DELCATH SYSTEMS, INC.
Form S-1
October 11, 2017
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As filed with the Securities and Exchange Commission on October 10, 2017

No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Delcath Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**06-1245881**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

1633 Broadway

Suite 22C

New York, New York 10019

(212) 489-2100

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

Jennifer K. Simpson

President and

Chief Executive Officer

Delcath Systems, Inc.

1633 Broadway

Suite 22C

New York, New York 10019

(212) 489-2100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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

Jolie Kahn, Esq.

Wexler, Burkhart, Hirschberg & Unger

377 Oak Street

Garden City, NY 11530

(516) 222-2230

Robert Charron, Esq.

Ellenoff Grossman & Schole LLP

1345 Avenue of the Americas

New York, NY 10105

Approximate date of commencement of proposed sale to the public:

As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price** [(1)(2)]	**Amount of Registration Fee**
Units, each Unit consisting of one share of Common Stock, par value $0.001 per share and one common warrant to purchase one share of Common Stock	$17,250,000	$2147.63

(3)		
(i) Common Stock included in the Units (4)		
(ii) Common warrants included in the Units (4)		
Pre-funded Units, each Pre-funded Unit consisting of one pre-funded warrant to purchase one share of Common Stock and one common warrant to purchase 1 share of Common Stock (3)	$15,000,000	$1867.50
(i) Pre-funded warrants included in the Pre-funded Units (4)		
(ii) Common warrants included in the Pre-funded Units (4)		
Shares of Common Stock underlying pre-funded warrants included in the Pre-funded Units (3)		
Shares of Common Stock underlying common warrants included in the Units and the Pre-funded Units (3)	$32,500,000	$4015.12
Total	$64,500,000	$8030.25

(1) Estimated pursuant to Rule 457(o) of the Securities Act of 1933 solely for purposes of calculating the amount of the registration fee.

(2) Pursuant to Rule 416 of the Securities Act of 1933, this Registration Statement also shall cover any additional shares of common stock that shall become issuable by reason of any stock dividend, stock split, recapitalization, or other similar transaction by the registrant.

(3) The proposed maximum aggregate offering price of the Units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-funded Units offered and sold in the offering, and as such the proposed maximum aggregate offering price of the Units and Pre-funded Units (including the common stock issuable upon exercise of the pre-funded warrants included in the Pre-funded Units), if any, is $15,000,000.

(4) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act of 1933, as amended.

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

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated October 10, 2017

Units

Each Unit Consisting of One Share of Common Stock

and

One Warrant to Purchase One Share of Common Stock

Up to _____ Units (each Unit consists of 1Share of Common Stock and 1 Common Warrant to purchase 1 Share of Common Stock)

or

Up to _____ Pre-funded Units (each Pre-funded Unit consists of 1Pre-funded Warrant to Purchase 1 Share of Common Stock and 1 Common Warrant to Purchase

1 Share of Common Stock

(_____ Shares of Common Stock Underlying the Pre-funded Warrants) and

(_____ Shares of Common Stock Underlying the Common Warrants)

We are offering up to units (each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock). Each common warrant contained in a unit has an exercise price of $ per share. The common warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units.

We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one

share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that would otherwise result in the purchaser s beneficial ownership exceeding 4.99% of our outstanding common stock (or at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit will equal the price per unit being sold to the public in this offering minus $0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit will be $0.01 per share. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. Each common warrant contained in a pre-funded unit has an exercise price of $ per share. The common warrants contained in the pre-funded units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the pre-funded units. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants can only be purchased together in this offering but the securities contained in the units or pre-funded units will be issued separately.

Our common stock is quoted on the OTCQB under the symbol DCTH. The last reported sale price of our common stock on October 9, 2017 was $0.0566 per share. There is no established public trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system.

Investing in our securities involves risks, including those described in the Risk Factors section beginning on page 8 of this prospectus.

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

	Per Unit (1)	Per Pre-Funded Unit	Total
Price to the public	$	$	$
Underwriting discount(2)	$	$	$
Proceeds, before expenses, to us(3)	$	$	$

(1) The public offering price and underwriting discount per unit corresponds to (i) a public offering price per share of common stock of $ and (ii) a public offering price per common warrant of $.
(2) We have agreed to reimburse the underwriter for certain of its expenses. See Underwriting for a description of the compensation to be received by the underwriter.
(3) Excludes potential proceeds from the exercise of the warrants through this prospectus.

The underwriter expects to deliver the securities to the purchasers on or about , 2017.

The underwriter has the option to purchase up to an additional (i) shares of common stock, and/or (ii) additional common warrants to purchase up to shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per common warrant set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase

shares of common stock and/or common warrants, in any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock and 15% of the common warrants sold in the primary offering. The over-allotment option is exercisable for 45 days from the date of this prospectus.

Oppenheimer & Co.

The date of this prospectus is , 2017

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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 underwriter 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 or incorporated by reference into 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. The drug Melphalan alone and doxorubicin has been previously approved by FDA for various oncologic indications for other sponsors. 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), which we plan to initiate when financial resources permit. Our clinical development plan (CDP) also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in colorectal cancer metastatic to the liver (mCRC) and pancreatic cancer metastatic to the liver.

The direction and focus of our CDP for CHEMOSAT and Melphalan/HDS is informed by prior clinical development conducted between 2004 and 2010, non-clinical, commercial CHEMOSAT cases performed on patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European

commercial and United States regulatory activity has led to the implementation of several safety improvements to our product and the associated medical procedure.

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

Cancers in the Liver A Significant Unmet Need

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

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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.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers including HCC and ICC are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 40,710 new cases of HCC and ICC will be diagnosed in the United States in 2017. Approximately 75-90% of these patients are diagnosed with HCC. Excluding patients who are eligible for surgical resection or certain focal treatments, we estimate that approximately 15,000 patients with HCC in the United States and Europe may be eligible for treatment with Melphalan/HDS. We estimate that an additional 9,300 patients diagnosed with ICC may also be eligible for treatment with Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients in the United States is approximately 18%. For patients 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%. Globally, with 782,000 new cases in 2012, HCC was the fifth most common cancer in men and the ninth in women according to GLOBOCAN. GLOBOCAN estimates indicate that HCC was responsible for 746,000 deaths in 2012 (9.1% of the total cancer deaths), making it the second most common cause of death from cancer worldwide.

The prognosis for primary liver cancer is very poor, as indicated by an overall ratio of mortality to incidence of 0.95. The American Cancer Society s *Cancer Facts & Figures 2017* outlines the treatment options for HCC as follows: Early stage liver cancer can sometimes be successfully treated with surgery to remove part of the liver (partial hepatectomy); however, few patients have sufficient healthy liver tissue for this option. Liver transplantation may be possible in individuals with small tumors who are not candidates for partial hepatectomy. Other treatment options include tumor ablation (destruction) or embolization (blocking blood flow). Few options exist for patients diagnosed at an advanced stage. Sorafenib (Nexavar®) is a targeted drug approved for the treatment of HCC in patients who are

not candidates for surgery and do not have severe cirrhosis.

Based on third party research, we estimate that up to 15,000 of the 65,000 patients diagnosed annually in the United States and Europe could be eligible candidates for treatment with the Melphalan/HDS. The FDA has granted orphan drug status to the Melphalan/HDS for treatment of patients with unresectable HCC. We believe that there is a large unmet medical need in first line therapy for patients with HCC, with Sorafenib the only currently approved systemic therapy in the United States, Europe and certain Asian markets.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of HCC cases diagnosed in the United States and Europe annually. Outside of resection, which is the only cure for ICC, there is currently no standard of care. Based on third party research, 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.

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About CHEMOSAT and Melphalan/HDS Kit

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

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

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 or incorporate by reference 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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The Offering

Units offered by us in this offering:	units, each consisting of one share of our common stock and one common warrant to purchase one share of our common stock
Pre-funded units offered by us in this offering:	We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that would otherwise result in the purchaser s beneficial ownership exceeding 4.99% of our outstanding common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit will equal the price at which the units are being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit will be $0.01 per share. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold.
Common warrants offered by us in the offering	Common warrants to purchase an aggregate of shares of our common stock. Each unit and each pre-funded unit includes a common warrant to purchase one share of our common stock. Each common warrant will have an exercise price of $ per share, will be immediately separable from the common stock or pre-funded warrant, as the case may be, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Common stock to be outstanding after this offering	shares, excluding the shares underlying the warrants.
Overallotment option	We have granted the underwriter an option to purchase additional shares of common stock equal to 15% of the shares in the offering and/or additional common warrants equal to 15% of the warrants in the offering at the assumed public offering price per share of common stock and the assumed public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commission. This option is exercisable, in whole or in part, for a period of 45 days from the date of this prospectus
Reverse stock split	Effective on September 21, 2017, the two holders of 590 shares of the Company s

	Series C preferred stock, voting with the Company s common stock with each share of Series C preferred stock having 880,375 votes per share, representing 51% of the outstanding shares of the Company s Series C preferred stock (on an as voted basis) and common stock as of such date, executed a written consent in lieu of a special meeting of stockholders (the Majority Stockholder Consent), approving the following matter, which had previously been approved by the Board of Directors of the Company on September 12, 2017:
	authority for our Board of Directors, without further stockholder approval, to effect a reverse stock split of all of the outstanding common stock of the Company, by the filing of a Certificate of Amendment to the Company s Articles of Incorporation with the Secretary of State of Delaware, in a ratio of 1:50, 1:100 or 1:350, with the Company s Board of Directors having the discretion as to whether or not the reverse split is to be effected, and with the exact exchange ratio of 1:50, 1:100 or 1:350 as determined by the Board of Directors in its sole discretion, at any time before the earlier of (a) September 19, 2018; and (b) the date of the Company s 2018 annual meeting of stockholders.
	On October 4, 2017, we filed a Definitive Information Statement on Schedule 14C with regard to the foregoing, which we anticipate will be mailed to our shareholders on or about October 10, 2017. On the 20th calendar day subsequent to the mailing date, we will file a Certificate of Amendment to our Articles of Incorporation effecting a reverse split of our issued and outstanding common stock in one of the three ratios approved by our majority shareholders, as approved by our Board of Directors. We will not seek to have this Registration Statement declared effective until this reverse split is effected.
Use of proceeds	We expect to use the net proceeds from this offering (including any resulting from the exercise of the warrants, if any) to fund the clinical and regulatory development of clinical studies, commercialization of our products, obtaining regulatory approvals, as well as for working capital and other general corporate purposes, including funding the costs of operating as a public company. See Use of Proceeds.
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 or incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities
Transfer agent and registrar	American Stock Transfer and Trust Company, LLC

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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 October 4, 2017:

55,000 shares issuable upon the exercise of stock options at a weighted average exercise price of $96.99 per share;

0.3 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $12.57 per share;

18,000 shares reserved for future issuance under our 2009 Equity Incentive Plan, as amended;

0.1 million unvested restricted shares; and

shares issuable upon exercise of the common warrants offered hereby.

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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, 2016 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, each of which is incorporated by reference herein. 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, 2016 and the summary historical balance sheet data as of December 31, 2016 from our audited financial statements. We derived the summary historical financial data as of and for the six months ended June 30, 2017 and 2016 from our unaudited financial statements. In our opinion, the unaudited financial statements have been prepared on the same basis as our audited financial statements and include all adjustments (consisting of only normal recurring adjustments) necessary for a fair presentation of the information set forth therein. The results for any interim period are not necessarily indicative of the results that may be expected for a full fiscal year.

	Six Months Ended June 30,		Year Ended December 31,	
	2017	2016	2016	2015
	(in thousands, except share and per share data)			
STATEMENT OF OPERATIONS DATA:				
Product revenue	$ 1,327	$ 880	$ 1,992	$ 1,747
Cost of goods sold	354	261	(550)	(462)
Gross profit	973	619	1,442	1,285
Operating Expenses:				
Selling, general and administrative	$ 4,947	$ 4,633	$ 9,434	$ 10,009
Research and development	4,840	3,289	8,448	6,486
Total operating expenses	9,787	7,952	17,882	16,495
Operating loss	(8,814)	(7,333)	(16,440)	(15,210)
Change in fair value of warrant liability, net	1,200	491	12,780	564
Interest income (expense)	(15,282)	(1,631)	17	9
Other income (expense) and interest income (expense)	7	(7)	(14,328)	(67)
Net loss	$ (13,276)	$ (8,480)	$ (17,971)	$ (14,704)
Common share data:				
Basic loss per share and diluted*	$ (0.09)	$ (5.72)	$ (10.59)	$ (14.56)
	148,674,658	1,483,148	1,696,237	1,010,105

Weighted average number of basic common shares outstanding*				
Weighted average number of diluted common shares outstanding*	148,722,094	1,483,148	1,696,237	1,010,105

* Reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

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	As of June 30, 2017	As of December 31, 2016
BALANCE SHEET DATA:		
Cash and cash equivalents	$ 1,816	4,409
Total assets	18,603	35,239
Total current liabilities	17,210	36,095
Accumulated deficit	(292,464)	(279,188)
Stockholders equity (deficit)	867	(1,490)

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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

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We 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 we 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 we 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, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. Further, in January 2016 we received agreement on a Special Protocol Assessment (SPA) from the FDA and have 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, we conduct and participate 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, we initiated a Phase 2 clinical trial with Melphalan/HDS Kit for HCC in both the United States and Europe. In 2015, we expanded the Phase 2 clinical trial for HCC 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 independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm issued a report dated March 28, 2017 in connection with the audit of our financial statements as of December 31, 2016, 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, 2016 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 we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment.

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We do not expect to generate significant revenue for the foreseeable future.

Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT and Melphalan/HDS and currently we have only developed this system for the treatment of cancers in the liver. If CHEMOSAT and Melphalan/HDS for the treatment of cancers in the liver fails as a commercial product, we have no other products to sell. In addition, since CHEMOSAT is currently only authorized for marketing in the European Economic Area (EEA) and limited other jurisdictions, if we are unsuccessful in commercializing the product in the EEA and if Melphalan/HDS is not approved in the United States and elsewhere, we will have no means of generating revenue. In September 2013, the FDA issued a CRL with respect to our NDA for our Melphalan/HDS system. 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, we do 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 our product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT and Melphalan/HDS may not be successful in clinical trials, approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all.

Continuing losses may exhaust our capital resources.

As of December 31, 2016, we had $4.4 million in cash and cash equivalents. At June 30, 2017, we had $1.8 million in cash and cash equivalents. We have had minimal revenue to date, and we have a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended December 31, 2016 and 2015, we incurred net losses of approximately $18.0 million and $14.7 million, respectively, and for the three and six months ended June 30, 2017 and 2016, we incurred net losses of approximately, $1.9 million and $13.3 million, and $6.7 million and $8.5 million, respectively, and we expect to continue to incur losses in the second half of 2017 and 2018. To date, we have funded our operations through a combination of private placements and public offerings of our securities, including convertible notes. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development, regulatory approval process and commercialization of CHEMOSAT and Melphalan/HDS or any other versions of the system.

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

We will require additional financing to complete our clinical trial program or seek other approvals, to conduct future development and clinical trials and to further commercialize our product in the EEA and any other markets where we receive approval for our system. In addition, we are 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, we could be subject to legal liability and our ability to complete our development projects or our clinical trials could be impaired. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to commercialize CHEMOSAT and Melphalan/HDS, obtain regulatory approvals or complete our development projects or our clinical trials.

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.

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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.

We are not permitted to market Melphalan/HDS in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we 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 we could encounter problems that cause us 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 we do;
- 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 we develop 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, we submitted the Melphalan/HDS NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA declined to approve our NDA and issued a CRL. The FDA comments in the CRL included, but were not limited to, a statement that we 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, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors. However, even if we complete clinical trials and satisfy all the requirements of the CRL, we 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 we develop in the future;

impose additional costs on us;

diminish any competitive advantages that may be attained; and

adversely affect our ability to generate revenues.

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We have 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 we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our 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. Our ability to market and promote CHEMOSAT is limited to this approved indication. To the extent that our promotion of CHEMOSAT is found to be outside the scope of our approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize CHEMOSAT in the EEA.

We are 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, our ability to commercialize CHEMOSAT in the EEA will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our 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 our device 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 our product and/or to prescribe the use of melphalan independently, our sales opportunities in the EEA will be significantly impaired.

