceed the aggregate amounts that would have otherwise been received by RHK Capital if the offering were to have been fully subscribed. See Plan of Distribution on page 117 of this prospectus for a description of the fees and expenses to be paid to RHK Capital for services performed in connection with this rights offering.

(2) Assumes that the rights offering is fully subscribed and that the maximum offering amount in the aggregate of $50.0 million is subscribed.

The exercise of your subscription rights for shares of our common stock involves risks. See Risk Factors beginning on page 16 of this prospectus, as well as the risk factors and other information in any documents we incorporate by reference into this prospectus, to read about important factors you should consider before exercising your subscription rights.

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

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

If you have any questions or need further information about this rights offering, please call D.F. King, our information agent for the rights offering, at (212) 269-5550 (bankers and brokers) or (877) 732-3612 (all others) or email at DCTH@dfking.com.

The date of this prospectus is August 6, 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, such as hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Metastatic liver disease, also called liver metastasis, or secondary liver cancer, is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer.

Ocular Melanoma

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

Intrahepatic Cholangiocarcinoma

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

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

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

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

About CHEMOSAT and Melphalan/HDS Kit

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

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

Risks of Investing

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

Corporate Information

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

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SUMMARY OF THE OFFERING

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

Securities Offered

We are distributing, at no charge, to holders of our common stock, and holders of certain of our instruments convertible or exchangeable into our common stock, on an as converted basis, non-transferrable subscription rights (500 shares per right) to purchase up to an aggregate of 28,571,429 shares of our common stock. Holders of our common stock will receive one subscription right for each share of common stock owned and holders of certain of our instruments convertible or exchangeable into our common stock will receive one subscription right for each share of common stock they would own upon full conversion of certain of our instruments convertible or exercisable into our common stock owned and settled by, 4:00 p.m., New York City time, on August 3, 2018; provided, that, the rights may only be exercised for a maximum of the lesser of 28,571,429 shares or $50.0 million of subscription proceeds.

Basic Subscription Privilege

The basic subscription privilege of each subscription right will entitle you to purchase one share of our common stock at a subscription price of $1.75 per share.

Over-Subscription Privilege

If you fully exercise your basic subscription privilege and basic subscription rights are exercised for an amount less than $50,000,000, you may also exercise an over-subscription right to purchase additional shares of common stock that remain unsubscribed at the expiration of the rights offering pro rata, subject to the availability and pro rata allocation of shares among stockholders exercising this over-subscription right.

Record Date

August 3, 2018.

Expiration Date of the Rights Offering

5:00 p.m., Eastern time, on August 27, 2018.

Subscription Price

$1.75 per share, payable in cash. To be effective, any payment related to the exercise of a right must clear prior to the expiration of the rights offering.

Placement Period and Backstop Commitment

If the rights offering is not fully subscribed following expiration of the rights offering, RHK Capital has agreed to use its commercially reasonable efforts to place any unsubscribed shares at the subscription price for an additional period. The number of shares that may be sold by us during this period will depend upon the number of shares that are subscribed for pursuant to the exercise of subscription rights by our common stockholders. Other than the backstop

commitment described below, no assurance can be given that any unsubscribed shares will be sold during this period.

On June 4, 2018, we entered into a Backstop Commitment Purchase Agreement with Discover Growth Fund and on July 20, 2018 we entered into the same form of agreement with Discover Growth Fund, LLC (the Backstop

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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. The standby purchaser will not be able to purchase any of the shares in this registered offering for the Backstop Agreement.

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, 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. The Backstop Agreement will terminate on or before June 30, 2019.

Use of Proceeds

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

Non-Transferability of Rights

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

Shares Outstanding Before the Rights Offering

932,158 shares of our common stock, as of July 27, 2018.

Shares Outstanding After the Rights Offering

Assuming 28,571,429 shares of our common stock are issued in the rights offering through the exercise of subscription rights, we anticipate that 29,503,587 shares of our common stock will be outstanding following the completion of the rights offering.

Risk Factors

Since our inception, we have incurred substantial losses. We will need the funding sought under this prospectus to remain a going concern, maintain operations, and to activate our business plan, which includes, among other things, advertising, retaining channels of distribution, retaining supplier relationships and recruiting experienced personnel. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should carefully consider all of the risks which are discussed more fully in Risk Factors beginning on page 16 of this prospectus.

Reverse Stock Split

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

Dividend policy	We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.
OTCQB symbol for common stock	DCTH
Risk factors	See Risk Factors and other information included in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities

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Transfer agent and registrar American Stock Transfer and Trust Company, LLC

The number of shares of our common stock outstanding prior to and immediately after this offering, as set forth above, excludes the following potentially dilutive securities as of July 26, 2018:

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

Questions and Answers About the Rights Offering

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

Why are we conducting the rights offering?

We are conducting the offering to raise capital that we intend to use to further our clinical trial program and for general corporate purposes.

What is the rights offering?

