DELCATH SYSTEMS, INC.
Form S-1/A
February 05, 2018
Table of Contents

As filed with the Securities and Exchange Commission on February 5, 2018

No. 333-220898

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 4 TO 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 $0.01 per share and Series D common warrants to purchase two shares of Common Stock (3)	$10,000,000	$1245.00
(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 Series D common warrants to purchase two shares of Common Stock (3)	$10,000,000	$1245.00
(i) Pre-funded warrants included in the Pre-funded Units		
(ii) Common warrants included in the Pre-funded Units		
Total	$20,000,000	$2490.00

(1) Estimated pursuant to Rule 457(o) of the Securities Act of 1933 solely for purposes of calculating the amount of the registration fee, paid with original filing of this Registration Statement on Form S-1.

(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 shares 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 warrants offered and sold in the offering, and as such the proposed maximum aggregate offering price of the shares and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $10,000,000.00. The warrants(but not the pre-funded warrants) being offered in the Units and the Pre Funded Units are not exercisable for one year from the date of issuance and those are not being registered hereunder.

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.

Table of Contents

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 February 5, 2018

250,000,000 Units Consisting of

Up to 250,000,000 Series A Units Consisting of One Share of Common Stock

and

Series D Warrants to purchase Two Shares of Common Stock

Up to 250,000,000 Series B Units consisting of pre-funded warrants to purchase one Share of Common Stock and Series D Warrants to purchase up to two Shares of Common Stock

We are offering up to 250,000,000 Series A units in the aggregate each unit consisting of one share of our common stock and Series D common warrants to purchase two shares of our common stock. Each Series D common warrant contained in a unit has an exercise price of $ per share. The Series D common warrants contained in the Series A units will be exercisable one year from the date of issuance and the Series D common warrants will expire five years from the date of initial exercisability. The shares underlying the Series D common warrants are not being included for registration under this prospectus. The shares of common stock and the Series D common warrants issued as part of the Series A units are immediately separable and will be issued separately, but can only be purchased together in this offering.

We are also offering for sale 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, Series B units (each Series B unit consisting of one pre-funded warrant to purchase one share of our common stock and Series D common warrants to purchase two shares 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 Series B 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 Series B 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 Series B units sold in this offering but not the shares underlying the Series D common warrants. Each Series D common warrant contained in a Series B unit has an exercise price of $ per share. The Series D common warrants contained in the Series B units will be exercisable one year from the date of

issuance and will expire five years from the date of initial exercisability. For each Series B unit we sell, the number of Series A units we are offering will be decreased on a one-for-one basis. The Series A units and the Series B 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 Series A units or Series B units will be issued separately.

When offered in the United States, this offering is being made only to investors which qualify as institutional investors under the securities laws and regulations of their state of domicile.

Table of Contents

Our common stock is quoted on the OTCQB under the symbol DCTH. The last reported sale price of our common stock on January 31, 2018 was $0.0318 per share. There is no established public trading market for the warrants or pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants pre-funded warrants on any national securities exchange or other 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 Series A Unit (1)	Per Series B Unit (1)	Total
Price to the public	$	$	$
Placement Agent Fees (2)	$	$	$
Proceeds, before expenses, to us (2)	$	$	$

(1) The public offering price and placement agent fee per Series A unit and Series B unit corresponds to a public offering price per share of common stock of $ and a public offering price per Series B unit of $.

(2) We have also agreed to reimburse the placement agent for certain of its expenses. See Plan of Distribution for a description of the compensation to be received by the placement agent. The amount of the offering proceeds to us presented in this table does not give effect to any exercise of the warrants being issued which are not exercisable for one year from the date of issuance.

We have retained Roth Capital Partners LLC as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. The placement agent is not required to sell any specific number or dollar amount of securities being offered hereby but will use its best efforts to sell the securities offered. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent s fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. Because the securities in this offering are being offered on a best efforts basis, no person or entity is obligated to purchase any of the securities offered. No minimum amount is required to be sold, and no escrow account will be maintained. All proceeds, net of placement agent expenses and fees, will be available to us upon receipt.

We have agreed to pay the placement agent a total cash fee equal to 7% of the gross proceeds of this offering. In addition to the placement agent s fees, we have agreed to pay the placement agent an expense allowance of $75,000, to reimburse the placement agent for fees and expenses of its legal counsel and its other out of pocket expenses, subject to increase only with our prior approval. See Plan of Distribution.

The placement agent expects to deliver the securities to the purchasers on or about , 2018.

Roth Capital Partners

The date of this prospectus is , 2018

Table of Contents

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	8
Cautionary Statement Concerning Forward-Looking Statements	31
Use of Proceeds	32
Dilution	33
Capitalization	34
Price Range Of Common Stock And Dividend Policy	35
Our Business	36
Security Ownership of Certain Beneficial Owners and Management	59
Directors, Executive Officers and Corporate Governance	60
Section 16(a) Beneficial Ownership Reporting Compliance	67
Executive Compensation	67
Certain Relationships and Related Transactions, and Director Independence	72
Description of Capital Stock	73
Description of Securities We Are Offering	77
Certain U.S. Federal Income Tax Considerations	80
Plan of Distribution	86
Legal Matters	91
Experts	91
Where You Can Find More Information	91
Financial Statements and Management s Discussion and Analysis	F-1

Table of Contents

ABOUT THIS PROSPECTUS

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

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

Industry and Market Data

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

Table of Contents

PROSPECTUS SUMMARY

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

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

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

In the United States, Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the FDA. 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.

Table of Contents

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

Cancers in the Liver A Significant Unmet Need

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

Liver Cancers Incidence and Mortality

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

Ocular Melanoma

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

Table of Contents

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-yearsurvival 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 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

Table of Contents

for each treatment. Patients treated in clinical trial settings are permitted up to six treatments. In non-clinical commercial settings patients have received up to eight treatments. In the United States, if we receive FDA approval, melphalan hydrochloride for injection will be included with the system and marketed as the drug/device melphalan/HDS Kit. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Risks of Investing

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

Corporate Information

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

The Offering

Units offered by us in this offering:	250,000,000 Series A units, each one to purchase one share of our common stock and Series D common warrants, each to purchase two shares of our common stock.
Pre-funded units offered by us in this offering:	We are also offering to each purchaser whose purchase of shares of common stock 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, Series B units, each consisting of a pre-funded warrant to purchase one share of our common stock and Series D warrants to purchase two shares of our common stock in lieu of Series A 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 warrant 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 will be $0.01 per warrant share. For each Series B unit we sell, the number of Series A units we are offering will be decreased on a one-for-one basis.