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

In April 2012, we obtained the required certification from our European Notified Body, enabling us 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, we are 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, we are subject to ongoing audits by our 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, we will be subject to similar ongoing regulatory obligations and oversight in those countries where we obtain approval. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices (GCPs), and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that we conduct 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;

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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 we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our 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.

We 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. We are seeking approval of Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for Melphalan/HDS with melphalan and every other chemotherapeutic agent or other compound used with our system that we intend 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 we use in our 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. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of melphalan or other chemotherapeutic agents, the value of our company, our results of operations and our ability to raise additional capital will be harmed.

In August 2012, we submitted a 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 we 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 our business, financial condition and results of operations.

Even if we obtain regulatory approval for the Melphalan/HDS system in the United States, our 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, we may only market the Melphalan/HDS, if approved by the FDA, for its approved indication and we 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, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

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If future clinical trials are unsuccessful, significantly delayed or not completed, we 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, we 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 we received agreement on a SPA from the FDA and have initiated a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases. In March 2017, we received agreement on a SPA from the FDA for a registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC), a trial we expect to initiate when financial resources permit.

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

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-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;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- our 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 our NDA submissions;

the FDA or foreign regulatory authorities may change its approval policies or adopt new regulations that may negatively affect or delay our 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 us to cease the development of Melphalan/HDS for other indications. If we are unable to develop Melphalan/HDS for other indications the future growth of our business could be negatively impacted. In addition, we have 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 our ability to commercialize CHEMOSAT/ Melphalan/HDS.

We rely 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 us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for Melphalan/HDS, but we rely on academic institutions, corporate partners, contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. We rely upon third parties to conduct monitoring and data collection of our ongoing and future clinical trials, includingour Phase 3 ocular melanoma trial and pivotal ICC trial. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us 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. Our reliance on third parties does not relieve us of these responsibilities and requirements, and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA s cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and we may fail 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, we may not be able to successfully commercialize CHEMOSAT in the EEA.

We have obtained the right to affix the CE Mark for CHEMOSAT, and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell CHEMOSAT. In Germany, we have 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 in2016 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 we are able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries. In the United Kingdom, we began seeking a block fund grant in 2014. Ongoing changes to the process and funding streams have resulted in delays that made the award and timing of any block grant funding difficult to predict. Accordingly, we may not receive the grant in a timely manner or at all.

In other countries, until we obtain government reimbursement, we 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 we will qualify for such funding. Even if we do 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 our 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.

Our ability to commercialize our systems 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. We 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 us to establish and maintain price levels sufficient for us to realize an appropriate return on our 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.

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.

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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. We expect 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 and Melphalan/HDS

There is only one approved third-party manufacturer of melphalan in the EEA. If this manufacturer fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the EEA.

Under the 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, we are aware that there is currently only one approved manufacturer of melphalan in the EEA, with whom we have no supply arrangements or other affiliation, and therefore we will not have any control over the quality, availability, price or labeling of melphalan in that market. As a result, there may not be sufficient supply of melphalan for use with our system, and any adverse change in the sole manufacturer s commercial operations or regulatory approval status may seriously impair our sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where we may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, we will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

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

We have 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 our branded melphalan for injection. The agreement with Synerx and Bioniche currently represents our sole source of branded melphalan in the United States. We intend to use the melphalan supplied by Synerx and Bioniche to conduct our Phase 2 clinical trial for HCC and ICC in the United States and our global Phase 3 trial for ocular melanoma liver metatases. We may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that we will use in the future for our clinical trial program and the commercialization of CHEMOSAT and Melphalan/HDS, as well as for

labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. To manufacture melphalan or other chemotherapeutic agents on our own, we 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 we choose to manufacture for our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our 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.

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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.

We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS.

We do not have written contracts with all our suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we 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. Components of CHEMOSAT and Melphalan/HDS are currently manufactured for us in small quantities and we may require significantly greater quantities to further commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need 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.

We have limited experience in marketing and commercializing our products, and as a result, we may not be successful in commercializing CHEMOSAT in the EEA.

We have 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 we have obtained the right to affix the CE Mark, we currently have limited sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue our strategy to commercialize CHEMOSAT in the EEA, we 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 we cannot successfully develop the infrastructure to market and commercialize CHEMOSAT, our ability to generate revenues in the EEA may be harmed, and we may not generate sufficient revenue to sustain our business or we may be required to enter into strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms.

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

Even if we receive FDA or other foreign regulatory approvals, we 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 we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize CHEMOSAT and Melphalan/HDS may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. If we are unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market our products in the United States or foreign countries, particularly in Asia, our efforts to commercialize CHEMOSAT and Melphalan/HDS or any other product outside of the EEA may be less successful.

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

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

We 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, we may face competition in our search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all. Our 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 our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our 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 our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We are not able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We 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 our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Currently we have only received authorization to market CHEMOSAT in the EEA, and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of our products to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our 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 our 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 we establish 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 our 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 we fail to overcome the challenges we encounter in our international operations, our business and results of operations may be materially adversely affected.

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

Since all of our 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 no clinical experience with our 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:

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- whether our future clinical trials demonstrate significantly improved patient outcomes;
- our ability to educate and train physicians to perform the procedure and drive acceptance of the use of CHEMOSAT;
- our 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.

We intend 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 our product, the market may not accept CHEMOSAT and our efforts to commercialize CHEMOSAT in the EEA may be unsuccessful.

Similar considerations apply in any other market where we receive 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 our 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 our 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, our revenues or profitability will be substantially reduced.

Our ability to develop CHEMOSAT and Melphalan/HDS for other indications could affect our orphan drug exclusivity. In November 2008, the FDA granted us two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted us an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted us an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. The FDA granted us orphan drug designation of the drug melphalan for the treatment of HCC in October 2013 and for the treatment of ICC in July 2015. If CHEMOSAT and Melphalan/HDS is approved for an indication different than the indications for which we have received orphan drug designations, we will not obtain orphan drug exclusivity, which could increase our competition. If another company has orphan drug designations for these same indications and receives marketing approval before we do, then we will be blocked from marketing approval for seven years from the date of their approval for the same indication of use.

The loss of key personnel could adversely affect our business.

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

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.

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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

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

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

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

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

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

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

Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

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

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

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the United States patent system from a first-to-invent system to a first-to-file system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office (USPTO) recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. As case law continues to develop in response to this legislation, it is not yet clear what the full impact of the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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

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

We rely on our trademarks as one means to distinguish our product from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement.

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

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

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

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

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

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work

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for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

Risks Related to Products Liability

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

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

Risks Related to this Offering

Our management team will have broad discretion over the use of the net proceeds from this offering.

Our management will use its discretion to direct the net proceeds from this offering. Our management s judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

Investors in this offering will experience immediate and substantial dilution.

The public offering price of the securities offered pursuant to this prospectus may be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma net tangible book value per share of common stock from the price per share that you pay for the common stock. If the holders of our outstanding options or warrants exercise those options or warrants at prices below the public offering price, you will incur further dilution.

Further substantial dilution will occur if the true-up provision of our warrants issued in conjunction with the amended restructuring agreement is triggered.

The warrants are a new issue of securities with no established trading market.

The warrants are a new issue of securities with no established trading market. The warrants will not be listed on any securities exchange or quotation system. A trading market for the warrants may not develop and even if a market develops it may not provide meaningful liquidity. The absence of a trading market or liquidity for the warrants may adversely affect their value.

The exercise price and number of certain outstanding warrants will be adjusted in connection with this and possibly other offerings.

The 0.3 million warrants issued in our February 2015, July 2015 and October 2016 offerings are subject to an exercise price adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is also subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. In addition to the potential dilutive effect of this provision, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

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Risks Related to the Note Financing

Our indebtedness reduces our financial flexibility and could impede our ability to operate.

In October 2016, we issued an aggregate $35 million principal amount of senior secured convertible notes (the notes). The notes are payable in fourteen equal installments beginning in January 2017. Although the notes are payable through the issuance of shares of our common stock to the noteholders, our ability to issue stock, instead of paying cash, to satisfy our payment obligations under the notes, is limited and subject to various conditions (including trading volume and stock price conditions for these notes) that we may not be able to meet. If we cannot meet these conditions, we could be required to repay some or all of the amounts due under the notes in cash, and we may not have the funds available to make one or more of such payments when due. Even if we do have funds so available, the use of cash to make such payments could adversely affect our ability to fund operations due to the diversion of necessary cash flow to fund operations to utilization for note payments. Furthermore, the notes impose certain restrictive covenants on us which may impede our ability to operate our business or raise further funds in the capital markets. For example, there are restrictions on incurring additional indebtedness, with exceptions, while the notes are outstanding.

Such payments are based upon a formula which uses as a conversion price a discount to market formula with a floor price of $0.05, thus the amount of shares issued can be significantly dilutive to our stockholders.

As part of the note financing, we are required to repay the principal on the notes in fourteen equal installments in cash or shares of common stock. The issuance of shares of our common stock pursuant to the notes will result in significant dilution to our stockholders.

The notes will be repayable in cash or shares of common stock, at our election, subject to satisfaction of certain conditions. As of the date of this prospectus, we do not believe that we will have the financial ability, nor would it be in the best interests of our stockholders, to make all payments on the notes in cash when due. Thus, we intend, as of the date hereof, to make such payments in shares of our common stock, to the greatest extent possible. The price at which we will be required to make any installment payments in shares of common stock is equal to the lowest of (i) the then prevailing conversion price, and (ii) initially 85% of the arithmetic average of the lower of (x) the three lowest daily weighted average prices of the common stock during the twenty (20) consecutive trading day period ending on the trading day immediately preceding the installment date and (y) the volume weighted average price of the common stock on the trading day immediately preceding the installment date; provided, that the amount determined in this clause (ii) shall in no event be less than $0.05.

This floor price will not adjust upon a further reverse stock split, so the price of our stock is subject to further substantial dilution as a result of the conversion floor on these Notes.

Our obligations to the holders of our notes are secured by a security interest in substantially all of our assets, so if we default on those obligations, the note holders could foreclose on our assets.

Our obligations under the notes and the transaction documents relating to the notes are secured by a first priority security interest in substantially all of our assets. As a result, if we default under our obligations under the notes or the transaction documents, the holders of the notes, acting through their appointed agent, could foreclose on their security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

The holders of the notes have certain additional rights upon an event of default under the notes which could harm our business, financial condition and results of operations and could require us to reduce or cease operations.

Under the notes, the holders have certain rights upon an event of default. Such rights include (i) the remaining principal amount of the notes bearing interest at a rate of 15% per annum, (ii) receipt of payment in cash of an amount equal to (x) the remaining principal amount of the notes, accrued and unpaid interest and accrued and unpaid Late Charges (as defined in the notes) on such principal and interest, multiplied by (y) the redemption premium, equal to 118%, in addition to any and all other amounts due thereunder and (iii) the holder having the right to demand redemption of all or a portion of the notes, as described below. At any time after certain notice requirements for an event of default are triggered, a holder of notes may require us to redeem all or any portion of the note by delivering written notice. Each portion of the note subject to redemption would be redeemed by us in cash by wire transfer of immediately available funds at a price equal to the greater of (x) 118% of the principal amount being redeemed or (y) the product of (A) the conversion rate then in effect multiplied by (B) 118% of the volume weighted average price of the common stock on any trading day during the period commencing on the date immediately preceding such event of default and ending on the date such redemption payment is made. We may not have sufficient funds to settle the redemption price and, as described above, this could trigger rights under the security interest granted to the holders and result in the foreclosure of their security interests and liquidation of some or all of our assets.

The exercise of any of these rights upon an event of default could substantially harm our financial condition and force us to reduce or cease operations.

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Risks Related to Our Common Stock

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

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

- Failure of our products to achieve or maintain market acceptance or commercial success;
- fluctuations in our quarterly operating results or the operating results of our competitors;
- variance in our financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- changes in our pricing policies or the pricing policies of our competitors;

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

changes in legislation or regulatory policies, practices or actions;

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

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

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

The 0.3 million warrants issued in our February 2015, July 2015 and October 2016 offerings are subject to an exercise price adjustment upon certain equity issuances below $0.14 per share (as may be further adjusted). In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

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

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

providing for a staggered board; and

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

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

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

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

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

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

incur substantial debt that may place strains on our operations;

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

assume substantial actual or contingent liabilities;

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

suffer the loss of key personnel, or

merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

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

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

We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of October , 2017, we had an aggregate of 500 million shares of common stock authorized and of that only 0.9 million not issued or outstanding, including 0.3 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of $12.57 or 55,000 options to purchase warrants at a weighted average exercise price of $96.99. We may issue all of these shares without any action or approval by our shareholders. We may expand our business through

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

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, could, would, will, may, can, and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus and the documents incorporated by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 in Item 1A under Risk Factors as well as in Item 7A Quantitative and Qualitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

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

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents incorporated by reference, as of the date of such documents. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after such applicable date or to reflect the occurrence of unanticipated events.

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USE OF PROCEEDS

We expect to receive net proceeds from the sale of the securities that we are offering to be approximately $13.9 million, after deduction of underwriting discounts, and commissions and estimated expenses payable by us. This amount does not include the proceeds that we may receive in connection with any exercise of the warrants issued in this offering. We cannot predict when or if the warrants will be exercised, however, and it is possible that the warrants may expire and never be exercised.

We intend to use the net proceeds from this offering (including any resulting from the exercise of the warrants, if any) for:

- the clinical and regulatory development of clinical studies, including the Phase 3 Ocular Melanoma liver metastases trial, a registration trial for intrahepatic cholangiocarcinoma, investigator initiated trials mCRC and pancreatic cancer metastatic to the liver, and European Union Commercial Registry;
- commercialization of our products,
- obtaining regulatory approvals;
- research;
- capital expenditures and development of joint ventures and licensing arrangements for our products;
- working capital; and
- the balance, if any, for other general corporate purposes.

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

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of clinical and regulatory development programs and the amount and timing of product revenue, if any. In addition, we might decide to postpone or not pursue certain activities if, among other factors, the net proceeds from this offering and our other sources of cash are less than expected. As a result, management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds. Pending the uses described above, we intend to invest the net proceeds in interest-bearing investment-grade securities or deposits.

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DILUTION

If you invest in our common stock and warrants, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the adjusted net tangible book value per share of our common stock after this offering.

The net tangible book value of our common stock as of June 30, 2017, was approximately $0.9 million, or approximately $0.00 per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities divided by the total number of shares of our common stock outstanding.

Dilution per share to new investors represents the difference between the amount per share paid by purchasers for our common stock in this offering and the net tangible book value per share of our common stock immediately following the completion of this offering.

After giving effect to the sale of units offered by this prospectus and after deducting the estimated underwriting discount, commissions and our estimated offering expenses and excluding the proceeds, if any from the exercise of the warrants issued pursuant to this offering, our pro forma net tangible book value as of June 30, 2017 would have been approximately $14.7 million or approximately $ per share. This represents an immediate increase in net tangible book value of approximately $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to purchasers of our common stock in this offering, as illustrated by the following table:

Assumed offering price for one unit consisting of one share of common stock and one warrant	$
Net tangible book value per share as of June 30, 2017	$ 0.0
Increase per share attributable to new investors	$
Pro forma net tangible book value per share as of June 30, 2017 after giving effect to this offering	$
Dilution per share to new investors	$

The discussion of dilution, and the table quantifying it, assume no exercise of any outstanding options or warrants or other potentially dilutive securities. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

The table above excludes the following potentially dilutive securities as of October 4, 2017:

- 55,000 shares issuable upon the exercise of stock options at a weighted average exercise price of $96.99 per share;
- 0.3 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $12.57 per share;

18,000 shares reserved for future issuance under our 2009 Equity Incentive Plan, as amended;

0.1 million unvested restricted shares; and

shares issuable upon exercise of the common warrants offered hereby.

To the extent that any of these options or warrants are exercised or the restricted shares vest, these will cause dilution per share to the investors purchasing securities in this offering.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and consolidated capitalization as of June 30, 2017 on: (i) an historical basis; and (ii) an as adjusted basis to give effect to this offering.

You should read the following table in conjunction with the sections entitled Use of Proceeds, and Description of Capital Stock in this prospectus, and Selected Historical Combined Consolidated Financial Data, Management s Discussion and Analysis of Financial Condition and Results of Operations, and our financial statements and related notes thereto in our Annual Report of Form 10-K and our Quarterly Report on Form 10-Q incorporated by reference into this prospectus.