We are distributing to holders of our common stock, $0.01 par value, and holders of certain of our instruments convertible or exchangeable into our common stock, on an as converted basis, at no charge, non-transferable subscription rights to purchase shares of common stock. On the record date, August 3, 2018, you will receive 500 subscription rights for each whole share of common stock owned and 500 subscription rights for every share of common stock you would own upon full exchange or conversion of the certain of our instruments convertible or exchangeable into our common stock owned and settled by 4:00 p.m., Eastern Time, on August 1, 2018. Each subscription right will entitle the holder to a basic subscription privilege and an over-subscription privilege.

What are the basic subscription privilege?

A basic subscription privilege will entitle you to purchase 500 shares of common stock, at the subscription price, for each share of common stock held by you on 4:00 p.m., Eastern Time, on August 1, 2018, the Record Date. For example, if you owned 500 shares of common stock on the record date, you will receive 250,000 subscription rights. You may exercise all or a portion of your basic subscription privilege or you may choose not to exercise any basic subscription privilege at all.

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

you should contact your nominee as soon as possible.

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

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

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

What is the over-subscription privilege?

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

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

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

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

Will fractional shares be issued upon exercise of subscription rights?

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

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

On July 27, 2018, 932,158 shares of our common stock were outstanding. Based on the foregoing, and assuming no other transactions by us involving our common stock prior to the expiration of the rights offering, is fully subscribed

for the maximum number of shares of common stock available, approximately 29,503,587

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

How was the subscription price formula determined?

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

- the current and historical trading prices of our common stock on the OTCQB and Nasdaq;
- the price at which stockholders might be willing to participate in the rights offering;
- our need for additional capital and liquidity;
- the cost of capital from other sources; and
- comparable precedent transactions, including the percentage of shares offered, the terms of the subscription rights being offered, the subscription price and the discount that the subscription price represented to the immediately prevailing closing prices for those offerings.

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

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

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

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

How soon must I act to exercise my subscription rights?

If you received a subscription rights certificate and elect to exercise any or all of your subscription rights, the subscription agent must receive your completed and signed subscription rights certificate and payment for both your basic subscription privilege and any over-subscription privilege you elect to exercise before the rights offering expires on August 27, 2018, at 5:00 PM Eastern Time. If you hold your shares in the name of a broker, dealer, custodian bank, or other nominee, your nominee may establish a deadline before the expiration of the rights offering by which you must provide it with your instructions to exercise your subscription rights, along with the required subscription payment.

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May I transfer my subscription rights?

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

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

Yes, on June 4, 2018, we entered into a Backstop Commitment Purchase Agreement with Discover Growth Fund 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. The standby purchaser will not be able to purchase any of the shares in this registered offering for the Backstop Agreement.

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. The Backstop Agreement will terminate on or before June 30, 2019.

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

There is no minimum purchase requirement in the rights offering.

Are there any conditions to completing the rights offering?

There are no other conditions to completion.

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

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

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

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

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

No. Our board of directors is not making a recommendation regarding your exercise of the subscription rights. Stockholders who exercise subscription rights will incur investment risk on new money invested. We

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cannot predict the price at which our shares of common stock will trade after the rights offering. On July 27, 2018 the closing price of our common stock was $2.49 per share. The market price for our common stock may be above the subscription price or may be below the subscription price. If you exercise your subscription rights, you may not be able to sell the underlying shares of our common stock in the future at the same price or a higher price. You should make your decision based on your assessment of our business and financial condition, our prospects for the future, the terms of the rights offering and the information contained in this prospectus. See Risk Factors for discussion of some of the risks involved in investing in our securities.

How do I exercise my subscription rights?

If you are a stockholder of record (meaning you hold your shares of our common stock or certain of our instruments convertible or exchangeable into shares of our common stock in your name and not through a broker, dealer, bank, or other nominee) and you wish to participate in the rights offering, you must deliver a properly completed and signed subscription rights certificate, together with payment of the subscription price for both your basic subscription privilege and any over-subscription privilege you elect to exercise, to the subscription agent before 5:00 PM Eastern Time, on August 27, 2018. If you are exercising your subscription rights through your broker, dealer, bank, or other nominee, you should promptly contact your broker, dealer, bank, or other nominee and submit your subscription documents and payment for the shares of common stock subscribed for in accordance with the instructions and within the time period provided by your broker, dealer, bank or other nominee.

What if my shares are held in street name ?

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

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

What form of payment is required?

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

When will I receive my new shares of common stock?

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

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

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

How much will the Company receive from the rights offering?

Assuming the rights offering is fully subscribed either on its own or in conjunction with the backstop and concurrent placement by the dealer-manager for unsubscribed for shares for the $50.0 million maximum amount, including any over-subscription privilege, we estimate that the net proceeds from the rights offering will be approximately $46.0 million, after deducting fees and expenses payable to the dealer-manager, and after deducting other expenses payable by us.

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

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

Are there risks in exercising my subscription rights?

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

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

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

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

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

subscription agent will return payments through the record holder of your shares.