Table of Contents

Common stock to be outstanding after this offering	shares.
Reverse stock split	On November 6, 2017, we effected a reverse stock split at which time our common stock began trading on the OTCQB on a one-for-three hundred and fifty (1:350) split-adjusted basis. All owners of record as of the open of the OTCQB market on November 6, 2017 received one issued and outstanding share of our common stock in exchange for three hundred and fifty issued and outstanding shares of our common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-three hundred and fifty exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of our common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in our interim condensed consolidated financial statements contained in this prospectus for the quarter ended September 30, 2017 and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.
Use of proceeds	We expect to use the net proceeds from this offering 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.
Best efforts offering:	We have engaged Roth Capital Partners LLC to act as our exclusive placement agent to offer the securities to prospective investors, on a best efforts basis. The placement agent is not required to sell any specific number or dollar amount of the securities offered by this prospectus, but will use its best efforts to sell such securities.
Series D warrants	As part of the Series A units and Series B units we are also selling to investors Series D warrants to purchase two shares of common stock for each share of common stock or pre-funded warrant purchased in this offering (the Warrants). The Warrants will be exercisable beginning on the one year anniversary of the date of issuance and expire five years from the date of initial exercisability. We currently do not have sufficient shares authorized for exercise of the Series D warrants and the Series D warrants will not be exercisable unless the Company s files an amendment to its articles of incorporation (the Authorized Share Amendment), approved by its stockholders (such approval, the Authorized Share Approval), to increase the number of authorized shares of the Company s common stock such that all of the Warrants may be exercised in full by the holders of the, at an exercise price per share of $, subject to adjustment pursuant to the terms of the Warrants (the Exercise Price). The common stock issuable upon the exercise of the Series D warrants (the Warrant Shares) are not being registered under the Securities Act of 1933, as amended (the Securities Act), pursuant to the registration statement of which this prospectus forms a part and are not being offered pursuant to this prospectus.
Dividend policy	We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for

	general corporate purposes.
OTCQB symbol for common stock	DCTH
Risk factors	See Risk Factors and other information included in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities
Transfer agent and registrar	American Stock Transfer and Trust Company, LLC

Table of Contents

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 January 31, 2018:

129 shares issuable upon the exercise of stock options at a weighted average exercise price of $8,771.60 per share;

7.0 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $3.14 per share;

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

Warrant Shares underlying the Series D warrants; and

285 unvested restricted shares.

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 September 30, 2017, and in this prospectus. We derived the following summary historical financial statement of operations data and other data for each of the two years in the period ended December 31, 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 nine months ended September 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.

	Nine Months Ended September 30,		Year ended December 31,	
	2017	2016	2016	2015
	(in thousands, except share and per share data)			
STATEMENT OF OPERATIONS DATA:				
Product revenue	$ 2,011	$ 1,316	$ 1,992	$ 1,747
Cost of goods sold	527	373	(550)	(462)
Gross profit	1,484	943	1,442	1,285
Operating Expenses:				

Selling, general and administrative	$ 7,807	$ 7,025	$ 9,434	$ 10,009

Table of Contents

Research and development	7,119	5,975	8,448	6,486
Total operating expenses	14,926	13,000	17,882	16,495
Operating loss	(13,442)	(12,057)	(16,440)	(15,210)
Change in fair value of warrant liability, net	1,227	9,171	12,780	564
Gain on warrant extinguishment	9,613			
Loss on debt settlements	(2,592)			
Interest expense	(20,324)	(6,584)	17	9
Other income (expense)	5	(15)	(14,328)	(67)
Net loss	$ (25,873)	$ (9,485)	$ (17,971)	$ (14,704)
Common share data:				
Basic and diluted loss per share*	$ (34.99)	$ (2,232.30)	$ (3,707)	$ (5,096)
Weighted average number of basic and diluted common shares outstanding*	754,421	4,249	4,847	2,887

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

Table of Contents

	As of September 30, 2017	As of December 31, 2016
BALANCE SHEET DATA:		
Cash and cash equivalents	$ 2,495	4,409
Total assets	14,486	35,239
Total current liabilities	15,892	36,095
Accumulated deficit	(305,587)	(279,188)
Stockholders (deficit)	(1,850)	(1,490)

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.

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 September 30, 2017, we had $2.5 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 nine months ended September 30, 2017 and 2016, we incurred net losses of approximately, $12.6 million and $25.9 million, and $1.0 million and $9.5 million, respectively, and we expect to continue to incur losses in the last quarter 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, and are unable to raise funds by further sales of our securities, 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, which would result in a complete loss of your investment.

Table of Contents

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, which would result in a complete loss of your investment.

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

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

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

Risks Related to FDA and Foreign Regulatory Approval

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

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

Table of Contents

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.

Table of Contents

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:

Table of Contents

refusals or delays in the approval of applications or supplements to approved applications;

refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;

restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;

fines, Warning Letters or holds on clinical trials;

import or export restrictions;

injunctions or the imposition of civil or criminal penalties;

restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or

recommendations by regulatory authorities against entering into governmental contracts with us.

If 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.

Table of Contents

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.

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;

Table of Contents

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, including our 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.

Table of Contents

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.

Table of Contents

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 are two third-party manufacturers of melphalan in the EEA of which we are aware. If any of these manufacturers fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, 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 are currently only two approved manufacturers of melphalan in the EEA, with whom we have no supply arrangements or other affiliation at this time, 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 metastases. We may pursue

17

Table of Contents

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.

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.

18

Table of Contents

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.

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

Table of Contents

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:

Table of Contents

- 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.

Table of Contents

Risks Related to Intellectual Property

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

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

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

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

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

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

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

22

Table of Contents

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

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

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

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in the CHEMOSAT/Melphalan/HDS methods and/or devices that cause such methods and/or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us.

Our success depends in part on our ability to commercialize CHEMOSAT 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

Table of Contents

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.

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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

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.

Table of Contents

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.

The exclusive jurisdiction and waiver of trial by jury clauses set forth in the form of securities purchase agreement and warrants to be issued to purchasers in this offering may have the effect of limiting a purchaser s rights to bring legal action against us and could limit a purchaser s ability to obtain a favorable judicial forum for disputes with us.

The securities purchase agreement, which will be executed by all purchasers of securities in this offering, provides for investors to consent to exclusive jurisdiction to courts located in New York, New York and provides for a waiver of the right to a trial by jury. These provisions are also set forth in the pre-funded warrants to be issued to purchasers in this offering. These provisions may have the effect of limiting the ability of investors to bring a legal claim against us due to geographic limitations and/or preference for a trial by jury and may limit an investor s ability to bring a claim in a judicial forum that it finds favorable for disputes with us. Alternatively, if a court were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Investors in this offering will experience immediate and substantial dilution.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to 250,000,000 shares in this offering, at an assumed public offering price of $0.04 per share, and after deducting the placement agent fees and commissions and other estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of approximately $0.01 per share, or approximately 28.6% at the assumed public offering price. In addition, in the past, we issued options and warrants to acquire shares of 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.

The pre-funded warrants and the Series D warrants are each a new issue of securities with no established trading market.

The pre-funded warrants and the Series D warrants are each 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 7.0 million warrants issued in our February 2015, July 2015 and October 2016 offerings, and in transactions signed in October and November 2017 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.

Table of Contents

Risks Related to Our Common Stock

We have a history of reverse splits, which have severely impacted our common stock price.