	June 30, 2017	
	Actual	As Adjusted
	(unaudited)	
Cash and cash equivalents	$ 1,816	$ 15,691
Warrant liability	43	43
Stockholders equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively		
Common stock, $.01 par value; 500,000,000 shares authorized; 424,526.067 and 4,131,527 shares issued and 424,408,256 and 4,112,417 shares outstanding at June 30, 2017 and December 31, 2016, respectively*	4,245	
Additional paid-in capital	289,186	
Accumulated deficit	(292,464)	
Treasury stock, at cost; 110 shares at June 30, 2017 and December 31, 2016, respectively*	(51)	
Accumulated other comprehensive income	(49)	
Total stockholders deficit	867	
Total capitalization	$ 18,603	$

* reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016.

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Equity Compensation Plans

Summary equity compensation plan data

The following table sets forth information, as of June 30, 2017, about our equity compensation plans (including the potential effect of debt instruments convertible into common stock) in effect as of that date:

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)(2)	(b) Weighted-average exercise price of outstanding options	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (	55,486	$ 95.51	17,022
Equity compensation plans not approved by security holders		$	
Totals	55,486	$ 95.51	17,022

(1) The description of the material terms of non-plan issuances of equity instruments is discussed in Note [5] to the accompanying consolidated financial statements.
(2) Net of equity instruments forfeited, exercised or expired.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is quoted on the OTCQB under the symbol DCTH. The table below sets forth, for the periods indicated, the quarterly high and low sale prices per share of our common stock since 2015. The information in the table below reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016.

	High	Low
2015:		
First Quarter	$ 24.93	$ 15.36
Second Quarter	23.04	12.96
Third Quarter	14.72	6.38

Fourth Quarter	9.96	6.24

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2016:		
First Quarter	$ 8.64	$ 4.00
Second Quarter	5.70	3.68
Third Quarter	4.61	2.48
Fourth Quarter	2.74	0.90
2017		
First Quarter	$ 0.87	$ 0.08
Second Quarter	$ 0.27	$ 0.02

The last reported trading price of our common stock on October 9, 2017 was $0.0566. As of October 9, 2017, we had approximately 100 holders of record of our common stock.

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

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OUR BUSINESS

About Delcath

Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our investigational product 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.

Our clinical development program for CHEMOSAT and Melphalan/HDS is comprised of The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (The FOCUS Trial), a Global Phase 3 clinical trial that is investigating overall survival in mOM, and a registration trial for intrahepatic cholangiocarcinoma (ICC) we plan to initiate when financial resources permit. 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.

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

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing the CHEMOSAT system in select markets in the European Union (EU) where the prospect of securing 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.

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,

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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.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers including HCC and ICC are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 40,710 new cases of HCC and ICC will be diagnosed in the United States in 2017. Approximately 75-90% of these patients are diagnosed with HCC. Excluding patients who are eligible for surgical resection or certain focal treatments, we estimate that approximately 15,000 patients with HCC in the United States and Europe may be eligible for treatment with Melphalan/HDS. We estimate that an additional 9,300 patients diagnosed with ICC may also be eligible for treatment with Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients 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%. Globally, with 782,000 new cases in 2012, HCC was the fifth most common cancer in men and the ninth in women according to GLOBOCAN. GLOBOCAN estimates indicate that HCC was responsible for 746,000 deaths in 2012 (9.1% of the total cancer deaths), making it the second most common cause of death from cancer worldwide.

The prognosis for primary liver cancer is very poor, as indicated by an overall ratio of mortality to incidence of 0.95. The American Cancer Society s *Cancer Facts & Figures 2017* outlines the treatment options for HCC as follows: Early stage liver cancer can sometimes be successfully treated with surgery to remove part of the liver (partial hepatectomy); however, few patients have sufficient healthy liver tissue for this option. Liver transplantation may be possible in individuals with small tumors who are not candidates for partial hepatectomy. Other treatment options include tumor ablation (destruction) or embolization (blocking blood flow). Few options exist for patients diagnosed at an advanced stage. Sorafenib (Nexavar®) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery and do not have severe cirrhosis.

Based on third party research, we estimate that up to 15,000 of the 65,000 patients diagnosed annually in the United States and Europe could be eligible candidates for treatment with the Melphalan/HDS. The FDA has granted orphan drug status to the Melphalan/HDS for treatment of patients with unresectable HCC. We believe that there is a large unmet medical need in first line therapy for patients with HCC, with Sorafenib the only currently approved systemic

therapy in the United States, Europe and certain Asian markets.

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of HCC cases diagnosed in the United States and Europe annually. Outside of resection, which is the only cure for ICC, there is currently no standard of care. Based on third party research, 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.

About CHEMOSAT and Melphalan/HDS

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

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administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters absorb chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug and related toxic side effects, before the filtered blood is returned to the patient s circulatory system.

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

Risks associated with the CHEMOSAT and Melphalan/HDS Procedure

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

Procedure and Product Refinements

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

Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile. In 2016, physicians in Europe and the United States also presented the results of research that signaled an improved safety profile as well as efficacy in multiple tumor types at several major medical conferences.

Phase 3 Melanoma Metastases Trial

In February 2010, we concluded a randomized Phase 3 multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive PHP treatments with melphalan using the Melphalan/HDS, or to a control group providing best alternative care (BAC). Patients assigned to the PHP arm were eligible to receive up to six cycles of treatment at approximately

four to eight week intervals. Patients randomized to the BAC arm were permitted to cross-over into the PHP arm at radiographic documentation of hepatic disease progression. A majority of the BAC patients did in fact cross over to the PHP arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

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

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Phase 2 Multi-Histology, Unresectable Hepatic Tumor Trial

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

Phase 2 Multi-Histology Clinical Trial HCC Cohort

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

Prior United States Regulatory Experience

Based on the results from our prior clinical development in August 2012, we submitted an NDA under Section 505(b)(2) of the Federal Food Drug Cosmetic Act (FFDCA) seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, and subsequently amended the indication to ocular melanoma metastatic to the liver. Data submitted to the Food and Drug Administration (FDA) used the early clinical trial versions of the system along with early clinical procedure techniques. Our NDA was accepted for filing by the FDA on October 15, 2012, and was designated for standard review with an initial Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013.

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

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

2013 Complete Response Letter

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

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

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Current Clinical Development Program

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

(the FOCUS Trial) - NCT02678572

In January 2016, we initiated a new pivotal Phase 3 clinical trial in hepatic dominant ocular melanoma with the first patient enrolled in February 2016 looking at overall survival of patients (length of time from treatment to death). Called the FOCUS Trial, this new global Phase 3 trial will evaluate the safety, efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with hepatic dominant OM. The primary endpoint is a comparison of overall survival between the two study arms. Secondary and exploratory endpoints include progression-free survival, overall response rate and Quality of Life (QoL) measures. In the FOCUS trial s treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years.

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

The FOCUS Trial is being conducted under a SPA we concluded with the FDA in January 2016. Under the terms of the SPA, the FOCUS Trial is the only Phase 3 trial required for submission of an NDA. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the entire data in the application.

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

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

In March 2017 we announced another SPA agreement with the FDA for the design of a new pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma (ICC) titled *A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following*

Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma (Pivotal ICC Trial). Under the SPA, the Pivotal ICC Trial will enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint is overall survival (OS) and secondary and exploratory endpoints include safety, progression-free survival (PFS), overall response rate (ORR) and quality-of-life measures. This Pivotal ICC Trial is designed to be cost effective and pursued in a financially prudent manner when financial resources permit. The SPA agreement for this trial indicates that the pivotal trial design adequately addresses objectives that, if met, would support regulatory requirements for approval of Melphalan/HDS in ICC. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the entire data in the application.

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

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

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

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

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

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

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

Clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy.

A substantial portion of the Company s operating expenses consist of research and development expenses incurred in connection with its clinical trials. See the Company s Consolidated Financial included in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 29, 2017.

European Investigator Initiated Trials

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

European Clinical Data Generation

On April 2, 2015, we announced the activation of our prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry will gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. A prospective registry is an organized system that uses observational study methods to collect defined clinical data under

normal conditions of use to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Registry data is non-randomized, and as such cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable data repository from a commercial setting that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe. Cancer centers in Germany, the United Kingdom, and the Netherlands are participating in the registry and patient enrollment has begun.

Recent Data Presentations

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

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

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

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

Across all patients, the overall response rate (ORR) was 19.2 percent, with ocular melanoma patients experiencing the highest ORR (33.3 percent). As has been published previously, high tumor volumes negatively impact overall survival (OS). Median OS was 261 days for the entire patient group. Two patients with cholangiocarcinoma and one patient with ocular melanoma had the longest survival with 566, 465, and 477 days respectively. Overall, PHP with Melphalan/HDS was well tolerated. Complications including thrombocytopenia, cardiovascular events, ulcerous bleeding, and edema were reported. These results are summarized in the Journal of Cancer Research and Clinical Oncology article, *Safety and Efficacy of Chemosaturation in Patients with Primary and Secondary Liver Tumors.*

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

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

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

Also in February 2017, we announced results of a retrospective, multicenter study presented at the *Regional Cancer Therapies 12th International Symposium* in an oral presentation titled, *Percutaneous Hepatic Perfusion for Unresectable Metastatic Ocular Melanoma to the Liver: A Multi-Institutional Report of Outcomes*. This analysis demonstrated that 45.7 percent of patients with ocular melanoma that metastasized to the liver who underwent PHP using Melphalan/HDS experienced a complete or partial response. The study further showed that among those who responded to treatment, overall survival was projected to be more than three years. The analysis was conducted by teams from Moffitt Cancer Center in Tampa, Fla., and the University of Southampton in the United Kingdom. The presentation was led by Dr. Alexandra Gangi of the Moffitt Cancer Center.

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The analysis reviewed outcomes of 49 patients treated between 2008 and 2016 with Melphalan/HDS at either the Moffitt Cancer Center or the University of Southampton. Patients underwent a total of 115 PHP treatments. The median number of treatments per patient was two, with patients receiving one-to-six treatments.

Hepatic response to PHP was evaluable in 46 patients, among whom 45.7 percent showed complete or partial response, and 37.0 percent had stable disease. Median overall survival was not reached, but was projected to be 657 days (1.8 years). Among patients with a complete or partial response, overall survival was projected to be 1,207 days. Most common side effects following treatment were anemia, thrombocytopenia and neutropenia.

Market Access & Commercial Clinical Adoption

European Union

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

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

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. Medical devices are typically reimbursed under Diagnosis Related Groups (DRG) as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, the Company is actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

Germany

In October 2015, we announced that the Institut für das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a national Zusatzentgeld (ZE) reimbursement code for procedures performed with CHEMOSAT in Germany. The ZE diagnostic-related group (DRG) code is a national reimbursement code that augments existing DRG codes until a specific new DRG code can be created, and will replace the previous Neue Untersuchungs und Behandlungsmethoden (NUB) procedure that required patients in Germany to apply individually

for reimbursement of their CHEMOSAT treatment. With the establishment of a ZE code for CHEMOSAT, the procedure is now permanently represented in the DRG catalog in Germany. In 2016, coverage levels were negotiated between hospitals in Germany and regional sickness funds. Coverage levels determined via this process are renegotiated annually.

United Kingdom

In May 2014, NICE, a non-departmental public body that provides guidance and advice to improve health and social care in the UK, completed a clinical review of CHEMOSAT. The NICE review indicated that as the current body of evidence on the safety and efficacy of PHP with CHEMOSAT for primary or metastatic liver cancer is limited, the procedure should be performed within the context of research by clinicians with specific training in its use and techniques. Delcath expects to consult again with the Interventional Procedures Advisory

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Committee at the National Institute for Clinical Excellence (NICE) in England, to provide recent clinical evidence with a view to moving existing Interventional Procedural Guidance from research to specialist status. This would enable greater scope for commercialization because it would allow more use by NHS clinicians of the therapy. It might also pave the way for a full Medical Technology Assessment as a way towards longer term reimbursement with the NHS.

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

Netherlands

In the Netherlands CHEMOSAT has been performed at the Netherlands Cancer Institute in 2013 and at Leiden University Medical Centre since 2014. In June 2017 the Medical Oncology National Treatment Guidelines for Uveal Melanoma were updated and now include recommendations to consider CHEMOSAT in the treatment of liver metastases. An application to the Dutch Health Care Institute (ZIN) to approve CHEMOSAT as a treatment option for ocular melanoma liver metastases and also an application for reimbursement Dutch Health Care Authority (NZA) for the formulation of a reimbursement code (DBC) has been made. These applications are currently under review by the respective bodies.

Spain

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

Turkey

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

Distribution Partners

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

Regulatory Status

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing,

labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review

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and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, has primary jurisdiction over its pre-market development and review.

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

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

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

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the

IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the European Economic Area (EEA) and other jurisdictions in which we may conduct clinical trials.

Orphan Drug Exclusivity

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

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

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

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds eight U.S. utility patents, one U.S. design patent, six pending U.S. utility patent applications (one of which has been allowed), four issued foreign counterpart utility patents (including the validation of one European patent in two European countries, and the validation of another European patent in four European countries), six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications (one of which has been allowed). The company holds U.S. and some foreign trademarks for DELCATH, CHEMOSAT, CHEMOFUSE, ISOFUSE, PHP, and THE DELCATH PHP SYSTEM.

In July 2017, one of our pending patent applications for our chemotherapy filtration system was approved by the U.S. Patent Office. When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT and Melphalan/HDS that will enable us to expand our platform beyond the treatment of cancers in the liver.

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

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

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

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

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Delcath Systems, Inc. Patents and Patent Applications

Patents Issued in the United States

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
7,022,097	Method For Treating Glandular Diseases and Malignancies	04/04/2006	Owned	06/24/2023
9,707,331	Apparatus For Removing Chemotherapy Compounds from Blood	07/18/2017	Owned	09/17/2034
D708749	Dual Filter	07/08/2014	Owned	07/08/2028
9,314,561	Filter and Frame Apparatus and Method of Use	04/19/2016	Owned	02/07/2034
9,541,544	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	01/10/2017	Owned	08/28/2033
8,679,057	Recovery Catheter Assembly	03/25/2014	Licensed	03/04/2031
9,265,914	Recovery Catheter Assembly	02/23/2016	Licensed	04/05/2031
9,108,029	Recovery Catheter Assembly and Method	08/18/2015	Licensed	02/09/2034

Patent Applications in the United States

Application No.	Application Title	Filing Date	Owned or Licensed
15/651,141	Apparatus For Removing Chemotherapy Compounds from Blood	07/17/2017	Owned
15/071,896	Filter and Frame Apparatus and Method of Use	03/16/2016	Owned
15/346,239	A Method of Selecting Chemotherapeutic Agents for an Isolated Organ or Regional Therapy	11/08/2016	Owned
14/995,677	Recovery Catheter Assembly	01/14/2016	Licensed
14/797,108	Recovery Catheter Assembly and Method	07/11/2015	Licensed
15/728,296	Recovery Catheter Assembly and Method	10/09/2015	Licensed

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Foreign Patents

Patent No.	Title	Issuance Date	Owned or Licensed	Expiration Date
84.098	**Dual Filter (Argentina)**	**06/29/2012**	**Owned**	**06/29/2027**
343454	**Dual Filter (Australia)**	**07/23/2012**	**Owned**	**06/25/2022**
146201	**Dual Filter (Canada)**	**05/15/2013**	**Owned**	**05/15/2023**
ZL 201230277905.5	**Dual Filter (China)**	**03/20/2013**	**Owned**	**06/22/2022**
001333173	**Dual Filter (Europe)**	**06/27/2012**	**Owned**	**06/25/2037**
1456186	**Dual Filter Cartridge for Fluid Filtration (Japan)**	**10/26/2012**	**Owned**	**10/26/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Albania)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Austria)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Belgium)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Bulgaria)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Croatia)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Cyprus)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Czech Republic)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Denmark)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Estonia)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Finland)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (France)**	**04/12/2017**	**Owned**	**12/29/2032**
602012031191.6	**Filter and Frame Apparatus and Method of Use (Germany)**	**04/12/2017**	**Owned**	**12/29/2032**

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2797644	**Filter and Frame Apparatus and Method of Use (Great Britain)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Greece)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Hungary)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Iceland)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Ireland)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Italy)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Latvia)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Lithuania)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Luxembourg)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Macedonia)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Malta)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Monaco)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Netherlands)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Norway)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Poland)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Portugal)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Romania)**	**04/12/2017**	**Owned**	**12/29/2032**

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2797644	**Filter and Frame Apparatus and Method of Use (San Marino)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Serbia)**		**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Slovakia)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Slovenia)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Spain)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Sweden)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Switzerland)**	**04/12/2017**	**Owned**	**12/29/2032**
2797644	**Filter and Frame Apparatus and Method of Use (Turkey)**	**04/12/2017**	**Owned**	**12/29/2032**
2011224640	**Recovery Catheter Assembly (Australian)**	**08/20/2015**	**Licensed**	**03/04/2031**
ZL201180022704.3	**Recovery Catheter Assembly (China)**	**08/26/2015**	**Licensed**	**03/04/2031**
1183257	**Recovery Catheter Assembly (Hong Kong)**	**08/12/2016**	**Licensed**	**03/04/2031**
5982081	**Recovery Catheter Assembly (Japan)**	**08/05/2016**	**Licensed**	**03/04/2031**

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Foreign Patent Applications

Application No.	Title	Filing Date	Owned or Licensed
12847108.3	Apparatus For Removing Chemotherapy Compounds from Blood (Europe)	11/07/2012	Owned
17176952.4	Apparatus For Removing Chemotherapy Compounds from Blood (Europe)	11/07/2012	Owned
17165333.0	Filter and Frame Apparatus and Method of Use (Europe)	12/29/2012	Owned
15104220.7	Filter and Frame Apparatus and Method of Use (Hong Kong)	07/07/2017	Owned
2015210390	Recovery Catheter Assembly (Australia)	03/04/2011	Licensed
2793561	Recovery Catheter Assembly (Canada)	09/05/2012	Licensed
201510452193.9	Recovery Catheter Assembly (China)	11/06/2012	Licensed
11709548.9	Recovery Catheter Assembly (Europe)	03/04/2011	Licensed
2016-081587	Recovery Catheter Assembly (Japan)	09/06/2012	Licensed

Other Regulatory Requirements

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

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or

conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

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

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European Regulatory Environment

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

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

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

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product s design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body s assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer s behalf

with regard to the manufacturer s obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

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

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EEA reference our product, and the labels vary from country to

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country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT system and must use melphalan independently at their discretion.