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

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

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

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

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

The U.S. federal income tax consequences of the Rights Offering to shareholders will depend on whether the Rights Offering is part of a disproportionate distribution. We intend to take the reporting position that the Subscription Rights issued to common shareholders pursuant to the Rights Offering (a) are not part of a disproportionate distribution and (b) will not be a taxable distribution with respect to your existing securities. The disproportionate distribution rules are complicated, however, and their application is uncertain, and thus our tax counsel is not rendering a definitive opinion regarding the application of such rules. The position we are taking is not binding on the Internal Revenue Service (IRS) or the courts and it is possible that the IRS could successfully challenge our reporting position and assert that the Rights Offering is a taxable distribution. You should consult your tax advisor as to the tax consequences of the rights offering in light of your particular circumstances. For a more detailed discussion, see Certain U.S. Federal Income Tax Consequences on page 111.

To whom should I send my forms and payment?

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

American Stock Transfer & Trust Company, LLC

Operations Center

Attn: Reorganization Department

6201 15th Avenue

Brooklyn, New York 11219

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

Whom should I contact if I have other questions?

If you have any questions about the rights offering, including questions about subscription procedures and requests for additional copies of this prospectus or other documents, please contact the information agent, D. F. King, at (212) 269-5550 (bankers and brokers) or (877) 732-3612 (all others) or email at DCTH@dfking.com.

Who is the dealer-manager for this offering and placement agent for any unsubscribed shares?

RHK Capital will act as the dealer-manager for the rights offering. RHK Capital is not underwriting any of the subscription rights being sold in this offering and does not make any recommendation with respect to such

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rights (including with respect to the exercise of such subscription rights). As contemplated by the dealer-manager agreement, RHK Capital will not solicit any holders of the securities (including the rights) or engage in the offer and sale of such securities in any jurisdiction in which such securities are not qualified or registered for sale in accordance with, or exempt from, the state securities or blue sky laws or Canadian provincial securities laws of such jurisdiction unless and until (i) we have advised RHK Capital that such securities have been qualified or registered in accordance with, or are exempt from application of, the state securities or blue sky laws or the Canadian provincial securities laws of such jurisdiction, as applicable, and (ii) RHK Capital possesses all required licenses and registrations to solicit or offer such securities in that jurisdiction.

If the rights offering is not fully subscribed following expiration of the rights offering, RHK Capital has additionally agreed to use its commercially reasonable efforts to place any unsubscribed shares at the subscription price for an additional period of up to 45 days. The number of shares that may be sold by us during this period will depend upon the number of shares that are subscribed for pursuant to the exercise of subscription rights by our stockholders. See Plan of Distribution on page 118 for a discussion of the fees and expenses to be paid to RHK Capital in connection with this rights offering.

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Summary of Historical Financial Data

You should read the summary of historical financial data set forth below in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operation and the consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2017, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and in this prospectus. We derived the following summary historical financial statement of operations data and other data for each of the two years in the period ended December 31, 2017 and the summary historical balance sheet data as of March 31, 2018 from our audited financial statements. We derived the following summary historical financial statement of operations data and other data for the quarter ended March 31, 2018 from our unaudited quarterly financial statements.

	Quarter ended March 31 2018	Year ended December 31, 2017	2016
	(in thousands, except share and per share data)		
STATEMENT OF OPERATIONS DATA:			
Product revenue	$ 702	$ 2,715	$ 1,992
Cost of goods sold	(147)	(701)	(550)
Gross profit	555	2,014	1,442
Operating Expenses:			
Selling, general and administrative	2,366	9,684	9,434
Research and development	5,692	10,495	8,448
Total operating expenses	8,058	20,179	17,882
Operating loss	(7,503)	(18,165)	(16,440)
Change in fair value of warrant liability, net	14,697	15,103	12,780
Gain on warrant extinguishment		9,613	
Loss on debt settlements and extinguishments		(29,924)	
Interest expense	(2)	(21,703)	(14,328)
Other income (expense)	(5)	(41)	17
Net income (loss)	$ 7,187	$ (45,117)	$ (17,971)
Common share data:			
Basic and diluted income (loss) per share*	$ 10.91	$ 3,250	$ 1,853,500
Weighted average number of basic and diluted common shares outstanding*	658,893	14,039	10

* Reflects a one-for-five hundred (1:500) reverse stock split effected May 2, 2018, a one-for-three hundred fifty (1:350) reverse stock split effected on November 6, 2017, and a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016.

	As of March 31, 2018
BALANCE SHEET DATA:	
Cash and cash equivalents	$ 2,029
Total assets	6,418
Total current liabilities	12,275
Accumulated deficit	(317,645)
Stockholders equity	(6,202)

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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.

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.

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.

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Continuing losses may exhaust our capital resources.

As of March 31, 2018, the Company had $2.0 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 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.

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:

- 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,

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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 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

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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 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;

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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;

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 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.

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

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

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our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product.

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 licen