Since our initial public offering in 2000, we have executed 3 reverse stock splits, for a cumulative ratio since our IPO of 89,600:1. Each such reverse split has resulted in an effective decline in the price of our common stock. For example, our most recent reverse split of 350:1 was effected on November 6, 2017, resulting in an opening price of $10.50. By November 30, 2017, our common stock closed at $0.09 and has continued to decline through the date of this prospectus. As part of the offer of Series D warrants, we are obligated to seek stockholder approval for both an increase in the number of our authorized shares and a further reverse stock split in a ratio to be approved by our shareholders. There can be no assurance that such reverse split will not result in a further significant diminution of the value of 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 and generally downward since 2010. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, our history of reverse stock splits, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospects. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this Risk Factors section and other factors, including:

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

success of competitive products and services;

changes in market valuations or earnings of our competitors;

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

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

changes in legislation or regulatory policies, practices or actions;

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

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

Table of Contents

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

The 7.0 million warrants issued in our February 2015, July 2015 and October 2016 offerings, and in transactions signed in October and November 2017 are subject to an exercise price adjustment upon certain equity issuances below $122.50, $49.00 and $2.45 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.

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;

Table of Contents

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 January 25, 2018, we had an aggregate of 500 million shares of common stock authorized and of that 277 million not issued or outstanding, including 7.0 million shares issuable upon the exercise of the outstanding warrants at a weighted average price of $3.14. We may issue all of these shares without any action or approval by our shareholders. We may expand our business through complementary or strategic business combinations or 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.

We do not have sufficient shares of our common stock authorized to exercise the Series D warrants.

We currently have 500 million shares of our common stock authorized for issuance under our Certificate of Incorporation, and upon consummation of the offering of common stock hereunder, we will have approximately 470 million shares of our common stock issued and outstanding. Our Series D warrants, in the aggregate, require reservation of 500 million shares of our common stock for issuance upon exercise of the Series D warrants. Unless and until we are able to amend our certificate of incorporation to increase our authorized common shares by at least an additional 500 million shares, there are insufficient shares authorized for exercise of the Series D warrants. Increase in authorized common shares requires approval of our shareholders, and there is no assurance that our shareholders will approve this increase in authorized shares although we intend to seek such approval shortly after consummation of the offering of common stock and Series D warrants contemplated by this prospectus.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, will, may, can, continue, potential, should, and the negative of these terms or other comparable terminology identify forward-looking statements. Statements in this prospectus that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on

Table of Contents

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. 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.

USE OF PROCEEDS

Based on an assumed public offering price of $0.04 per share, which was the last reported sales price of our common stock on the OTCQB on January 12, 2018, we expect to receive net proceeds from the sale of the securities that we are offering to be approximately $9.0 million, after deduction of placement agent fees, and commissions and estimated expenses payable by us.

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;

Table of Contents

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. The securities purchase agreement being entered into with certain purchasers in this offering limit our ability to raise capital both (i) for a set number of days, and (ii) for so long as warrants issued hereunder are outstanding, in any sort of variable priced financing. Even without receipt of proceeds from this offering, we have sufficient cash to operate for the next 90 days, and we do not intend to enter into any sort of variable priced financing in the future due to the highly dilutive nature of those financings.

DILUTION

If you invest in our common stock, 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 deficit of our common stock as of September 30, 2017, was approximately $(1.9) million, or approximately ($1.30) 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 250,000,000 shares offered by this prospectus at the assumed public offering price of $0.04 per share, which was the last reported sales price on January 12, 2018 on the OTCQB, after deducting the estimated placement agent fees, commissions and our estimated offering expenses, our pro forma net tangible book value as of September 30, 2017 would have been approximately $7.2 million or approximately $0.03 per share. This represents an immediate increase in net tangible book value of approximately $1.33 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $0.01 per share to purchasers of our common stock in this offering, as illustrated by the following table:

Assumed offering price for one share of common stock	$ 0.04
Net tangible book deficit per share as of September 30, 2017	$ (1.30)
Increase per share attributable to new investors	$ 1.33
Pro forma net tangible book value per share as of September 30, 2017 after giving effect to this offering	$ 0.03
Dilution per share to new investors	$ 0.01

Table of Contents

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 January 31, 2018:

- 129 shares issuable upon the exercise of stock options at a weighted average exercise price of $8,771.60 per share;
- 7.0 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $3.14 per share;
- 76 shares reserved for future issuance under our 2009 Equity Incentive Plan, as amended;
- Warrant Shares underlying the Series D warrants to be issued hereunder; and
- 285 unvested restricted shares.

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and consolidated capitalization as of September 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 on Form 10-K for the year ended December 31, 2016 and the three and nine months ended September 30, 2017.

Table of Contents

	September 30, 2017	
	Actual	As Adjusted
	(unaudited)	
Cash and cash equivalents	$ 2,495	$ 11,528
Stockholders equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively		
Common stock, $.01 par value; 500,000,000 shares authorized; and 1,426,153 and 11,805 shares issued and 1,425,862 and 11,750 shares outstanding at September 30, 2017 and December 31, 2016, respectively*	14	2,514
Additional paid-in capital	303,800	310,340
Accumulated deficit	(305,587)	(305,587)
Treasury stock, at cost; 1 shares at September 30, 2017 and December 31, 2016, respectively*	(51)	(51)
Accumulated other comprehensive income	(34)	(34)
Total stockholders deficit	(1,850)	7,182
Total capitalization	$ 14,486	$ 23,518

* reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017.

Equity Compensation Plans

Summary equity compensation plan data

The following table sets forth information, as of September 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 (1)	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding

				securities reflected in column (a))(1)
Equity compensation plans approved by security holders	158	$	33,428.50	49
Equity compensation plans not approved by security holders				
Totals	158	$	33,428.50	49

(1) Reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017.
(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-three hundred fifty (1:350) reverse stock split effected on November 6, 2017.

Table of Contents

	High	Low
2015:		
First Quarter	$ 8,736.50	$ 5,376.00
Second Quarter	8,064.00	4,536.00
Third Quarter	5,152.00	2,240.00
Fourth Quarter	3,472.00	2,184.00
2016:		
First Quarter	$ 3,024.00	$ 1,400.00
Second Quarter	1,995.00	1,288.00
Third Quarter	1,613.50	868.00
Fourth Quarter	959.00	315.00
2017:		
First Quarter	$ 304.50	$ 28.00
Second Quarter	94.50	7.00
Third Quarter	72.53	19.23
Fourth Quarter	50.35	0.03

The last reported trading price of our common stock on January 12, 2018 was $0.04. As of January 31, 2018, we had approximately 40 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.

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.

36

Table of Contents

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, 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.

Table of Contents

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-yearsurvival 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.

38

Table of Contents

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 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.

39

Table of Contents

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.

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.

Table of Contents

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.

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

41

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

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

Table of Contents

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.

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.

Table of Contents

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 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.

Table of Contents

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

Table of Contents

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

Table of Contents

can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

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

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

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. The Company currently holds 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.

49

Table of Contents

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.

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

50

Table of Contents

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

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		**04/12/2017**	**Owned**	**12/29/2032**

	Filter and Frame Apparatus and Method of Use (France)			
602012031191.6	**Filter and Frame Apparatus and Method of Use (Germany)**	**04/12/2017**	**Owned**	**12/29/2032**

Table of Contents

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
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**

Table of Contents

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.

53

Table of Contents

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

European Regulatory Environment

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

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

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

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product s design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the 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.