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

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The European Commission reviewed the medical devices legislative framework in 2012 with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. We do not believe the adopted regulatory changes will impact our business at this time, though future changes to the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

Other International Regulations

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

Competition

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

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

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

For HCC, sorafenib (Nexavar, Onyx Pharmaceuticals) remains the only targeted drug approved for the treatment of HCC in patients who are not candidates for surgery.

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar , GlaxoSmithKline), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST , GlaxoSmithKline) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy , Bristol Myers Squibb) and the B-RAF targeted drug vemurafenib (Zelboraf , Genentech) may also make up the competitive landscape for the treatment of metastatic liver disease.

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Many of these treatments are approved in Europe and other global markets.

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

Manufacturing and Quality Assurance

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

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

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds nine United States utility patents, one United States design patent, five pending United States utility patent applications, eleven issued foreign counterpart utility patents, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications (one of which has been allowed). We presently have issued utility and design patents with claims related to certain features of the current version of CHEMOSAT and Melphalan/HDS in the United States and Japan and a design patent protection in Argentina, Australia, Canada, China and Europe.

When appropriate, the Company actively pursues protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the

CHEMOSAT and Melphalan/HDS that will enable us to expand our platform beyond the treatment of cancers in the liver. There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

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

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Certain of our United States and foreign patents have already expired [and other patents relating to the CHEMOSAT and Melphalan/HDS will expire in 2017]. In certain circumstances, United States patent law allows for the extension of a patent s duration for a period of up to five years after FDA approval. The Company intends to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted Delcath five orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, the Company believes that it will provide us with added protection once commercialization of an orphan drug designated product begins.

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

Employees

During 2016, Delcath added 7 employees to support clinical trial implementations in the EU and United States and to meet the demands of commercial sales. As of September 25, 2017, Delcath had 46 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

Properties

Our corporate offices currently occupy 6,877 square feet of office space at 1633 Broadway, Suite 22C, New York, New York under a sub-lease agreement that expires in March 2019. The Company leases two additional spaces in the United States including approximately 6,000 square feet at 95-97 Park Road in Queensbury, New York and 17,320 square feet of office space at 810 Seventh Avenue, New York, New York. The lease agreements expire in October 2018 and March 2021 respectively. The Company has subleased the office space at 810 Seventh Avenue to unaffiliated third-parties. Delcath owns a building containing approximately 10,320 square feet at 566 Queensbury Avenue in Queensbury, NY. These facilities house manufacturing, quality assurance and quality control, research and development, and office space. The Company also owns approximately four acres of land at 12 and 14 Park Road in Queensbury, New York. In addition, the Company leases a facility for office and manufacturing containing approximately 19,200 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease agreement that expires August 2, 2021. The Company has sublet 5,662 square feet of this facility to an unaffiliated third-party. The Company believes substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following tables contain information regarding the beneficial ownership of our common stock as of September 21, 2017, held by: (i) each of our directors; (ii) each of our named executive officers in the Summary Compensation Table; (iii) all of our directors and executive officers as a group; and (iv) each person or group known by us to own beneficially more than 5% of the outstanding common stock. We are not aware of any 5% or more holders of our Common Stock as of September 21, 2017 except as set forth below. The information set forth in the table below excludes shares issuable upon exercise of our outstanding warrants held by certain investors that are presently exercisable, subject to limitations on exercisability for more than 4.9% or 9.9% of our outstanding shares of common stock, depending upon the particular investor. Except as indicated in the footnotes below, the address of the persons or groups named below is c/o Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019.

Directors and Officers

	Shares Beneficially Owned (1)	
Name of Beneficial Owner:	**Number**	**Percent**
Named Executive Officers and Directors:		
Jennifer K. Simpson, Ph.D.(2)	46,987	*
John Purpura, M.S.(3)	38,827	*
Barbra C. Keck, M.B.A.(4)	26,158	*
Harold S. Koplewicz, M.D.(5)	4,688	*
Roger G. Stoll, Ph.D.(6)	6,637	*
William D. Rueckert(7)	5,625	*
Marco Taglietti, M.D.(8)	16,875	*
All directors and executive officers as a group (7 people)[9]:	145,797	*

* Less than 1%

(1) Except as indicated in these footnotes: (i) the persons named in this table have sole voting and investment power with respect to all shares of common stock beneficially owned; (ii) the number of shares beneficially owned by each person as of September 19, 2017, includes any vested and unvested shares of restricted stock and any shares of common stock that such person or group has the right to acquire within 60 days of September 19, 2017, upon the exercise of stock options; and (iii) for each person or group included in the table, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the 490,022,209 shares of common stock outstanding on September 19, 2017, plus the number of shares of common stock that such person or group has the right to acquire within 60 days of September 19, 2017.

(2) Includes 5,079 shares of common stock, which Dr. Simpson has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017.

(3) Includes 3,429 shares of common stock, which Mr. Purpura has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017.

(4) Includes 2,271 shares of common stock, which Ms. Keck has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017, and 4 shares held in a joint account with her spouse.

(5) Includes 1,875 shares of common stock, which Dr. Koplewicz has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017. Mr. Koplewicz resigned as a director effective September 15, 2017.

(6) Includes 3,688 shares of common stock, which Dr. Stoll has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017

(7) Includes 3,125 shares of common stock, which Mr. Rueckert has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017.

(8) Includes 3,125 shares of common stock, which Dr. Taglietti has the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017.

(9) Includes 22,592 shares of common stock, which certain directors and executive officers have the right to acquire upon exercise of outstanding options exercisable within 60 days of September 19, 2017.

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FIVE PERCENT HOLDERS

	Title of Class	Address of Beneficial Owner	Amount and nature of beneficial ownership (Series C Preferred Stock)	Percent of Class (Series C Stock)
Hudson Bay Master Fund Ltd.	Common Stock, Series C Preferred Stock	777 Third Avenue, 30th Floor New York, NY 10017 Attention: George Antonopoulos	501.5(1)	85%
Alto Opportunity Master Fund, SPC- Segregated Master Portfolio A.	Series C Preferred Stock	1180 Avenue of the Americas, Suite 842 New York, NY 10036 Attn: Waqas Khatri	88.5(2)	15%

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(1) Hudson Bay Capital Management, L.P., the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management, L.P. The Series C Preferred Stock votes along with the common stock with880,375 votes.

(2) Ayrton Capital LLC serves as the investment manager of Alto Opportunity Master Fund, SPC- Segregated Master Portfolio A and has voting and investment power over these securities. Waqas Khatri is the manager of Ayrton Capital LLC. Each of Alto Opportunity Master Fund, SPC Segregated Master Portfolio A and Waqas Khatri disclaims beneficial ownership over the securities, except to the extent of its pecuniary interest therein. The Series C Preferred Stock votes along with the common stock with 880,375 votes.

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DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position with Delcath	Director Since
Class I Directors Term expiring at the 2019 Annual Meeting			
William D. Rueckert	64	Director	2014
Marco Taglietti, M.D.	57	Director	2014
Class III Directors Terms expiring at the 2018 Annual Meeting			
Roger G. Stoll, Ph.D.	74	Chairman	2008
Jennifer K. Simpson, Ph.D.	48	Director	2015
Class I Directors Terms Expiring at the 2019 Annual Meeting.			

William D. Rueckert was appointed as a Director in December 2014. Mr. Rueckert has served on many public and private corporate boards in both the life science and banking industries. He is currently President of Oyster Management Group, LLC, an investment partnership specializing in community banking. From 2007 until 2012 he served on the board of Novogen Ltd. (ASX, NASDAQ) a biotechnology company based in Sydney, Australia. He acted as Chairman from 2010 until 2012, and as acting CEO led the restructuring of the company, spinning off its major subsidiary, Marshall Edwards, Inc. (now MEI Pharma, Inc. NASDAQ.) He is currently a director of MEI Pharma, Inc. (NASDAQ), a San Diego based company that is developing novel oncology therapies. Until its sale to H. Lundbeck A/S, he was a director of Chelsea Therapeutics International, Ltd. (NASDAQ) whose drug candidate, Northera, was approved by the FDA in 2014. He has also served on the boards of several banks including Westport Bank and Trust, Lafayette American Bank and Hudson United Bank (all NASDAQ.) He currently serves on the board of Fairfield County Bank, a mutually owned, community bank based in Ridgefield, Connecticut, and Bleachers, Inc., a privately held company that streams live and archived sports and entertainment events from independent schools. Among his civic associations, Mr. Rueckert is a Director and President of the Cleveland H. Dodge Foundation, Co-Chairman of the Board of Trustees of Teachers College, Columbia University, a Director of the Y Retirement Fund, a Trustee of International House, an Emeritus Director of the YMCA of Greater New York, a Trustee of the American University of Beirut and a Director of Wave Hill, Inc. He earned a BA in Spanish in 1977 from the University of New Hampshire. The Nominating Committee considered Mr. Rueckert s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Mr. Rueckert should serve as director of Delcath.

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

Dr. Taglietti s experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Dr. Taglietti should serve as director of Delcath.

Class III Directors Terms Expiring at the 2018 Annual Meeting.

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

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

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Information About our Executive Officers

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

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

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

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

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

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

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Board of Directors. We have currently have four directors serving on the Board of Directors. The Board of Directors oversees the business affairs of the Company and monitors the performance of management. In accordance with our corporate governance principles, our Board does not involve itself in day-to-day operations. The directors keep themselves informed through discussions with the Chairman of the Board, Roger G. Stoll, Jennifer K. Simpson, in her capacity as Director and Chief Executive Officer, or CEO, and other key executives, and by reading the reports and other materials that management sends them and by participating in Board and committee meetings. Our directors hold office until their successors have been elected and qualified unless the director resigns or is removed or by reason of death or other cause is unable to serve in the capacity of director.

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

Attendance. The Board of Directors met 17 times in 2016 (including regularly scheduled and annual meetings). During 2016, each director attended at least 75% of the aggregate of: (i) the total number of meetings of the Board (held during the period for which he or she served as a director) and (ii) the total number of meetings held by all committees of the Board of Directors on which he or she served (held during the period that he or she served). It is Delcath s policy that, absent unusual or unforeseen circumstances, all directors are expected to attend annual meetings of stockholders, and all attended our 2016 Annual Meeting.

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

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

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

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Risk Assessment of Compensation Programs. Our Compensation and Stock Option Committee annually evaluates whether our compensation programs encourage excessive risk-taking by employees at the expense of long-term Company value. Based upon its assessment, including a review of the overall annual award limitations and individual annual limitations in the Delcath 2009 Stock Incentive Plan and the Compensation Committee s role in the consideration and approval of certain awards, the Compensation and Stock Option Committee does not believe that our compensation programs encourage excessive or inappropriate risk-taking, motivate imprudent risk-taking or create risks that are reasonably likely to have a material adverse effect on the Company.

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

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

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

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

The Board has determined that each member of the Audit Committee, William D. Rueckert (Chair), and Marco Taglietti (since April 6, 2016) qualifies as an audit committee financial expert as defined by SEC rules. During 2016, the Audit Committee met four times. Each member of the Audit Committee is independent within the meaning of the NASDAQ listing rules and otherwise meets the financial statement proficiency requirements of the NASDAQ listing rules. The Audit Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

Compensation and Stock Option Committee. The Compensation and Stock Option Committee (the Compensation Committee) assists the Board of Directors in the discharge of the Board s responsibilities with respect to the

compensation of Delcath s directors, executive officers, and other key employees and consultants. The Compensation Committee establishes our overall compensation philosophy and is authorized to approve the compensation payable to our executive officers, including our named executive officers, and other key employees, including all perquisites, equity incentive awards, cash bonuses, and severance packages. The Compensation Committee also administers certain of our employee benefit plans, including its equity incentive plans, and is responsible for assessing the independence of compensation consultants and legal advisors. The Compensation Committee has concluded that each of Wexler, Burkhart,

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Hirschberg & Unger, LLP, outside legal counsel to the Compensation Committee and the Company, as well as Pearl Meyer & Partners, compensation consultant to the Compensation Committee, qualified as independent. The Compensation Committee exercises sole power to retain compensation consultants and advisors and to determine the scope of the associated engagements.

The current members of the Compensation and Stock Option Committee are Marco Taglietti (Chair) and William D. Rueckert (since April 6, 2016), each of whom is independent within the meaning of the NASDAQ listing rules. During 2016, the Compensation and Stock Option Committee met nine times. The Compensation and Stock Option Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

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

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

The current members of the Nominating Committee are William D. Rueckert and Marco Taglietti, each of whom is independent, within the meaning of the NASDAQ listing rules. During 2016, the Nominating Committee met one time. The Nominating Committee has a written charter, which is available on our website; go to www.delcath.com, click on Investors, then Corporate Governance.

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

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

Nominating Committee. One or more members of the Nominating Committee may contact the proposed candidate to request additional information.

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

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

REPORT OF THE AUDIT COMMITTEE

The Audit Committee reviewed and discussed the Company s audited financial statements for the fiscal year ended December 31, 2016, with management and Grant Thornton, the Company s independent registered public accounting firm for the fiscal year ended December 31, 2016. The Audit Committee also discussed with Grant Thornton the matters required to be discussed by the Statement on Auditing Standards No. 16, as amended, as adopted by the Public Company Accounting Oversight Board in Rule 3200T regarding Communication with Audit Committees. The Audit Committee has received and reviewed the written disclosures and the letter from Grant Thornton required by applicable requirements of the Public Company Accounting Oversight Board regarding Grant Thornton s communications with the Audit Committee concerning independence, and has discussed with Grant Thornton its independence from the Company.

Based on the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company s audited financial statements be included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2016, for filing with the Securities and Exchange Commission.

Submitted by the Audit Committee of the Board of Directors,

William Rueckert (Chair)

May 9, 2017

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SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who are beneficial owners of more than 10% of our common stock to file with the Securities and Exchange Commission reports of holdings and changes in beneficial ownership of Delcath s equity securities. Based on a review of copies of reports furnished to Delcath or written representations that no reports were required, we believe that all reports were timely filed in 2016.

EXECUTIVE COMPENSATION

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

Our Compensation Committee engaged an independent compensation consulting firm, Pearl Meyer, to assist with the formulation of our executive compensation programs for 2016.