Table of Contents

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

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

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

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

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

Table of Contents

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 local and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Covidian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others.

For 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.

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

56

Table of Contents

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

Table of Contents

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 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.

Table of Contents

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following tables contain information regarding the beneficial ownership of our common stock as of January 31, 2018, 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 January 31, 2018 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)	132	*
John Purpura, M.S.(3)	106	*
Barbra C. Keck, M.B.A.(4)	73	*
Simon Pedder, PhD.(5)		*
Roger G. Stoll, Ph.D.(6)	9	*
William D. Rueckert(7)	17	*
Marco Taglietti, M.D.(8)	49	*
All directors and executive officers as a group (7 people)(9):		*

* 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 January , 2018, 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 January 31, 2018, 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 182,981,824 shares of common stock outstanding on January 31, 2018, plus the number of shares of common stock that such person or group has the right to acquire within 60 days of January 31, 2018.

(2) Includes 13 shares of common stock, which Dr. Simpson has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 31, 2018.

(3) Includes 7 shares of common stock, which Mr. Purpura has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 31, 2018.

(4) Includes 5 shares of common stock, which Ms. Keck has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 31, 2018, and 4 shares held in a joint account with her spouse.
(5) Dr. Pedder has not yet received an equity grant.
(6) Includes 5 shares of common stock, which Dr. Stoll has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 31, 2018
(7) Includes 10 shares of common stock, which Mr. Rueckert has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 31, 2018.
(8) Includes 10 shares of common stock, which Dr. Taglietti has the right to acquire upon exercise of outstanding options exercisable within 60 days of January 31, 2018.
(9) Includes 55 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 January 31, 2018.

Table of Contents

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			
Simon Pedder, Ph.D.	56	Director	2017
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.

Table of Contents

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.

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

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

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

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

Table of Contents

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

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.

Table of Contents

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

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

Attendance. The Board of Directors met 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

Table of Contents

particular area report directly to the Board committee charged with oversight of the associated function and, if the circumstances require, the whole Board. The Board committees review various risk exposures with the full Board and otherwise keep the full Board abreast of the committees risk oversight activities throughout the year, as necessary or appropriate.

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

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) and Simon Pedder (since November 14, 2017) 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

Table of Contents

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

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

The current members of the Compensation and Stock Option Committee are Marco Taglietti (Chair) and William D. Rueckert (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

Table of Contents

at Delcath s principal office, 1633 Broadway, Suite 22C, New York, New York 10019. If a stockholder intends to nominate a person for election to the Board of Directors at an annual meeting, the stockholder must provide Delcath with written notice of his or her intention no later than the deadline for receiving a stockholder proposal for inclusion in Delcath s proxy statement for such meeting (as described below under the heading Stockholder Proposals For the 2018 Annual Meeting) and must otherwise comply with our amended and restated certificate of incorporation. Copies of any recommendation received in accordance with these procedures will be distributed to each member of the Nominating Committee. One or more members of the Nominating Committee may contact the proposed candidate to request additional information.

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

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.

66

Table of Contents

Submitted by the Audit Committee of the Board of Directors,

William Rueckert (Chair)

May 9, 2017

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 2017.

Our Compensation Committee considers the input it receives from our stockholders when designing and evaluating our executive compensation practices. At our 2017 annual meeting of stockholders, our stockholders approved, on an advisory basis, the 2016 compensation of our executive officers described in our 2016 proxy statement. Approximately 71% 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.

Table of Contents

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

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

Base Salary. Effective February 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 2016 and 2017.

Executive	Hire Date	2015 Base Salary	Percent Increase in 2016	2016 Base Salary	Percent Increase in 2017	2017 Base Salary
Jennifer K. Simpson, Ph.D.	3/23/2012	$ 427,000	3.0%	$ 439,810	3.0%	$ 453,004
Barbra C. Keck, M.B.A.	1/5/2009	$ 240,000	3.0%	$ 247,200	21.4%	$ 300,000
John Purpura, M.S.	11/16/2009	$ 270,569	13.5%	$ 307,000	3.0%	$ 316,210

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 2017:

Executive	Target Incentive Bonus Opportunity		2017 Incentive Award Earned	
	Target Bonus Expressed as %	Dollars ($)	Actual Payout as	Dollars ($)

	of Base Salary		a % of Target Bonus	
Jennifer K. Simpson, Ph.D.	50.0%	$ 226,502	(1)	(1)
Barbra C. Keck, M.B.A.	35.0%	$ 105,000	(1)	(1)
John Purpura, M.S.	45.0%	$ 142,295	(1)	(1)

(1) To be determined.

For 2017, AIP goals are to be based entirely on Company performance as noted in the table below to focus all the executives on the same critical challenges facing the Company.

Table of Contents

Company performance in 2017 has been measured based upon achievement of objectives in the following areas: (1) Clinical Trials; (2) Capital; and (3) Sales.

Actual 2017 corporate performance, including assigned weighting and actual achievement in each area is still undergoing assessment by our Compensation Committee.

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 2017. 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 2017 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 2017, and (ii) our two other most highly-compensated executive officers who were serving as executive officers on December 31, 2017. We refer to these individuals as our named executive officers.

Table of Contents

Name & Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[2]	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Jennifer K. Simpson, Ph.D.	2017	453,004	(3)	7,476				(3)
President and Chief Executive Officer	2016	439,810	149,535					589,345
Barbra C. Keck, M.B.A.	2017	293,400	(3)	4,788				(3)
Chief Financial Officer and Secretary[1]	2016	247,200	58,834					306,034
John Purpura, M.S.	2017	316,210	(3)	7,140				(3)
Executive Vice President Global Head of Operations	2016	291,442	93,942					385,384

(1) Effective February 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.

(3) Still to be determined.

Outstanding Equity Awards at Fiscal Year-End Table 2017.

The following table sets forth information relating to unexercised options and unvested restricted shares held by the named executive officers as of December 31, 2017.

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.	2		$ 26,880	11/14/2023		
	11	5	$ 6,664	6/10/2025	12	1.08
					89	8.01
Barbra C. Keck, M.B.A.	1		$ 26,880	11/14/2023		
	4	2	$ 6,664	6/10/2025	4	0.36
					57	5.13
John Purpura, M.S.	1		$ 381,696	11/16/2019		
	1		$ 26,880	11/14/2023		

5	3	$	6,664	6/10/2025	6	0.54
					85	7.65

Table of Contents

Director Compensation 2017

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 2017.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	All Other Compensation	Total
Harold S. Koplewicz. M.D.[1]	$ 45,333	$	$	$	$ 45,333
Simon Pedder, Ph.D.[2]	$ 7,000	$	$	$	$ 7,000
William D. Rueckert	$ 72,000	$	$	$	$ 72,000
Roger G. Stoll, Ph.D.	$ 68,000	$	$	$	$ 68,000
Marco Taglietti, M.D.	$ 65,000	$	$	$	$ 65,000

(1) Dr. Koplewicz resigned as a director in September 2017.
(2) Dr. Pedder was appointed as a director in November 2017.

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

Table of Contents

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 2017.

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 four of our five directors (each of Simon Pedder, William D. Rueckert, Roger Stoll 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.

Table of Contents

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.

DESCRIPTION OF CAPITAL STOCK

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

Authorized Capital Stock

Our authorized capital stock consists of 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 January 25, 2018, we had 222,981,824 shares of common stock outstanding and no shares of preferred stock outstanding. As of January 25, 2018, we had 7.0 million shares issuable upon the exercise of outstanding warrants at a weighted average exercise price of $3.14 per share, 129 shares issuable upon the exercise of stock options at a weighted average exercise price of $8,771.60 per share, and 285 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.

Table of Contents

Dividends

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

Liquidation and Dissolution

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

Other Rights and Restrictions

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

Listing

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

Transfer Agent and Registrar

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

Preferred Stock

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

Recent Preferred Stock Issuances

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 $1,288.00 (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 3,261 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 on August 28, 2017.

On July 11, 2017, we entered into an Amended and Restated Securities Purchase Agreement (the Amended Purchase Agreement) with certain institutional investors for the sale by the Company of 2,360 shares of Series B Preferred Stock (the Series B Preferred Stock) at a purchase price of $1,000 per share, in a private placement. The aggregate gross proceeds for the sale of the

Table of Contents

Series B Preferred Stock is $2.0 million. The Company intends to use the proceeds from the transaction for general corporate purposes. The restricted shares of Series B Preferred Stock have no registration rights and thus will not be eligible for legend removal for a period of at least six months from the date of closing. This Amended Purchase Agreement amends the July 5, 2017 Securities Purchase Agreement (the Purchase Agreement) into which we entered with certain institutional investors (the Investors) for the sale by the Company of 2,360 shares of Series B Preferred Stock in a registered direct offering. The Series B Preferred Stock shall be entitled to the whole number of votes equal to $2.0 million divided by $65.35 (the closing bid price on July 5, 2017, the date of sale of the Series B Preferred Stock), or 30,607 votes. The Series B Preferred Stock has no liquidation or other rights which are preferential to our common stock. The Series B Preferred Stock was redeemed for $2,360,000 in August 2017.

On August 28, 2017, the Company entered into a Restructuring Agreement (the Agreement) with one of the institutional investors (the Investor) who was a party to the SPA. 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 Preferred Stock and (iii) 2,006 shares of Series B Convertible Preferred Stock.

Pursuant to the Agreement, (a) on the date thereof the Company 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) the Company redeemed all the Series A Preferred Shares outstanding for a cash payment to the Investor of $4.20 and (v) the Company redeemed the Series B Preferred Shares for a cash payment to the Investor of $2,006,000 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) by September 15, 2017, the Company and the Investor shall have taken 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) the Company 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 114,286 shares of its 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 $122.50 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 the Company s Common Stock for each Warrant Share exercised pursuant to this provision. 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. As a result of not having effected a reverse stock split by September 15, 2017, the Additional Restructuring did not occur.

Amendment to Restructuring Agreement

As a result of the lack of requisite approval by Delcath stockholders for the Company s proposed reverse stock split, the parties and the two investors in the Notes entered into an amendment to the August restructuring agreement on October 10, 2017 as follows: (i) on the date that the Company effects a reverse split of its common stock, (x) the Company 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 for new warrants to purchase an aggregate of 127,551 shares of Common Stock, and the Company 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 the registration statement on Form S-1 that was filed with the SEC on October 11, 2017 the following shall occur: (i) pursuant to Section 3(b) of the Restricted Notes, the Company 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 of the Notes to 200% of the purchase price of a share of our common stock in the offering contemplated by the 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 the 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 the registration statement, all installments to be made under the notes shall be deemed automatically deferred with no conversions during that 75 day period, (iv) the Company agreed 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.

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 1,484,061 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. The Series C Preferred Stock was redeemed for $590,000 in November 2017.

On November 15, 2017, Delcath Systems, Inc. (the Company) entered into exchange agreements (Exchange Agreements) with each of the two investors from its June 2016 private placement of senior secured convertible notes as contemplated by that certain Securities Purchase Agreement, dated June 6, 2016, by and among the Company and such investors. As of November 15, 2017, those investors held $11,157,970 aggregate principal amount of investor notes (the Investor Notes), including (a) such aggregate principal amount of the Investor Notes as set forth on the signature page of the Investor hereto that does not include Restricted Principal as of the date hereof and all accrued and unpaid interest under the Investor Notes (such portion of the Investor Notes, the Unrestricted Investor Notes) and such aggregate principal amount of the Investor Notes as set forth on the signature page of the investors hereto that solely consists of Restricted Principal as of the date hereof (such portion of the Investor Notes, the Restricted Investor Notes).

On November 15, 2017, the Company authorized a new series of senior secured convertible notes of the Company, in the aggregate original principal amount as set forth above (the Exchange Notes), which Exchange Notes shall be convertible into shares of Common Stock in accordance with the terms of the Exchange Notes. Subject to the terms and conditions of the Exchange Agreements, the Company and the investors exchanged (the Exchange) the Unrestricted Investor Notes for (a) $10,562,425 aggregate principal amount of the Exchange Notes (the New Notes , and the shares of Common Stock issuable pursuant to the terms of the New Notes, including, without limitation, upon conversion or otherwise, collectively, the New Conversion Shares) and (b) warrants to purchase an aggregate of 7,000,000 shares of Common Stock (the New Warrants , as exercised, the New Warrant Shares).

The New Conversion Shares and the New Warrant Shares are collectively referred to herein as the New Underlying Securities and, together with the New Notes and the New Warrants, the New Securities .

The New Notes, which were satisfied in full on December 28, 2017, bore the following terms:

The New Notes did not bear interest except upon the occurrence of an event of default upon which the interest rate is 15% per annum.

The initial conversion price was $1.50 per share for an optional conversion and at any time, an investor could have instead engaged in an alternate conversion for which the conversion price is 82% (75% if an event of default) of the lowest vwap for the Company s common stock on the three trading days prior to and including the date of the conversion. All conversions attributable to the Restricted Notes could have been converted at the lower of the optional conversion price and the alternate conversion price, then in effect.

The obligation to prepay the Notes was extended to March 31, 2018, except in the case of an event of default or change in control.

Assuming equity conditions as stated in the New Notes are met, the investors would consent to release cash to the Company from the existing controlled accounts upon conversion of the New Notes.

The New Notes contained provisions waiving Section 8 of the Restricted Investor Notes, including, without limitation, any requirements for the Company to effect installment conversions or redemptions.

Table of Contents

The New Notes contained customary and usual terms including but not limited to, events of default upon failure to trade on an eligible market, failure to timely deliver shares upon conversion, failure to maintain converted share reserve, for conversions, failure to make payments thereunder when due, failure to remove legends, cross defaults to other indebtedness, bankruptcy and the like, and any material adverse effect in the Company s financial condition, as well as remedies and negative covenants substantially similar to those in the Investor Notes.

The New Warrants bear the following terms:

The Warrants will be exercisable for five years from the date of issuance.

The initial exercise price of the warrants is 115% of the closing bid price of the Company s common stock as of the trading day ended immediately prior to the time of execution of the Exchange Agreement.