Our Compensation Committee considers the input it receives from our stockholders when designing and evaluating our executive compensation practices. At our 2016 annual meeting of stockholders, our stockholders approved, on an advisory basis, the 2015 compensation of our executive officers described in our 2016 proxy statement. Approximately 74% of the votes present or represented and entitled to vote on the matter were voted For such advisory say-on-pay approval.

Compensation Components. The three primary components of executive compensation are base salary, annual incentive cash awards and long-term equity incentive awards:

Base Salary. We pay our executive officers a base salary, which our Compensation Committee reviews and determines annually. Base salaries are used to compensate our executive officers for performing the core responsibilities of their positions and to provide them with a level of security with respect to a portion of their total compensation. Base salaries are set in part based on the executive s unique skills, experience and expected contribution to the Company, as well as individual performance, including the impact of such performance on our business results, and the period of the executive s performance. Decisions regarding base salary increases take into account the executive s current base salary, third-party benchmark and survey data, and the salary compensation paid to executive officers within and outside the Company, as well as the Company s overall performance, its ability to afford such increases, its success in achieving its operational and strategic goals and objectives, and the executive officer s contribution to Company performance.

Annual Incentive Cash Awards. Annual incentive compensation is intended to establish a direct correlation between annual cash awards and the performance of the Company. The Company s Annual Incentive Plan (AIP) is an annual incentive cash bonus plan designed to align the interests of participants with the interests

of the Company and its stockholders. The AIP is designed to strengthen the link between a participant s pay and his or her overall performance and the Company s performance, focus participants on critical individual and corporate objectives, offer a competitive cash incentive, and encourage and reward performance and competencies critical to the Company s success.

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

Base Salary. Effective February 21, 2017, Barbra Keck, previously the Senior Vice President of Finance, Principal Accounting Officer and Principal Financial Officer of the Company, became the Chief Financial Officer of the Company. In connection with her promotion to Chief Financial Officer, Ms. Keck s annual base salary was increased from $247,200 in 2016 to $300,000 in 2017.

The following table summarizes the amount of base salary and year-over-year increase for each of our named executive officers for 2015 and 2016.

Executive	Hire Date	2015 Base Salary	Percent Increase in 2016	2016 Base Salary
Jennifer K. Simpson, Ph.D.	3/23/2012	$ 427,000	3.0%	$ 439,810
Barbra C. Keck, M.B.A.	1/5/2009	$ 240,000	3.0%	$ 247,200
John Purpura, M.S.	11/16/2009	$ 270,569	13.5%	$ 307,000

Annual Incentive Plan. Under the AIP, annual incentive target award opportunities are expressed as a percentage of a participant s actual base salary for the performance year, beginning January 1. The following table sets forth, for each executive, the applicable target bonus percentage of base salary to which each executive could have been entitled, as well as the actual bonus earned based on company performance in 2016:

	Target Incentive Bonus Opportunity		2016 Incentive Award Earned	
Executive	Target Bonus Expressed as % of Base Salary	Dollars ($)	Actual Payout as a % of Target Bonus	Dollars ($)
Jennifer K. Simpson, Ph.D.	50.0%	$ 219,905	68.0%	$ 149,535
Barbra C. Keck, M.B.A.	35.0%	$ 86,520	68.0%	$ 58,834
John Purpura, M.S.	45.0%	$ 138,150	68.0%	$ 93,942

For 2016, AIP goals were based entirely on Company performance as noted in the table below to focus all the executives on the same critical challenges facing the Company.

Company performance in 2016 was measured based upon achievement of objectives in the following areas: (1) Clinical Trials; (2) Capital; and (3) Sales. The table below summarizes the corporate performance in 2016, the

assigned weighting and the actual achievement for each area:

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Performance Measure	Weighting	Summary of Target Goals	Actual Performance	Percentage Earned (as% of Target Goals)
Clinical Trials	45.0%	Treatment of patients and completion of preliminary activities to support a new regulatory path	FOCUS Trial initiated, accrual/treatment of patients ongoing; preliminary activities for ICC development completed	19.50%
Cash Management	5.0%	Achieve average quarterly cash burn rate in accordance with approved budget.	Actual operating cash spend of $4.4 - $5.0 per quarter exceeded our target goal.	5.00%
Capital	45.0%	Raise sufficient, unrestricted funds to meet the Company s needs through 2Q 2017.	Actual cash balance was $4.4 million at December 31, 2016.	38.50%
Sales	5.0%	Achieve sales for 2016 of at least $2.1 million.	Actual sales were $2.0 million for 2016.	5.00%
Total Percentage Earned (as a % of Target Goals)				**68.00%**

Long Term Incentive Plan. Grants under the LTIP are typically comprised of a mix of restricted stock and stock option awards granted in the first quarter of each year with the number of shares subject to the awards designed to deliver a competitive value targeted at the mid-market of the executive compensation comparison group. These guidelines are reviewed periodically based on prevailing compensation comparison group levels, however, and the Compensation and Stock Option Committee then uses these guidelines to determine long-term equity incentive awards for our named executive officers based upon a holistic assessment of Company and individual performance for the prior year and its view of the appropriate incentives to best help achieve the Company s business objectives. Our ability to provide awards at the mid-market level has been difficult to do in the past few years due to share availability. Such awards in the past few years have typically been at or below the market 25th percentile.

There were no long-term equity awards to our named executive officers in 2016. Due to the lack of available shares for issuance under the Company s Delcath 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2016 which in no way should create any negative inference concerning the Compensation and Stock Option Committee s evaluation of their performance.

Summary Compensation Table.

The following table sets forth the total compensation awarded to, earned by or paid to: (i) each person who served as a principal executive officer during 2016, and (ii) our two other most highly-compensated executive officers who were serving as executive officers on December 31, 2016, including our principal financial officer, during 2016. We refer to these individuals as our named executive officers.

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Name & Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[2]	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Jennifer K. Simpson, Ph.D.	2016	439,810	149,535					589,345
President and Chief Executive Officer	2015	427,000	108,885	239,636	60,729			836,251
Barbra C. Keck, M.B.A.	2016	247,200	58,834					306,034
Chief Financial Officer and Secretary[1]	2015	240,000	42,840	87,019	22,105			391,964
John Purpura, M.S.	2016	291,442	93,942					385,384
Executive Vice President Global Head of Operations	2015	270,569	55,196	119,595	30,325			475,685

(1) Effective February 21, 2017, Ms. Barbra C. Keck, previously the Senior Vice President of Finance, Principal Accounting Officer and Principal Financial Officer of the Company, became the Chief Financial Officer of the Company.

(2) Due to the lack of available shares for issuance under the Company s Delcath 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2016 which in no way should create any negative inference concerning the Compensation and Stock Option Committee s evaluation of their performance.

Outstanding Equity Awards at Fiscal Year-End Table 2016.

The following table sets forth information relating to unexercised options and unvested restricted shares held by the named executive officers as of December 31, 2016.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)
Jennifer K. Simpson, Ph.D.	234		811.52	3/23/2022		
	156		545.28	3/11/2023		
	726		76.80	11/14/2023		
	1,982	3,963	19.04	6/10/2025	8,390	7,719
Barbra C. Keck, M.B.A.	292		1,397.76	10/12/2019		
	39		1,643.52	3/10/2021		
	54		1,177.60	2/28/2022		
	54		545.28	3/11/2023		
	388		76.80	11/14/2023		
	723	1,441	19.04	6/10/2025	3,047	2,803

John Purpura, M.S.	585		1,090.56	11/16/2019		
	109		1,643.52	3/10/2021		
	156		1,177.60	2/28/2022		
	156		545.28	3/11/2023		
	443		76.80	11/14/2023		
	989	1,979	19.04	6/10/2025	4,188	3,853

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Director Compensation 2016

The Compensation and Stock Option Committee reviews and recommends to the Board of Directors appropriate director compensation programs for service as directors, committee chairs, and committee members.

In lieu of per-meeting fees, non-employee directors of the Company are paid an annual retainer of $43,000 and certain additional annual retainers for chairing or serving as a member of the committees of the Board as follows:

Name	Annual Retainer
Board Service	$ 43,000
Chair of Audit Committee	$ 20,000
Member of Audit Committee	$ 8,000
Chair of Compensation and Stock Option Committee	$ 12,000
Member of Compensation and Stock Option Committee	$ 5,000
Chair of Nominating and Corporate Governance Committee	$ 8,000
Member of Nominating and Corporate Governance Committee	$ 4,000

Dr. Stoll receives an annual retainer fee as Director and Chairman of the Board of $68,000. Additionally, we reimburse all non-employee directors for their reasonable out-of-pocket travel expenses incurred in attending meetings of our Board of Directors or any committees of the Board. Due to the low number of shares remaining available for issuance under the Company s Delcath 2009 Stock Incentive Plan, the Board of Directors did not grant any equity awards to non-employee directors during 2016 which in no way should create any negative inference concerning the Compensation and Stock Option Committee s evaluation of their performance.

The following table sets forth the compensation awarded to, earned by or paid to each non-employee director who served on our Board of Directors in 2016.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	All Other Compensation	Total
Harold S. Koplewicz. M.D.	$ 60,750	$	$		$ 60,750
Dennis H. Langer, M.D., J.D.	$ 14,000	$	$		$ 14,000
Laura A. Philips, Ph.D., M.B.A.	$ 15,750	$	$		$ 15,750
William D. Rueckert	$ 70,750	$	$		$ 70,750
Roger G. Stoll, Ph.D.	$ 68,000	$	$		$ 68,000
Marco Taglietti, M.D.	$ 63,250	$	$		$ 63,250

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Transactions with Related Persons. We have adopted a written policy for the review and approval or ratification of transactions between Delcath and Related Parties (as defined below). Under the policy, our Nominating Committee will review the material facts of proposed transactions involving Delcath in which a Related Party will have a direct or indirect material interest. The Nominating Committee will either approve or disapprove Delcath s entry into the transaction or, if advance approval is not feasible, will consider whether to ratify the transaction. The Nominating Committee may establish guidelines for ongoing transactions with a Related Party, and will review such transactions at least annually. If the aggregate amount of the transaction is expected to be less than $200,000, such approval or ratification may be made by the Chair of the Committee. In determining whether to approve or ratify a transaction with a Related Party, the Nominating Committee (or Chair) will consider, among other factors, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party and the extent of the Related Party s interest in the transaction.

Certain transactions are deemed pre-approved under the policy, including compensation of executive officers and directors (except that employment of an immediate family member of an executive officer requires specific approval), and transactions with a company at which the Related Party s only relationship is as a non-officer employee, director, or less than 10% owner if the aggregate amount involved does not exceed 2% of such company s total annual revenues (or, in the case of charitable contributions by Delcath, 2% of the charity s total annual receipts). Pre-approval is not required if the amount involved in the transaction is not expected to exceed $120,000 in any calendar year.

For purposes of the policy, a Related Party is generally anyone who since the beginning of the last full fiscal year is or was an executive officer, director or director nominee, owner of more than 5% of the common stock, or immediate family member of any of such persons.

No related person transactions occurred during 2016.

Compensation Committee Interlocks and Insider Participation. During 2016, Marco Taglietti and William D. Rueckert served as members of our Compensation and Stock Option Committee. Laura A. Philips and Dennis H. Langer, former directors, each served on the Compensation and Stock Option Committee until their resignations on April 3, 2016 and April 4, 2016, respectively. None of the current members or members serving during 2016 of the Compensation and Stock Option Committee is a current or former officer or employee of Delcath at the time of their service on the Compensation and Stock Option Committee, nor did any Compensation and Stock Option Committee member engage in any related person transaction that would be required to be disclosed under Item 404 of Regulation S-K. During 2016, none of Delcath s executive officers served on the compensation committee (or equivalent) or on the board of directors of another entity whose executive officers served on the Compensation and Stock Option Committee or our Board of Directors.

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

Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

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Staggered Board of Directors

Our certificate of incorporation and by-laws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons. We have adopted a written policy for the review and approval or ratification of transactions between Delcath and Related Parties (as defined below). Under the policy, our Nominating Committee will review the material facts of proposed transactions involving Delcath in which a Related Party will have a direct or indirect material interest. The Nominating Committee will either approve or disapprove Delcath s entry into the transaction or, if advance approval is not feasible, will consider whether to ratify the transaction. The Nominating Committee may establish guidelines for ongoing transactions with a Related Party, and will review such transactions at least annually. If the aggregate amount of the transaction is expected to be less than $200,000, such approval or ratification may be made by the Chair of the Committee. In determining whether to approve or ratify a transaction with a Related Party, the Nominating Committee (or Chair) will consider, among other factors, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party and the extent of the Related Party s interest in the transaction.

Certain transactions are deemed pre-approved under the policy, including compensation of executive officers and directors (except that employment of an immediate family member of an executive officer requires specific approval), and transactions with a company at which the Related Party s only relationship is as a non-officer employee, director, or less than 10% owner if the aggregate amount involved does not exceed 2% of such company s total annual revenues (or, in the case of charitable contributions by Delcath, 2% of the charity s total annual receipts). Pre-approval is not required if the amount involved in the transaction is not expected to exceed $120,000 in any calendar year.

For purposes of the policy, a Related Party is generally anyone who since the beginning of the last full fiscal year is or was an executive officer, director or director nominee, owner of more than 5% of the common stock, or immediate family member of any of such persons.

No related person transactions occurred during 2016.

Compensation Committee Interlocks and Insider Participation. During 2016, Marco Taglietti and William D. Rueckert served as members of our Compensation and Stock Option Committee. Laura A. Philips and Dennis H. Langer, former directors, each served on the Compensation and Stock Option Committee until their resignations on April 3, 2016 and April 4, 2016, respectively. None of the current members or members serving during 2016 of the Compensation and Stock Option Committee is a current or former officer or employee of Delcath at the time of their service on the Compensation and Stock Option Committee, nor did any Compensation and Stock Option Committee member engage in any related person transaction that would be required to be disclosed under Item 404 of Regulation S-K. During 2016, none of Delcath s executive officers served on the compensation committee (or equivalent) or on the board of directors of another entity whose executive officers served on the Compensation and Stock Option Committee or our Board of Directors.

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

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock, together with the additional information incorporated by reference and in any related free writing prospectuses, summarizes the material terms and provisions of our common stock and preferred stock. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated By-Laws, which are exhibits to the registration statement of which this

prospectus forms a part, and by applicable law. We refer in this section to our Amended and Restated Certificate of Incorporation, as amended, as our certificate of incorporation, and we refer to our Amended and Restated By-Laws as our by-laws. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 500,000,000 shares of our common stock, $0.01 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.01 par value per share. As of October 10, 2017, we had 490,022,209 shares of common stock outstanding and no shares of preferred stock outstanding. As of October 10, 2017, we had 0.3 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $12.57 per share, 55,000 shares issuable upon the exercise of stock options at a weighted average exercise price of $96.99 per share, and 0.1 million shares of unvested restricted stock.

Common Stock

Voting

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

Dividends

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

Liquidation and Dissolution

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

Other Rights and Restrictions

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

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Listing

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

Transfer Agent and Registrar

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

Preferred Stock

Our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval, none of which are outstanding. Our board of directors may issue preferred stock in one or more series and has the authority to fix the designation and powers, rights and preferences and the qualifications, limitations, or restrictions with respect to each class or series of such class without further vote or action by the stockholders. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management.

Recent Preferred Stock Issuances

Series A Preferred Stock

On June 29, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series A Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series A Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series A Preferred Stock). On July 2, 2017, we entered into an exchange agreement (the Exchange) with one of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock (the Series A Preferred Shares). The Exchange was made in reliance upon the exemption from registration provided by Rule 3(a)(9) of the Securities Act of 1933, as amended. The Series A Preferred Shares were entitled to the whole number of votes equal to $4.2 million divided by $3.68 (the closing bid price on June 13, 2016, the date of issuance of the Notes as adjusted for the reverse stock split effected in July 2016,) or 1,141,304 votes. The Series A Preferred Stock had no dividend, liquidation or other preferential rights to our common stock, and each share of Series A Preferred Stock was redeemed for the amount of $0.001, paid in cash pursuant to the Restructuring Agreement signed on August 28, 2017 and discussed in further detail below.