The Warrants contain full antidilution ratchet protection from lowered price securities issuances subsequent to the date of issuance for six months from the date of issuance and most favored nations protection for a year from the date of issuance.

The Warrants are exercisable on a cashless basis to the extent at any time commencing on the one year anniversary of the date of issuance the issuance of underlying securities is not covered by an effective registration statement.

To the extent the investors elect to apply any amounts in their controlled accounts to the balances of the New Notes, the number of shares into which the applicable New Warrant is exercisable shall be reduced by a formula set forth in the New Warrants.

Table of Contents

On December 28, 2017, we entered into exchange agreements (collectively, Exchange Agreements), each by and between us and an investor from its June 2016 private placement of senior secured convertible notes (as further exchanged, the Notes) originally issued pursuant to that certain Securities Purchase Agreement, dated June 6, 2016, by and among us and such investors. Pursuant to the Exchange Agreements, we (i) extinguished our remaining $3,027,408 in outstanding obligations under the Notes in full, (ii) obtained a release of restrictions on $2,046,897.66 in restricted cash held in our control accounts, (iii) issued to the investors shares (the Shares) of our common stock (or rights (Rights) to receive common stock to the extent such issuance of Shares would otherwise result in the beneficial ownership by any such investor of more than 4.9% or 9.9% of our issued and outstanding stock), as applicable, of an aggregate of 123,708,735 shares of our common stock (in each case, subject to trading restrictions set forth in leak out agreements we separately entered into with each investor (collectively, the Leak-Out Agreements)) and (iv) a cash payment to the investors of $829,830.54 from the restricted cash held in our control accounts. The number of shares of our issued and outstanding common stock immediately following issuance of the initial Shares to the investors is 114,054,852.

The Rights may be exercised in whole or in part by an investor, without payment of additional consideration, at any time an investor would not beneficially own more than 4.9% or 9.9% (as set forth in the applicable Exchange Agreement) of our common stock (along with any shares of our common stock owned by any Attribution Parties) outstanding immediately after giving effect to such exercise. The Shares and Rights were issued in transactions exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, and the Shares and Rights were also issued in compliance with Section 3(a)(9) thereunder such that for Rule 144 purposes the holding period for the Shares and Rights and shares of our common stock underlying the Rights may be tacked onto the holding period of the Notes.

As of the date of this Prospectus, all of the Rights have been exercised, and neither investor owns more than 4.9% of the issued and outstanding shares of our common stock.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) 250,000,000 Series A units, each unit consisting of one share of our common stock and Series D warrants to purchase two shares of our common stock, or (ii) up to 250,000,000 Series B units, each unit consisting of pre-funded warrants to purchase one share of our common stock and Series D common warrants to purchase up to two shares of our common stock. For each Series B unit we sell, the number of Series A units we are offering will be decreased on a one-for-one basis. We are also registering the shares of common stock issuable from time to time upon exercise of the pre-funded warrants 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 a share of common stock, less $.01, which $.01 is the exercise price for the pre-funded warrants. The purchaser is paying essentially the purchase price for a share of common stock at closing of the offering but is not deemed to beneficially own the shares of common stock included in the pre-paid warrant 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.

Table of Contents

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.

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% unless a holder otherwise elects at closing, as described below 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 warrants 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.

78

Table of Contents

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.

Series D 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. We are offering Series D warrants. Prospective investors should carefully review the terms and provisions of the form of Series D 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 exercisable one year after the date of issuance, and will expire on the fifth anniversary of the original exercisability 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.

Antidilution Protection

The warrants shall contain a provision which generally (subject to exclusion of certain types of excluded securities as set forth in the warrants) provides for a reduction in the exercise price of those warrants to the sales price of any securities sold by the Company at a price less than the exercise price of the warrants in effect at the time of issuance of the lower priced securities. The anti-dilution protection is in effect during the entire term 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. The Series C warrants and Series D warrants also contain an alternate consideration provision in the case of a fundamental transaction resulting in a change in the control which provides that the holder can request cash payment in an amount equal to the Black Scholes value of the remaining warrant at the time of the change in control.

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

Table of Contents

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.

Table of Contents

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;
- 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.

Table of Contents

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 and two warrants (to purchase two 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. 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.

82

Table of Contents

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.

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.

Table of Contents

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 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.

Table of Contents

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-Eor 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 anon-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

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.

Table of Contents

PLAN OF DISTRIBUTION

Roth Capital Partners, LLC, which we refer to as the placement agent, has agreed to act as the exclusive placement agent in connection with this offering. We will enter into a placement agent agreement with the placement agent prior to closing. The placement agent is not purchasing or selling any of the units, shares, Series D common warrants or pre-funded warrants offered by this prospectus, nor is it required to arrange the purchase or sale of any specific number or dollar amount of securities but has agreed to use its commercially reasonable best efforts to arrange for the sale of all of the securities offered hereby. We may not sell the entire amount of securities offered pursuant to this prospectus. There is no minimum amount of proceeds that is a condition to closing of this offering. The placement agent is not required to arrange the purchase or sale of any specific number or dollar amount of the units, shares, Series D common warrants or pre-funded warrants.

When offered in the United States, this offering is being made only to investors which qualify as institutional investors under the state securities laws and regulations of their state of domicile. The placement agent may engage sub-placement agents or selected dealers to assist in the placement of the securities offered hereby.

Investors purchasing any of the securities offered hereby will execute a securities purchase agreement with us, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part. This securities purchase agreement, as well as the warrants offered hereunder, contain clauses which require the parties to waive the right to trial by jury in any dispute between them and establish New York County, NY as the exclusive forum for resolution of those disputes.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings while any warrants offered hereunder are outstanding; (iii) agreement to not enter into any financings for a set number of days from closing; and (iv) agreement not to enter into any more than one stock split and one increase in authorized shares within a set number of months from closing.

The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and

- covenants regarding matters such as registration of warrant shares, no integration with other offerings, filing of an 8-K to disclose entering into these securities purchase agreements, no shareholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of common stock, no subsequent equity sales for__0 days and no more than one stock split for one year.

Placement Agent s Fees and Expenses

We have agreed to pay the placement agent an aggregate cash placement fee equal to 7% of the gross proceeds from the sale of the units, the shares of common stock, the Series D common warrants and the pre-funded warrants in this offering.

The following table shows the per Series A unit or Series B unit, as the case may be and total cash placement agent s fees (where applicable) we will pay to the placement agent in connection with the sale of the securities offered pursuant to this prospectus.

	Per Series A Unit	Per Series B Unit	Total
Public offering price	$	$	$
Placement agent fees	$	$	$
Proceeds to us before expenses	$	$	$

We have agreed to reimburse the placement agent for certain of its out-of-pocket and legal expenses in an aggregate amount not to exceed $75,000 without our prior approval, and subject to FINRA Rule 5110(f)(2)(D)(i).

If we decide to make an offering of our equity, equity-linked or debt securities at any time within twelve months of the consummation of this offering, we have granted the placement agent the right to act as at least a co-placement agent or co-sole book runner, as applicable, with at least 50% of the placement or underwriting fee for such offering under a separate agreement containing terms and conditions customary for the placement agent and mutually agreed upon by us and the placement agent.

Table of Contents

If the offering hereunder is not consummated, the placement agent shall be entitled to the foregoing cash placement fee to the extent that capital is provided by investors that the placement agent introduced to us, or conducted discussions on our behalf, in any offering of securities by us or our affiliates within six months following termination of our engagement of the placement agent.

Our obligation to issue and sell the securities offered hereby to the purchasers is subject to the conditions set forth in the securities purchase agreements. A purchaser s obligation to purchase the shares offered hereby is subject to the conditions set forth in the securities purchase agreement. Closing conditions for us include receipt of payment for the securities and the continued accuracy of representations and warranties of purchasers under the securities purchase agreements. Closing conditions for the benefit of holders under the securities purchase agreements and the placement agency agreement, include, (i) no stop order suspending the effectiveness of the registration statement of which this prospectus forms a part shall have been issued and no proceedings for such purpose shall have been initiated, (ii) the placement agent shall not have discovered and disclosed to us on or prior to closing that the registration statement or any amendment or supplement thereto contains an untrue statement of a fact which is material or omits to state any fact which is material and is required to be stated therein or is necessary to make the statements therein not misleading, (iii) the receipt of standard closing legal opinions from counsel to us, (iv) the receipt of an officer s certificate from one of our officers, (v) we shall not have sustained any loss or interference with its business pursuant to certain natural disasters and no changes affecting our the business, management, financial position, stockholders equity or results of operations, (vi) no actions by law, statute, rule, regulation or order shall have occurred which would prevent the issuance of the Shares, (vii) there shall not have occurred any general market collapse in the United States and the United States shall not have become engaged in a war or declared a state of emergency or another adverse change to general economic, political or financial conditions shall not have occurred, which make the sale of the Shares or Pre-funded Warrants impracticable or inadvisable, and (viii) the Financial Industry Regulatory Authority shall not have objected to the compensation of the placement agent.

To the extent that any of the aforementioned closing conditions are not met or waived by the investors or the placement agent at or prior to closing and the offering is terminated as a result, we will promptly return all received investor funds without interest added or any deductions made. If an investor has delivered funds into the account prior to signing a binding subscription agreement and prior to closing determines not to participate or does not sign a subscription agreement, such investor s funds will be returned promptly upon notice of the investor to us or the placement agent of the investor s determination not to participate. Such funds will be returned without deduction or interest.

We estimate that the total expenses of this offering, excluding the placement agent fees, will be approximately $0.3 million, which includes legal and printing costs, various other fees and reimbursement of the placements agent s expenses. At the closing, the common stock will be transmitted by American Stock Transfer & Trust Company, our transfer agent, to the investors by crediting the account of the investor with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (DWAC) if the Company is then a participant in such system. We will mail the pre-paid Warrants directly to the investors at the respective addresses set forth in their subscription agreement with us.

Indemnification

We have agreed to indemnify the placement agent against liabilities under the Securities Act. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

Electronic Distribution

This prospectus may be made available in electronic format on websites or through other online services maintained by the placement agent, or by an affiliate. Other than this prospectus in electronic format, the information on the placement agent s website and any information contained in any other website maintained by the placement agent is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by investors.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agent agreement and subscription agreements. A copy of the placement agent agreement and the form of subscription agreement with the investors are included as exhibits to the registration statement of which this prospectus forms a part. See Where You Can Find More Information .

Table of Contents

Regulation M Restrictions

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as a principal may be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants by the placement agent acting as a principal. Under these rules and regulations, the placement agent:

must not engage in any stabilization activity in connection with our securities; and

must not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Other

From time to time, the placement agent and its affiliates have provided, and may in the future provide, various investment banking, financial advisory and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees. In the course of their businesses, the placement agent and its affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the placement agent and its affiliates may at any time hold long or short positions in such securities or loans.

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.

The placement agent 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*.

Table of Contents

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

(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 placement agent 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 for 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;

Table of Contents

(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;

(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.

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.

Table of Contents

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 included in this prospectus and elsewhere in the registration statement have been so included 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.

Table of Contents

FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2016 AND DECEMBER 31, 2015

Report of Grant Thornton LLP Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets at December 31, 2016 and 2015	F-3
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2016 and 2015	F-4
Consolidated Statements of Stockholders Equity for the years ended December 31, 2016 and 2015	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015	F-6
Notes to Consolidated Financial Statements	F-7 F-25
UNAUDITED FINANCIAL STATEMENTS FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2017	
Condensed Consolidated Balance Sheets at September 30, 2017 and December 31, 2016	F-26
Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2017 and 2016	F-27
Condensed Consolidated Statements of Stockholders Deficiency for the Nine Months Ended September 30, 2017	F-28
Condensed Consolidated Statement of Cash Flows for the Nine Months Ended September 30, 2017 and 2016	F-29
Notes to Condensed Consolidated Financial Statements	F-30

Table of Contents

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Delcath Systems, Inc.

We have audited the accompanying consolidated balance sheets of Delcath Systems, Inc. and subsidiaries (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders equity (deficit,), and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Delcath Systems, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and as of December 31, 2016 has an accumulated deficit of $279.2 million. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company s ability to continue as a

going concern. Management s plans in regard to these matters are also discussed in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP

New York, New York

March 28, 2017 (except for Note 15, as to which the date is January 17, 2018)

Table of Contents

DELCATH SYSTEMS, INC.

Consolidated Balance Sheets as of December 31, 2016 and 2015

(in thousands, except share and per share data)

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 4,409	$ 12,607
Restricted cash	27,287	
Accounts receivables, net	403	277
Inventories	660	757
Prepaid expenses and other current assets	698	960
Deferred financing costs	699	
Total current assets	34,156	14,601
Property, plant and equipment, net	1,083	1,132
Total assets	$ 35,239	$ 15,733
Liabilities and Stockholders Equity (Deficit)		
Current liabilities		
Accounts payable	$ 594	$ 284
Accrued expenses	3,407	2,243
Convertible notes payable, net of debt discount	13,343	
Warrant liability	18,751	3,785
Total current liabilities	36,095	6,312
Deferred revenue	30	
Other non-current liabilities	604	820
Total liabilities	36,729	7,132
Commitments and contingencies (Note 12)		
Stockholders Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively		
Common stock, $.01 par value; 500,000,000 shares authorized; 11,805 and 3,991 shares issued and 11,750 and 3,887 shares outstanding at December 31, 2016 and December 31, 2015, respectively*		
Additional paid-in capital	277,790	269,877
Accumulated deficit	(279,188)	(261,217)
Treasury stock, at cost; 1 shares at December 31, 2016 and December 31, 2015, respectively*	(51)	(51)

Accumulated other comprehensive loss	(41)	(8)
Total stockholders equity (deficit)	(1,490)	8,601
Total liabilities and stockholders equity (deficit)	$ 35,239	$ 15,733

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

See Accompanying Notes to these Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Consolidated Statements of Operations and Comprehensive Loss

for the Years Ended December 31, 2016 and 2015

(in thousands, except share and per share data)