Series B Preferred Stock

On June 29, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series B Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series B Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series B Preferred Stock). On July 11, 2017, we entered into a securities purchase agreement with existing holders of Notes pursuant to which

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the investors purchased $2,360,000 of Series B Preferred Stock for a cash purchase price of $2,000,000 in a private placement. The Series B Preferred Stock was entitled to the whole number of votes equal to $2.0 million divided by $0.1867 (the closing bid price on July 5, 2017, the date of the original securities purchase agreement for the Series B Preferred Stock), or 10,712,372 votes. The Series B Preferred Stock had no dividend, liquidation or other preferential rights (but had the redemption rights described below) to our common stock and could have been converted into shares of our common stock at a price equal to $0.153 per share upon the earlier of the date of closing to the extent that the holder thereof reallocated shares of our common stock reserved for issuance under its Notes to conversion of the Series B Preferred Shares and otherwise upon receipt of shareholder approval of the Reverse Stock Split. The Series B Preferred Stock was redeemed for $2,360,000 pursuant to the Restructuring Agreement signed on August 28, 2017 and discussed in further detail below.

On August 28, 2017, we entered into a Restructuring Agreement (the Agreement) with one of the institutional investors (the Investor) who was a party to the Securities Purchase Agreement, dated June 6, 2016, by and among us, the Investor and certain other buyers signatory thereto (the Securities Purchase Agreement), pursuant to which the Investor and such other buyers acquired (i) certain senior secured convertible notes (the Notes), convertible into shares of our common stock, par value $0.01 per share (the Common Stock) and (ii) warrants to acquire shares of the Common Stock. As of the date the Agreement was entered into the Investor held $11,444,637 aggregate principal amount of Notes of which there was $10,092,857 aggregate Restricted Principal, (as defined in the Notes) of Notes (the Restricted Notes), secured by such aggregate cash amount held in a collateral account of the Company in the same amount (the Restricted Cash) and (y) $1,351,780 principal of Notes (the Unrestricted Notes), (ii) 4,200 shares of Series A Convertible Preferred Stock issued by us to the Investor (the Series A Preferred Shares) and (iii) 2,006 shares of Series B Convertible Preferred Stock issued by us to the Investor (the Series B Preferred Shares). All terms used and not defined herein are used as defined in the Securities Purchase Agreement.

Pursuant to the Agreement, (a) on the date thereof we and the Investor took the following actions (the Initial Restructuring): (i) the Investor released restrictions on $1,650,000 of Restricted Cash (the Initial Release), (ii) the Investor consented to the use of additional Restricted Cash to effect redemptions of the Series A Preferred Shares and the Series B Preferred Shares, (iii) the Investor cancelled $1,200,000 aggregate principal of the Notes (such portion of the Notes, the Cancellation Note), (iv) we redeemed all the Series A Preferred Shares outstanding for a cash payment to the Investor of $4.20 (the Series A Redemption Price) and (v) we redeemed the Series B Preferred Shares for a cash payment to the Investor of $2,006,000 (the Series B Redemption Price) and (b) upon the consummation of a reverse stock split of our Common Stock of at least twenty to one (the Reverse Stock Split Event , and such date, the Reverse Stock Split Date), we and the Investor shall take the following actions (the Additional Restructuring , and together with the Initial Restructuring, the Restructuring): (i) the Investor shall consent to the use of Restricted Cash to effect redemptions of $4,000,000 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Redemption Notes), (ii) we shall redeem the Redemption Notes for a redemption price of $6,436,852.80 (the Redemption Price) and (iii) the Company shall exchange (the Exchange), pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, $2,436,852.80 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Exchange Notes , and together with the Redemption Notes, the Restructured Notes) for new warrants to purchase 40,000,000 shares of our Common Stock (the New Warrants , as exercised, the New Warrant Shares). The New Warrants expire on the 42 month anniversary of the date of issuance and bear an exercise price of $0.35 per share (which shall be adjusted to the new lower purchase price per share if there is a subsequent down round financing). The Investor, in lieu of an exercise of the New Warrants pursuant to a cash payment of the aggregate exercise price of the number of New Warrants being exercised, may exercise the New Warrants, in whole or in part, by electing instead to receive upon such exercise two shares and one hundred and twenty-five thousandths of a share of our Common Stock for each Warrant Share exercised pursuant to this provision.]. As a result of the fact that a reverse stock split did not occur by September 15, 2017 (as required by the Restructuring Agreement), the second part of the contemplated restructuring will not take place without the consent of the Investor.

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The transactions set forth herein were being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended (the 1933 Act) and Rule 144(d)(3)(ii) of the 1933 Act.

Series C Preferred Stock

On September 12, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series C Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series C Certificate of Designations) which was filed with the State of Delaware on September 20, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series C Preferred Stock). On September 21, 2017, we entered into a securities purchase agreement (the SPA) with two of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $0.5 million aggregate purchase price for 590 shares of Series C Preferred Stock (the Series C Preferred Shares). The purchase of the Series C Preferred Stock is being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended. The Series C Preferred Shares shall be entitled to 519,421,250 votes and may only vote on approval of a reverse split of our outstanding common stock. The Series C Preferred Stock has no dividend, liquidation or other preferential rights to our common stock, and each share of Series C Preferred Stock shall be redeemable for the amount of $1,000.00, payable in cash, per share at our written election, and must be redeemed by us no later than December 21, 2017.

Our Board of Directors has determined that it is advisable and in our and our stockholders best interests that the Board of Directors be granted the authority to implement, in its sole discretion, a reverse stock split of the outstanding and treasury shares of our common stock at a specific exchange ratio set by the Board of Directors, at a range of ratios 1:50, 1:100 or 1:350, in the discretion of the Board of Directors and to be announced by press release, and to grant authorization to the Board of Directors to determine, in its sole discretion, whether to implement the reverse stock split, as well as its specific timing (but not later than September 19, 2018).

Accordingly, on September 21, 2017, shareholders holding a majority of votes of our capital stock approved an amendment to our amended and restated certificate of incorporation to effect a reverse stock split consistent with such terms and to grant authorization to the Board of Directors to determine, in its sole discretion, whether to implement the reverse stock split, as well as its specific timing and ratio (within the set of ratios listed above).

The Board of Directors strongly believes that the reverse stock split is necessary for the following reasons:

1. **To provide us with resources and flexibility with respect to our capital sufficient to execute our business plans and strategy** we do not have sufficient capital with which to run our business and meet our obligations and will need to raise further capital through sale of our equity securities.

2. **To enable repayment of certain senior secured convertible notes (the Notes) in shares of Common Stock** we are permitted to repay amounts due under the Notes in shares of our Common Stock based upon certain formulae set forth in the Notes, and we do not have sufficient authorized and unissued shares available with which to repay those obligations with shares of our common stock.

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This Action is substantially the same as Proposal 5 contained in our Definitive Proxy Statement for our Annual Meeting of Stockholders originally scheduled for June 5, 2017 and held on June 16, 2017 and the Proposal in our Definitive Proxy Statement for our Consent Solicitation, which expired on September 7, 2017. Although a majority of the shares of our outstanding common stock that were actually cast on such Action voted for such Action, the number of votes cast in favor of the Action was less than the majority of total outstanding shares of common stock as of the record date for that meeting, which is required for approval under Delaware law. As of the record date for our Annual Meeting of Stockholders, we had 167,883,213 shares of our common stock issued and outstanding. As of July 11, 2017, we had 490,022,209 shares issued and outstanding, which represents a 191.9% increase since the previous record date. As the Board of Directors continues to believe that the reverse stock split is necessary and appropriate and as a result of the significant recent changes to our stockholder base, the Board of Directors worked with our shareholders to purchase our Series C preferred stock which has 880,375 votes for share in order to effect the necessary reverse split of our common stock.

Accordingly, the Board of Directors has unanimously approved a resolution proposing an amendment to our amended and restated certificate of incorporation to allow for the reverse stock split and directed that it be approved by our shareholders which occurred by a written consent in lieu of a special meeting of shareholders on September 21, 2017.

Amendment to Restructuring Agreement

As a result of the lack of requisite approval by our stockholders for our proposed reverse stock split, the parties and the two investors in the 2016 convertible note placement entered into an amendment to the August restructuring agreement on October 10, 2017 as follows: (i) on the date that we do effect a reverse split of our common stock, (x) we will exchange, pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, an aggregate principal amount of those notes equal to $279,015.90 for new warrants to purchase an aggregate of 44,642,544 shares of our Common Stock, and we shall redeem all the Series C Preferred Shares then outstanding for a cash payment of $590,000 and (ii) upon the initial consummation, on or prior to December 15, 2017, by the Company of the offering contemplated by this registration statement on Form S-1 the following shall occur: (i) pursuant to Section 3(b) of the Restricted Notes, we shall be deemed (as adjusted downward by the Black-Scholes value of the warrants being issued in this offering) to have automatically, and irrevocably, adjusted the conversion price to 200% of the purchase price of a share of our common stock in the offering contemplated by this registration statement, (ii) the maturity date (as defined in the notes) shall automatically be extended to the earlier to occur of (x) the first anniversary of the date of consummation of the offering contemplated by this registration statement and (y) December 30, 2018, (iii) until the earlier of (x) this maturity date and (y) the 75th calendar day after the date of consummation of the offering contemplated by this registration statement on Form S-1, all installments to be made under the notes shall be deemed automatically deferred with no conversions during that 75 day period, (iv) we agree to redeem any portion of the outstanding notes at any time requested by either investor thereto with $7.3 million in cash to be reduced by $0.6 million to redeem the Series C Preferred Stock remaining in the restricted accounts with respect to the 2016 convertible notes and (v) the conversion floor price on the notes is $0.05 and not subject to adjustments.

The exercise price for the warrants issued in conjunction with the amended restructuring agreement is $0.35. The warrants contain a cashless exercise provision pursuant to which the warrants may be exercised for 133,927,632 shares of our common stock on or after the 75th day subsequent to the date of consummation of offering hereunder. On the 136th day subsequent to the date of consummation of the offering hereunder, there shall be a true up with regard to the issuance of shares upon exercise such that the difference between 133,927,632 shares and the number of shares that would be issuable if the exercise price were lowered to the average price per share of the variable weighted average price of our common stock for the five trading days commencing on the date which is 76 days after the date of consummation of the offering hereunder, but not lower than 33% of the variable weighted average price of a share of our common stock on the 81st date following the date of consummation of the offering hereunder. In lieu of the true

up , on or before the 135 date following the date of consummation of the offering hereunder, we may buy out that provision for $6,138,349.80.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) units, each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock, or (ii) up to pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. The share of common stock and accompanying common warrant included in each unit will be issued separately, and the pre-funded warrant to purchase one share of common stock and the accompanying common warrant included in each pre-funded unit will be issued separately. Units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and common warrants included in the units and the pre-funded units offered hereby.

Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption Description of Capital Stock in this prospectus.

Pre-Funded Warrants

Pre-funded warrants provide any purchaser in this offering with the ability purchase more than 4.99% of our issued and outstanding common stock. This is accomplished through purchasing pre-funded warrants at a price equal to the purchase price for units, less $.01, which $.01 is the exercise price for the pre-funded warrants. Each pre-funded unit is exerciseable into a unit as offered hereunder. Thus, the purchaser is paying essentially the purchase price for a unit at closing of the offering but is not deemed to beneficially own the shares of common stock included in the units until the purchaser exercises the pre-funded warrant. Once purchased, the purchase price of the pre-funded warrants is not refundable. While the warrant permits waiver of provisions by us and the holder of the warrant, this would not affect the pre-funding as that is the purchase price of the instrument which is paid at the time of closing and becomes part of our proceeds received from the offering. In addition, the pre-funded warrants are perpetual and do not have expiration date.

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Duration and Exercise Price

Each pre-funded warrant will have an initial exercise price per share equal to $0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying common warrants included in the pre-funded units, and may be transferred separately immediately thereafter.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder s pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded units in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system.

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Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Warrants

The following is a summary of all material terms and provisions of the warrants that are being offered hereby, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the warrants.

Duration and Exercise Price

Each warrant offered hereby will have an exercise price equal to $. The warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The warrants will be issued separately from the common stock, and may be transferred separately immediately thereafter. Warrants will be issued in certificated form only.

Exercisability

The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% of the outstanding common stock after exercise, except that upon at least 61 days prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder s warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise

If, at the time a holder exercises its warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

Fundamental Transactions

In the event of any fundamental transaction, as described in the warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the warrant

is exercisable immediately prior to such event.

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Transferability

Subject to applicable laws and a standard legend with regard to restriction on transfer only in compliance with a public offering or an available exemption therefrom, the warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

No Listing

There is no established trading market for the warrants, and we do not expect an active trading market to develop. We do not intend to list the warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants will be extremely limited.

Right as a Shareholder

Except as otherwise provided in the warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Waivers and Amendments

Subject to certain exceptions, any term of the warrants may be amended or waived with our written consent and the written consent of the holders of at least a majority of the then-outstanding warrants

CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of certain of the material U.S. federal income tax considerations with respect to the acquisition, ownership and disposition of the securities being sold in this offering applicable to non-U.S. holders (as defined below) who purchase our common stock or warrants pursuant to this offering. This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended (referred to as the Code), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock or warrants, or that any such contrary position would not be sustained by a court.

The discussion below of certain of the U.S. federal income tax consequences with respect to actual holders of common stock and warrants should also apply to holders of Units (as the deemed owners of the underlying common stock and warrants that comprise the Units).

For purposes of this discussion, a non-U.S. holder means a beneficial owner of our securities that, for U.S. federal income tax purposes, is not any of the following:

an individual who is a citizen or resident of the United States;

a corporation created or organized (or deemed to be created or organized) in or under the laws of the United States, any state thereof or the District of Columbia;

an estate the income of which is subject to U.S. federal income taxation regardless of its source;

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a trust if it either (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person for U.S. federal income tax purposes; or

an entity treated as a partnership or other pass-through entity for U.S. federal income tax purposes.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds shares of our common stock or warrants, the tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock or warrants and partners in such partnerships are urged to consult their tax advisors as to the particular U.S. federal income tax consequences of acquiring, holding and disposing of our common stock and warrants.

It is assumed in this discussion that a non-U.S. holder holds shares of our common stock and warrants as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxation that may be important to a non-U.S. holder in light of such holder s particular circumstances or that may be applicable to holders subject to special treatment under U.S. federal income tax laws (including, for example, financial institutions, dealers in securities, traders in securities that elect mark-to-market treatment, insurance companies, tax-exempt entities, holders who acquired our common stock pursuant to the exercise of employee stock options or otherwise as compensation, controlled foreign corporations, passive foreign investment companies, entities or arrangements treated as partnerships for U.S. federal income tax purposes, holders subject to the alternative minimum tax, certain former citizens or former long-term residents of the United States, holders deemed to sell our common stock or warrants under the constructive sale provisions of the Code and holders who hold our common stock or warrants as part of a straddle, hedge, synthetic security or conversion transaction), nor does it address any aspects of the unearned income Medicare contribution tax enacted pursuant to the Health Care and Education Reconciliation Act of 2010. In addition, except to the extent provided below, this discussion does not address U.S. federal tax laws other than those pertaining to the U.S. federal income tax, nor does it address any aspects of U.S. state, local or non-U.S. taxes. Accordingly, prospective investors are encouraged to consult with their own tax advisors regarding the U.S. federal non-income, state, local, non-U.S. income and other tax considerations of acquiring, holding and disposing of shares of our common stock and warrants.

THIS SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE DESCRIPTION OF ALL TAX CONSEQUENCES RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK AND WARRANTS. HOLDERS OF OUR COMMON STOCK AND WARRANTS ARE ENCOURAGED TO CONSULT WITH THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES TO THEM (INCLUDING THE APPLICATION AND EFFECT OF ANY STATE, LOCAL, NON-U.S. INCOME AND OTHER TAX LAWS) OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK.

Allocation of Purchase Price and Characterization of a Unit

There is no authority addressing the treatment, for U.S. federal income tax purposes, of securities with terms substantially the same as the units being offered in this offering, and, therefore, that treatment is not entirely clear. Each unit may be treated for U.S. federal income tax purposes as an investment unit consisting of one share of our common stock, one warrant (to purchase shares of our common stock). If this is the case, then for U.S. federal income tax purposes, each holder of a unit may be required to allocate the purchase price of a unit among the shares of common stock and the warrants that comprise the unit based on the relative fair market value of each at the time of issuance. The price allocated to each such share or warrant generally will be the holder s tax basis in such share

or warrant, as the case may be.

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Neither the foregoing description of the treatment of our common stock and warrants nor a holder s purchase price allocation is binding on the IRS or the courts. Because there are no authorities that directly address instruments that are similar to the units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, each holder is advised to consult its own tax advisor regarding the risks associated with an investment in a unit (including alternative characterizations of a unit) and regarding an allocation of the purchase price among the common stock and the warrant that comprise a unit. The balance of this discussion generally assumes that the characterization of the units described above is respected for U.S. federal income tax purposes.

Dividends

As discussed above under Price Range of Common Stock and Dividend Policy, we currently have no plans to make distributions of cash or other property on our common stock. In the event that we do make distributions of cash or other property on our common stock, generally such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first reduce a non-U.S. holder s adjusted basis in our common stock, but not below zero. Any excess will be treated as capital gain from the sale of our common stock in the manner described under Gain on Sale or Other Disposition of Our Common Stock below. In general, dividends, if any, paid by us to a non-U.S. holder will be subject to U.S. withholding tax at a rate of 30% of the gross amount (or a reduced rate prescribed by an applicable income tax treaty) unless the dividends are effectively connected with a trade or business carried on by the non-U.S. holder within the United States and, if required by an applicable income tax treaty, are attributable to a permanent establishment of the non-U.S. holder within the United States. Dividends effectively connected with this U.S. trade or business, and, if required by an applicable income tax treaty, attributable to such a permanent establishment of the non-U.S. holder, generally will not be subject to U.S. withholding tax if the non-U.S. holder provides the applicable withholding agent with certain forms, including IRS Form W-8ECI (or any successor form), and generally will be subject to U.S. federal income tax on a net income basis, in the same manner as if the non-U.S. holder were a U.S. person. A non-U.S. holder that is a corporation and receives effectively connected dividends may also be subject to an additional branch profits tax imposed at a 30% rate (or lower treaty rate), subject to certain adjustments.

A non-U.S. holder of shares of our common stock who wishes to claim the benefit of an applicable treaty rate (and avoid backup withholding, as discussed below) for dividends generally will be required (a) to complete IRS Form W-8BEN (or other applicable form) and certify under penalty of perjury that such holder is not a United States person as defined under the Code and is eligible for treaty benefits, or (b) if shares of our common stock are held through certain foreign intermediaries (including certain foreign partnerships), satisfy the relevant certification requirements of applicable U.S. Treasury Regulations. This certification must be provided to us or our paying agent prior to the payment to the non-U.S. holder of any dividends, and may be required to be updated periodically.

Gain on Disposition of our Securities

Subject to the discussions below of backup withholding and the Foreign Account Tax Compliance Act (FATCA) legislation, any gain realized by a non-U.S. holder on the sale or other disposition of our securities generally will not be subject to United States federal income tax, unless:

- the gain is effectively connected with a trade or business carried on by the non-U.S. holder within the United States (in which case the branch profits tax discussed above may also apply if the non-U.S. holder is a

corporation) and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment of the non-U.S. holder maintained in the United States;

the non-U.S. holder is an individual and is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are satisfied; or

we are or have been a U.S. real property holding corporation (a USRPHC) for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held such securities.

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Gain described in the first bullet point above will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in much the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a corporation may also be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult any applicable income tax treaties that may provide for different rules.

Gain recognized by an individual described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe that we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our interests in real property located within the United States relative to the fair market value of our interests in real property located outside the United States and our other business assets, however, there can be no assurance that we will not become a USRPHC in the future. Even if we were or were to become a USRPHC at any time during this period, generally gains realized upon a disposition of shares of our common stock (but not our warrants) by a non-U.S. holder that did not directly or indirectly own more than 5% of our common stock during this period would not be subject to U.S. federal income tax, provided that our common stock is regularly traded on an established securities market (within the meaning of Section 897(c)(3) of the Code). We expect our common stock to be regularly traded on an established securities market, although we cannot guarantee it will be so traded.

Acquisition of Common Stock Warrants Pursuant to the Exercise of a Warrant

A non-U.S. holder generally will not recognize gain or loss upon the acquisition of common stock pursuant to the exercise of a warrant for cash. Common stock acquired pursuant to the exercise of a warrant for cash generally will have a tax basis equal to the non-U.S. holder s tax basis in the warrant, increased by the amount paid to exercise the warrant. The holding period of such common stock generally would begin on the day after the date of receipt of such common stock upon exercise of the warrant and will not include the period during which the non-U.S. holder held the warrant. If a warrant is allowed to lapse unexercised, a non-U.S. holder generally will recognize a capital loss equal to such holder s tax basis in the warrant.

The tax consequences of a cashless exercise of a warrant are not clear under current tax law. A cashless exercise may be tax-free, either because the exercise is not a gain realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either tax-free situation, a non-U.S. holder s basis in the common stock or warrant received would equal the holder s basis in the warrant. If the cashless exercise were treated as not being a gain realization event, a non-U.S. holder s holding period in the common stock or warrant would be treated as commencing on the date following the date of exercise of the warrant. If the cashless exercise were treated as a recapitalization, the holding period of the common stock or warrant would include the holding period of the warrant being exercised. It is also possible that a cashless exercise could be treated as a taxable exchange in which gain or loss would be recognized. In such event, a non-U.S. holder could be deemed to have surrendered warrants equal to the number of shares of common stock and warrants having a value equal to the exercise price for the total number of warrants to be exercised. The non-U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the common stock or warrants represented by the warrants deemed surrendered and the non-U.S. holder s tax basis in the warrants deemed surrendered. In this case, a non-U.S. holder s tax basis in the common stock received or warrants would equal the sum of the fair market

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value of the common stock or warrants represented by the warrants deemed surrendered and the non-U.S. holder s tax basis in the warrants exercised. A non-U.S. holder s holding period for the common stock would commence on the date following the date of exercise of the warrant. Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court of law. Accordingly, non-U.S. holders should consult their tax advisors regarding the U.S. federal income tax consequences of a cashless exercise.

If the cashless exercise of a warrant results in taxable gain to a non-U.S. holder, then the consequences to such holder will be as described above under Gain on Disposition of our Securities.

Under Section 305 of the Code, an adjustment to the number of shares of common stock or warrants that will be issued on the exercise of the warrants, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to a non-U.S. holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such non-U.S. holder s proportionate interest in the earnings and profits or assets of our company, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to stockholders of our company). Adjustments to the exercise price of warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See Dividends .

Information Reporting and Backup Withholding

As discussed above under Price Range of Common Stock and Dividend Policy, we currently have no plans to pay regular dividends on our common stock. In the event that we do pay dividends, generally we or certain financial middlemen must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated. Copies of this information also may be made available under the provisions of a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

U.S. backup withholding (currently at a rate of 28%) is imposed on certain payments to persons that fail to furnish the information required under the U.S. information reporting requirements. Dividends paid to a non-U.S. holder of our common stock generally will be exempt from backup withholding if the non-U.S. holder provides to the applicable withholding agent a properly executed IRS Form W-8BEN, W-8BEN-E or W-8ECI (as applicable) or otherwise establishes an exemption.

Under U.S. Treasury regulations, the payment of proceeds from the disposition of our common stock or warrants by a non-U.S. holder effected at a U.S. office of a broker generally will be subject to information reporting and backup withholding, unless the beneficial owner, under penalties of perjury, certifies, among other things, its status as a non-U.S. holder or otherwise establishes an exemption. The certification procedures described in the above paragraph will satisfy these certification requirements as well. The payment of proceeds from the disposition of our common stock or warrants by a non-U.S. holder effected at a non-U.S. office of a broker generally will not be subject to backup withholding and information reporting, except that information reporting (but generally not backup withholding) may apply to payments if the broker is:

a U.S. person;

a controlled foreign corporation for U.S. federal income tax purposes;

a foreign person, 50% or more of whose gross income from certain periods is effectively connected with a U.S. trade or business; or

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a foreign partnership if at any time during its tax year (a) one or more of its partners are U.S. persons who, in the aggregate, hold more than 50% of the income or capital interests of the partnership or (b) the foreign partnership is engaged in a U.S. trade or business.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be credited against the non-U.S. holder s U.S. federal income tax liability, if any, and any excess refunded, provided that the required information is furnished to the IRS in a timely manner.

Legislation Affecting Taxation of Securities Held by or Through Foreign Entities

Withholding taxes may be imposed under FATCA on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends paid on, or gross proceeds from the sale or other disposition of, our common stock or warrants paid to a foreign financial institution or a non-financial foreign entity (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain specified United States persons or United States-owned foreign entities (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under the applicable Treasury Regulations and IRS guidance, withholding under FATCA generally will apply to payments of dividends on our common stock, as well as to payments of gross proceeds from the sale or other disposition of such stock or warrants on or after January 1, 2019. Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

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UNDERWRITING

We have entered into an underwriting agreement with the underwriter named below. Oppenheimer & Co. Inc. is acting as the sole underwriter in this offering. The underwriting agreement provides for the purchase of a specific number of units by the underwriter. Subject to the terms and conditions of the underwriting agreement, Oppenheimer & Co. Inc. has agreed to purchase the number of units set forth opposite its name below.

Underwriter	Number of Units	Number of Pre-Funded Units
Oppenheimer & Co. Inc.		
Total		

The underwriter has agreed to purchase all of the securities offered by this prospectus (other than those covered by the over-allotment option described below) if any are purchased.

The securities comprising the units should be ready for delivery on or about , 2017 against payment in immediately available funds. , 2017 is the 2nd trading day following the date of this prospectus. The underwriter is offering the units subject to various conditions and may reject all or part of any order. The underwriter proposes to offer the units directly to the public at the public offering price that appears on the cover page of this prospectus. In addition, the underwriter may offer some of the units to other securities dealers at such price less a concession not in excess of $ per unit. After the securities are released for sale to the public, the underwriter may change the offering price and other selling terms at various times. The underwriter has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority.

Discounts, Commissions and Expenses

We estimate that the total fees and expenses payable by us, excluding underwriting discounts and commissions, will be approximately $. The following table shows the underwriting discounts to be paid to the underwriter by us in connection with this offering:

	Per Unit	Total Without Exercise of Over Allotment Option	Total With Full Exercise of Over-Allotment Option
Public Offering Price per Unit (1)			
Underwriting Discount	$		
Proceeds to us			

(1)

The public offering price and underwriting discount per unit corresponds to (i) a public offering price per share of common stock of $ and (ii) a public offering price per common warrant of $.

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We estimate the total expenses payable by us for this offering to be approximately $ which amount includes (i) the underwriting discount of $ ($ if the over-allotment option is exercised in full), (ii) the reimbursement of expenses of the underwriter, including its legal fees and expenses, in connection with this offering equal to $125,000, and (iii) other estimated company expenses of approximately $ which includes legal, accounting and printing costs and various fees associated with the registration and listing of our shares.

Over-allotment Option

We have granted to the underwriter an over-allotment option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants equal to 15% of the number of shares of common stock sold in the primary offering and/or 15% of the common warrants sold in the primary offering, in any combination thereof, at the public offering price per share of common stock and the public offering price per common warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriter may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased, the underwriter will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered. If this option is exercised in full, the total price to the public will be $ and the total gross proceeds to us will be $.

Indemnification

Pursuant to the underwriting agreement, we have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriter or such other indemnified parties may be required to make in respect of those liabilities.

Lock-Up Agreements

We have agreed not to (i) offer, pledge, issue, sell, contract to sell, purchase, contract to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock; (ii) enter into any swap or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of shares of common stock; or (iii) file any registration statement with the SEC relating to the offering of any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, without the prior written consent of the underwriter for a period of days following the date of this prospectus, subject to an 18-day extension under certain circumstances (the Lock-up Period), for a price less than the public offering price per unit. This consent may be given at any time without public notice. These restrictions on future issuances do not apply to the securities to be sold in this offering.

In addition, each of our directors and executive officers has entered into a lock-up agreement with the underwriter. Under the lock-up agreements, the directors and executive officers may not, directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any shares of our common stock (including, without limitation, common stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act or securities convertible into or exercisable or exchangeable for our common stock, (ii) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of the beneficially owned shares or securities convertible into or exercisable or exchangeable for common stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or (iii) engage in any short selling of the common stock or securities convertible

into or exercisable or exchangeable for common stock for a period of days following the date of closing of this offering. The restrictions on future dispositions by our directors and officers are subject to exceptions

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for (i) one or more bona fide gift transfers of securities to immediate family members or to a trust, family partnership or family company the beneficiaries of which are exclusively members of immediate family, (ii) by will or intestate succession upon the death or (iii) as a bona fide gift. In addition, these restrictions shall not apply to sales of common stock by our directors and executive officers (i) pursuant to any trading plan established pursuant to Rule 10b5-1 of the Exchange Act, (ii) constituting restricted stock outstanding prior to the date hereof that vests during the Lock-Up Period, solely to the extent necessary to generate proceeds to fund any income taxes resulting from such vesting, and (iii) issued upon the exercise of stock options granted prior to the date hereof and scheduled to expire within six (6) months of the date hereof, solely to the extent necessary to generate proceeds to fund the exercise price thereof and any income taxes resulting from such exercise.

Price Stabilization, Short Positions and Penalty Bids

Rules of the Securities and Exchange Commission may limit the ability of the underwriter to bid for or purchase shares before the distribution of the shares is completed. However, the underwriter may engage in the following activities in accordance with the rules:

Stabilizing transactions The underwriter may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

Over-allotments and syndicate covering transactions The underwriter may sell more shares of our common stock in connection with this offering than the number of shares than they have committed to purchase. This overallotment creates a short position for the underwriter. This short sales position may involve either covered short sales or naked short sales. Covered short sales are short sales made in an amount not greater than the underwriter s over-allotment option to purchase additional shares in this offering described above. The underwriter may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriter must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. A naked short position occurs if the underwriter sells more shares than could be covered by the over-allotment option. This position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids. If the underwriter purchases shares in the open market in a stabilizing transaction or syndicate covering transactions, it may reclaim a selling concession from selling group members who sold those shares as part of this offering.

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Similar to other purchase transactions, the underwriter s purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither we nor any underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any underwriter make any representation that the underwriter will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Other Relationships

Upon completion of this offering, we have granted the underwriter a right of first refusal to act as sole underwriter or exclusive placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for 12 months from the closing date of this offering. The terms of any such engagement of the underwriter will be determined by separate agreement.

Conflicts of Interest

The underwriter is a full-service financial institution engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriter and its respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of its various business activities, the underwriter and its respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Electronic Delivery of Prelimary Prospectus

A prospectus in electronic format may be delivered to potential investors by the underwriter participating in this offering. The prospectus in electronic format will be identical to the paper version of such preliminary prospectus. Other than the prospectus in electronic format, the information on any underwriter s web site and any information contained in any other web site maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part.

Selling Restrictions

BELGIUM

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the securities has not been and will

not be approved by, the Belgian Banking, Finance and Insurance Commission (Commission bancaire, financière et des assurances/Commissie voor het Bank-, Financie- en Assurantiewezen). Any representation to the contrary is unlawful.

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The underwriter has undertaken not to offer sell, resell, transfer or deliver directly or indirectly, any securities, or to take any steps relating/ancillary thereto, and not to distribute or publish this document or any other material relating to the securities or to the offering in a manner which would be construed as: (a) a public offering under the Belgian Royal Decree of 7 July 1999 on the public character of financial transactions; or (b) an offering of securities to the public under Directive 2003/71/EC which triggers an obligation to publish a prospectus in Belgium. Any action contrary to these restrictions will cause the recipient and the issuer to be in violation of the Belgian securities laws.

FRANCE

Neither this prospectus nor any other offering material relating to the securities has been submitted to the clearance procedures of the *Autorité des marchés financiers* in France. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the securities has been or will be: (a) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (b) used in connection with any offer for subscription or sale of the securities to the public in France. Such offers, sales and distributions will be made in France only: (i) to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d investisseurs*), in each case investing for their own account, all as defined in and in accordance with Articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*; (ii) to investment services providers authorised to engage in portfolio management on behalf of third parties; or (iii) in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des marchés financiers*, does not constitute a public offer (*appel public à l épargne*). Such securities may be resold only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

UNITED KINGDOM/GERMANY/NORWAY/THE NETHERLANDS

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State) an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State other than the offers contemplated in this prospectus in name(s) of Member State(s) where prospectus will be approved or passported for the purposes of a non-exempt offer once this prospectus has been approved by the competent authority in such Member State and published and passported in accordance with the Prospectus Directive as implemented in name(s) of relevant Member State(s) only required where specific regulatory approvals being sought except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorised or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;

(c)

by the underwriter to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

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(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall result in a requirement for the publication by issuer or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

The underwriter has represented, warranted and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the ***FSMA***)) received by it in connection with the issue or sale of any securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and

(b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

ISRAEL

In the State of Israel, the securities offered hereby may not be offered to any person or entity other than the following:

(c) a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;

(d) a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;

(e) an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, (d) a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for their own account or fro the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(f) a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(g) a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;

(h) a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

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(i) an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;

(j) a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);

(k) an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and

(l) an entity, other than an entity formed for the purpose of purchasing securities in this offering, in which the shareholders equity (including pursuant to foreign accounting rules, international accounting regulations and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 250 million.

Any offeree of the securities offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This prospectus will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

ITALY

The offering of the securities offered hereby in Italy has not been registered with the Commissione Nazionale per la Società e la Borsa (CONSOB) pursuant to Italian securities legislation and, accordingly, the securities offered hereby cannot be offered, sold or delivered in the Republic of Italy (Italy) nor may any copy of this prospectus or any other document relating to the securities offered hereby be distributed in Italy other than to professional investors (*operatori qualificati*) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the securities offered hereby or distribution of copies of this document or any other document relating to the securities offered hereby in Italy must be made:

(a) by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993 (the Banking Act);

(b) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and

(c) in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

SWEDEN

This prospectus has not been nor will it be registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this prospectus may not be made available, nor may the securities offered hereunder be marketed and offered for sale in Sweden, other than under circumstances which are deemed not to require a prospectus under the Financial Instruments Trading Act (1991: 980). This offering will only be made to

qualified investors in Sweden. This offering will be made to no more than 100 persons or entities in Sweden.

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SWITZERLAND

The securities offered pursuant to this prospectus will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The issuer has not applied for a listing of the securities being offered pursuant to this prospectus on the SWX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the relevant listing rules. The securities being offered pursuant to this prospectus have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of securities.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in securities.

LEGAL MATTERS

Certain legal matters will be passed upon for us by Wexler, Burkhart, Hirschberg & Unger, LLP, Garden City, New York, including the validity of the common stock offered hereby.

EXPERTS

The audited consolidated financial statements of Delcath Systems, Inc. as and for the year ended December 31, 2016, incorporated by reference in this prospectus and elsewhere in this registration statement have been so incorporated by reference in reliance upon the report of Grant Thornton, LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

INFORMATION INCORPORATED BY REFERENCE

The SEC s rules allow us to incorporate by reference information into this prospectus. This means that we can disclose important information to you by referring you to another document. The information incorporated by reference is considered to be a part of this prospectus. This prospectus incorporates by reference the documents listed below:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as amended by our Form 10-K/A for the fiscal year ended December 31, 2016;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017;

our Definitive Proxy Statement on Schedule 14A, filed on April 29, 2017 (solely to the extent incorporated by reference into Part III of our Annual Report on Form 10-K for the year ended December 31, 2016);

our Current Reports on Form 8-K, filed on January 26, 2017, January 30, 2017, February 15, 2017, February 22, 2017, February 23, 2017, March 9, 2017, April 3, 2017 April 27, 2017, June 5, 2017, June 16, 2017, July 3, 2017, July 6, 2017, July 12, 2017, July 26, 2017, August 2 , 2017, August 8, 2017, August 21, 2017, August 28, 2017, September 5, 2017, September 13, 2017, September 21, 2017, September 21, 2017 and October 11, 2017; and

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

Any statement made in this prospectus or in a document incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus modifies or supersedes that statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

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We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus, other than exhibits which are specifically incorporated by reference into such documents. Requests should be directed our Secretary at Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019 or by calling us at 212-489-2100.

FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2016 AND DECEMBER 31, 2015 AND THE THREE AND SIX MONTHS ENDED JUNE 30, 2017 AND JUNE 30, 2016

Incorporated by reference fromour Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 29, 2017 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed with the SEC on August 8, 2017.

MANAGEMENT S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED DECEMBER 31, 2016 AND DECEMBER 31, 2016 AND THE THREE AND SIX MONTHS ENDED JUNE 30, 2017 AND JUNE 30, 2016

Incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 29, 2017 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed with the SEC on August 8, 2017.

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Units

Each Unit Consisting of One Share of Common Stock

and

One Warrant to Purchase Shares of Common Stock

Delcath Systems, Inc.

PRELIMINARY PROSPECTUS

OPPENHEIMER & CO.

, 2017

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PART II

Item 13. Other expenses of issuance and distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions to be paid by us in connection with the sale of the units, warrants and common shares being registered hereby. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the stock exchange listing fee.

SEC registration fee	$ *
FINRA filing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing and engraving expenses	*
Transfer agent and registrar fees and expenses	*
Other expenses	*
Total	$ *

* To be included by amendment

Item 14. Indemnification of directors and officers

Section 102(b)(7) of the DGCL allows a corporation to provide in its certificate of incorporation that a director of the corporation will not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except where the director breached the duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides for this limitation of liability.

Section 145 of the DGCL, or Section 145, provides that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, were or are a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation s best interests, provided that no indemnification is permitted without judicial approval if the officer,

director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director has actually and reasonably incurred.

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Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his or her status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145.

Our amended and restated bylaws provides that we must indemnify our directors and officers to the fullest extent permitted by the DGCL and must also pay expenses incurred in defending any such proceeding in advance of its final disposition upon delivery of an undertaking, by or on behalf of an indemnified person, to repay all amounts so advanced if it should be determined ultimately that such person is not entitled to be indemnified.

We have entered into indemnification agreements with certain of our executive officers and directors pursuant to which have agreed to indemnify such persons against all expenses and liabilities incurred or paid by such person in connection with any proceeding arising from the fact that such person is or was an officer or director of our company, and to advance expenses as incurred by or on behalf of such person in connection therewith.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, provision of our certificate of incorporation, our bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

We maintain standard policies of insurance that provide coverage (1) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (2) to us with respect to indemnification payments that we may make to such directors and officers.

The proposed form of Underwriting Agreement to be filed as Exhibit 1.1 to this Registration Statement will provide for indemnification of our directors and officers by the underwriter party thereto against certain liabilities. See Item 17. Undertakings for a description of the SEC s position regarding such indemnification provisions.

Item 15. Recent sales of unregistered securities

On June 6, 2016, the Company completed a private placement, exempt for registration purposes under Section 4(a)(2) of the Securities Act, of $35 million aggregate principal amount of senior secured convertible notes (the Notes) pursuant to a Securities Purchase Agreement dated June 6, 2016 (the SPA) between the Company and certain institutional investors as set forth in the Schedule of Buyers attached to the SPA, as described in the Company s Form 8-K filed with the Securities and Exchange Commission on June 7, 2016.

The Notes were issued at an 8 percent original issue discount to the principal amount of Notes (a purchase price of $920 for each $1,000 principal amount of Notes and related warrants) for aggregate proceeds of $32.2 million. The Notes do not bear any ordinary interest and provide that the Company will repay the principal amount of the Notes in equal monthly installments beginning seven months after the original date of issuance.

The Company also issued warrants to purchase 6.8 million additional shares of common stock to such institutional investors concurrently with the issuance of the Notes. The Company repurchased all of such warrants for cash, effective as of March 31, 2017.

Series A Preferred Stock

On June 29, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series A Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series A Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series A Preferred Stock). On July 2, 2017, we entered into an exchange agreement (the Exchange) with one of our investors which had purchased certain senior secured convertible notes (the Notes), convertible into shares of our common stock pursuant to a certain June 6, 2016 securities purchase agreement, of $4.2 million aggregate principal amount of such Notes for 4,200 shares of Series A Preferred Stock (the Series A Preferred Shares). The Exchange was made in reliance upon the exemption from registration provided by Rule 3(a)(9) of the Securities Act of 1933, as amended. The Series A Preferred Shares were entitled to the whole number of votes equal to $4.2 million divided by $3.68 (the closing bid price on June 13, 2016, the date of issuance of the Notes as adjusted for the reverse stock split effected in July 2016,) or 1,141,304 votes. The Series A Preferred Stock had no dividend, liquidation or other preferential rights to our common stock, and each share of Series A Preferred Stock was redeemed for the amount of $0.001, paid in cash pursuant to the Restructuring Agreement signed on August 28, 2017 and discussed in further detail below.

Series B Preferred Stock

On June 29, 2017, our Board authorized the establishment of a new series of preferred stock designated as Series B Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock (the Series B Certificate of Designations) which was filed with the State of Delaware on June 30, 2017 (together with any preferred shares issued in replacement thereof in accordance with the terms thereof, the Series B Preferred Stock). On July 11, 2017, we entered into a securities purchase agreement with existing holders of Notes pursuant to which the investors purchased $2,360,000 of Series B Preferred Stock for a cash purchase price of $2,000,000 in a private placement. The Series B Preferred Stock was entitled to the whole number of votes equal to $2.0 million divided by $0.1867 (the closing bid price on July 5, 2017, the date of the original securities purchase agreement for the Series B Preferred Stock), or 10,712,372 votes. The Series B Preferred Stock had no dividend, liquidation or other preferential rights (but had the redemption rights described below) to our common stock and could have been converted into shares of our common stock at a price equal to $0.153 per share upon the earlier of the date of closing to the extent that the holder thereof reallocated shares of our common stock reserved for issuance under its Notes to conversion of the Series B Preferred Shares and otherwise upon receipt of shareholder approval of the Reverse Stock Split. The Series B Preferred Stock was redeemed for $2,360,000 pursuant to the Restructuring Agreement signed on August 28, 2017 and discussed in further detail below.

On August 28, 2017, we entered into a Restructuring Agreement (the Agreement) with one of the institutional investors (the Investor) who was a party to the Securities Purchase Agreement, dated June 6, 2016, by and among us, the Investor and certain other buyers signatory thereto (the Securities Purchase Agreement), pursuant to which the Investor and such other buyers acquired (i) certain senior secured convertible notes (the Notes), convertible into shares of our common stock, par value $0.01 per share (the Common Stock) and (ii) warrants to acquire shares of the Common Stock. As of the date the Agreement was entered into the Investor held $11,444,637 aggregate principal amount of Notes of which there was $10,092,857 aggregate Restricted Principal, (as defined in the Notes) of Notes (the Restricted Notes), secured by such aggregate cash amount held in a collateral account of the Company in the same amount (the Restricted Cash) and (y) $1,351,780 principal of Notes (the Unrestricted Notes), (ii) 4,200 shares of Series A Convertible Preferred Stock issued by us to the Investor (the Series A Preferred Shares) and (iii) 2,006 shares of Series B Convertible Preferred Stock issued by us to the Investor (the Series B Preferred Shares). All terms used and not defined herein are used as defined in the Securities Purchase Agreement.

Pursuant to the Agreement, (a) on the date thereof we and the Investor took the following actions (the Initial Restructuring): (i) the Investor released restrictions on $1,650,000 of Restricted Cash (the Initial Release), (ii) the Investor consented to the use of additional Restricted Cash to effect redemptions of the Series A Preferred Shares and the Series B Preferred Shares, (iii) the Investor cancelled $1,200,000 aggregate principal of the Notes (such portion of the Notes, the Cancellation Note), (iv) we redeemed all the Series A Preferred Shares outstanding for a cash payment

to the Investor of $4.20 (the Series A Redemption Price) and (v) we redeemed the Series B Preferred Shares for a cash payment to the Investor of $2,006,000 (the Series B Redemption Price) and (b) upon the consummation of a reverse stock split of our Common Stock of at least twenty to one (the Reverse Stock Split Event , and such date, the Reverse Stock Split Date), we and the Investor shall take the following actions (the Additional Restructuring , and together with the Initial Restructuring, the Restructuring): (i) the Investor shall consent to the use of Restricted Cash to effect redemptions of $4,000,000 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Redemption Notes), (ii) we shall redeem the Redemption Notes for a redemption price of $6,436,852.80 (the Redemption Price) and (iii) the Company shall exchange (the Exchange), pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, $2,436,852.80 aggregate Restricted Principal of the Restricted Notes (such portion of the Restricted Notes, the Exchange Notes , and together with the Redemption Notes, the Restructured Notes) for new warrants to purchase 40,000,000 shares of our Common Stock (the New Warrants , as exercised, the New Warrant Shares). The New Warrants expire on the 42 month anniversary of the date of issuance and bear an exercise price of $0.35 per share (which shall be adjusted to the new lower purchase price per share if there is a subsequent down round financing). The Investor, in lieu of an exercise of the New Warrants pursuant to a cash payment of the aggregate exercise price of the number of New Warrants being exercised, may exercise the New Warrants, in whole or in part, by electing instead to receive upon such exercise two shares and one hundred and twenty-five thousandths of a share of our Common Stock for each Warrant Share exercised pursuant to this provision.]. As a result of the fact that a reverse stock split did not occur by September 15, 2017 (as required by the Restructuring Agreement), the second part of the contemplated restructuring will not take place without the consent of the Investor.

The transactions set forth herein were being made in reliance upon the exemption from registration provided by Rule 4(a)(2) of the Securities Act of 1933, as amended (the 1933 Act) and Rule 144(d)(3)(ii) of the 1933 Act.

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Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

The exhibit index attached hereto is incorporated herein by reference.

(b) Financial Statement Schedule

All schedules have been omitted because the information required to be set forth in the schedules is either not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

(1) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(2) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(3) The undersigned registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and this offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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EXHIBIT INDEX

Exhibit	Description
1.1	Form of Underwriting Agreement*
1.2	Form of Warrant*
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended to June 30, 2005 (incorporated by reference to Exhibit 3.1 to Company s Current Report on Form 8-K filed June 5, 2006 (Commission File No. 001-16133)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of April 8, 2014 (incorporated by reference to Exhibit 3.1 to Company s Current Report on Form 8-K filed April 8, 2014 (Commission File No. 001-16133)
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 20, 2016 (incorporated by reference to Exhibit 3.1 to Company s Current Report on Form 8-K filed July 21, 2016 (Commission File No. 001-16133)
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 20, 2016 (incorporated by reference to Exhibit 3.2 to Company s Current Report on Form 8-K filed July 21, 2016 (Commission File No. 001-16133)
3.5	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company s Registration Statement on Form SB-2 (Registration No. 333-39470))
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of June 30, 2017 (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed July 3, 2017 (Commission File No. 001-16133))
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of July 5, 2017 (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed July 6, 2017 (Commission File No. 001-16133))
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of September 20, 2017 (incorporated by reference to Exhibit 3.1 of the Company s Current Report on Form 8-K filed September 21, 2017 (Commission File No. 001-16133))
5.1	Opinion of Wexler, Burkhart, Hirschberg & Unger LLP**
23.1	Consent of Grant Thornton, LLP**
23.2	Consent of Wexler, Burkhardt, Hirschberg & Unger (included as part of Exhibit 5.1)
24.1	Powers of Attorney (included on signature page to this Registration Statement)**

* To be filed by amendment
** Filed herewith

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, Delcath Systems, Inc., a Delaware corporation, has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on October 10, 2017.

DELCATH SYSTEMS, INC.

By: /s/ Jennifer K. Simpson, Ph.D.
Name: Jennifer K. Simpson, Ph.D.
Title: President and Chief Executive Officer

Each person whose signature appears below constitutes and appoints Jennifer K. Simpson and Barbra C. Keck and each of them singly, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act and to file the same, with all exhibits thereto and all other documents in connection therewith, with the SEC, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their, his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-1 has been signed by the following persons in the capacities indicated.

SIGNATURE	TITLE	DATE
/s/ Jennifer K. Simpson, Ph.D. Jennifer K. Simpson, Ph.D.	President and Chief Executive Officer (Principal Executive Officer)	October 10, 2017
/s/ Barbra C. Keck, M.B.A. Barbra C. Keck, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	October 10, 2017
/s/ Roger G. Stoll, Ph.D. Roger G. Stoll, Ph.D.	Chairman of the Board	October 10, 2017
/s/ William D. Rueckert William D. Rueckert	Director	October 10, 2017

/s/ Marco Taglietti, M.D.

Marco Taglietti, M.D.	Director	October 10, 2017