	Year ended December 31,	
	2016	**2015**
Product revenue	$ 1,992	$ 1,747
Cost of goods sold	(550)	(462)
Gross profit	1,442	1,285
Operating expenses:		
Selling, general and administrative expenses	9,434	10,009
Research and development costs	8,448	6,486
Total operating expenses	17,882	16,495
Operating loss	(16,440)	(15,210)
Derivative instrument income	12,780	564
Interest income	17	9
Other expense and interest expense	(14,328)	(67)
Net loss	$ (17,971)	$ (14,704)
Other comprehensive loss:		
Foreign currency translation adjustments	$ (33)	$ (28)
Comprehensive Loss	$ (18,004)	$ (14,732)
Common share data:		
Basic and diluted loss per share*	$ (3,707)	$ (5,096)
Weighted average number of basic and diluted shares outstanding*	4,847	2,887

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

See Accompanying Notes to these Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Consolidated Statements of Stockholders Equity (Deficit)

for the Years Ended December 31, 2016 and 2015

(in thousands, except share data)

	Common Stock Issued $0.01 Par Value*		In Treasury*					
	# of Shares	Amount	# of shares	Amount	Additional Paid-in Capital*	Accumulated Deficit	Accumulated Other Comprehensive (loss) income	Total Stockholders Equity (Deficit)
Balance at December 31, 2014	1,740	$	(1)	$ (51)	$ 264,689	$ (246,513)	$ 20	$ 18,145
Compensation expense for issuance of stock options					349			349
Compensation expense for issuance of restricted stock	103				308			308
Sale of common stock, net of expenses	2,109				8,479			8,479
Exercise of warrants	39				176			176
Fair value of warrants issued classified as liability					(4,247)			(4,247)
Fair value of warrants exercised					123			123
Net loss						(14,704)		(14,704)
Foreign currency translation							(28)	(28)
Balance at December 31, 2015	3,991	$	(1)	$ (51)	$ 269,877	$ (261,217)	$ (8)	$ 8,601
Compensation expense for issuance of stock options					161			161
Compensation expense for issuance of restricted stock	7				266			266
Sale of common stock, net of expenses	1,223				1,011			1,011
Issuance of common stock for payments made in shares on convertible notes payable	5,158				649			649
					4,435			4,435

Fair value of Beneficial conversion feature of convertible note							
Fair value of warrants issued classified as liability				(707)			(707)
Exercise of warrants	1,426			1,372			1,372
Fair value of warrants exercised				726			726
Net loss					(17,971)		(17,971)
Foreign currency translation						(33)	(33)
Balance at December 31, 2016	11,805	$ (1)	$ (51)	$ 277,790	$ (279,188)	$ (41)	$ (1,490)

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

See Accompanying Notes to these Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Consolidated Statements of Cash Flows

for the Years Ended December 31, 2016 and 2015

(in thousands)

	Year ended December 31, 2016	2015
Cash flows from operating activities:		
Net loss	$ (17,971)	$ (14,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	161	349
Restricted stock compensation expense	266	308
Depreciation expense	305	617
Loss on disposal of equipment	1	15
Warrant liability fair value adjustment	(12,780)	(564)
Non-cash interest income	(1)	(1)
Debt discount and deferred finance costs amortization	14,268	
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	260	9
Increase in accounts receivable	(138)	(52)
(Increase) decrease in inventories	95	(420)
Increase (decrease) in accounts payable and accrued expenses	1,507	(1,757)
Increase in deferred revenue	30	
Decrease in other non-current liabilities	(216)	(220)
Net cash used in operating activities	(14,213)	(16,420)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(258)	(170)
Increase in restricted cash	(1,087)	
Proceeds from sales of property, plant and equipment		180
Net cash provided by (used in) investing activities	(1,345)	10
Cash flows from financing activities:		
Increase in restricted cash	(26,200)	
Net proceeds from convertible debt financing	31,226	
Net proceeds from sale of stock and exercise of warrants	2,383	8,655
Net cash provided by financing activities	7,409	8,655
Foreign currency effects on cash and cash equivalents	(49)	(107)

Net decrease in cash and cash equivalents		(8,198)		(7,862)
Cash and cash equivalents:				
Beginning of period		12,607		20,469
End of period	$	4,409	$	12,607
Supplemental non-cash activities:				
Conversion of convertible notes	$	649	$	
Fair value of warrants issued	$	28,472	$	4,247
Fair value of warrants exercised	$	726	$	123

See Accompanying Notes to these Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(1) Description of Business

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), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), 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.

Liquidity

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and has accumulated deficit of $279.2 million at December 31, 2016. As shown in the accompanying financial statements during the year ended December 31, 2016, the Company incurred net losses of $18.0 million and used $14.2 million of cash for its operating activities. These factors among others raise substantial doubt about the Company s ability to continue as a going concern for a reasonable period of time.

The Company s existence is dependent upon management s ability to obtain additional funding sources or to enter into strategic alliances. 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. There can be no assurance that the Company s efforts will result in the resolution of the Company s liquidity needs. 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. The accompanying consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. On June 13, 2016 we issued an aggregate $35 million principal amount of senior secured convertible notes (the Notes). As a result, Management believes that its capital resources are adequate to fund operations through the first quarter of 2018, but anticipates that additional working capital will be required to continue operations. 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. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development and clinical trial results; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

(2) Basis of Consolidated Financial Statement Presentation

The accounting and financial reporting policies of the Company conform to generally accepted accounting principles in the United States of America (GAAP). The preparation of consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company s consolidated financial statements. The consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(3) Summary of Significant Accounting Policies

Use of Estimates

The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company s consolidated balance sheets and the amount of revenues and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, valuation of inventory, impairment of long-lived assets, income taxes and operating expense accruals. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Cash Equivalents and Concentrations of Credit Risk

The Company considers investments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation (FDIC), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institution.

Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded as restricted cash on the accompanying consolidated balance sheets. On June 13, 2016, the Company issued $35.0 million in senior secured convertible notes and received $32.2 million in cash proceeds. Under the terms of the notes, at closing, an initial tranche of $3.0 million was available for immediate use by the Company for general corporate purposes. The remaining cash proceeds of $29.2 million were available in a tranche of $3.0 million on December 29, 2016 (First Release Date) and the remainder of $26.2 million will be available in four equal tranches to be released quarterly, beginning in February 2017 (Subsequent Release Dates), pursuant to an account control agreement whereby the restrictions on the proceeds are terminated when the Company meets certain equity conditions. The terms of the Notes are discussed in more detail in Note 9 contained in the Annual Report on Form 10-K. The cash is deposited in an account that is not FDIC insured.

Accounts Receivable

Accounts receivable, principally trade, are generally due within 30 days and are stated at amounts due from customers. Collections and payments from customers are monitored and a provision for estimated credit losses may be created based upon historical experience and specific customer collection issues that may be identified.

Inventories

Inventories are valued at the lower of cost or market value using the first-in, first-out method. The reported net value of inventory includes finished saleable products, work-in-process, and raw materials that will be sold or used in future periods. The Company reserves for expired, obsolete, and slow-moving inventory.

Prior to obtaining authorization to affix the CE Mark to its Generation Two CHEMOSAT System in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of December 31, 2016 includes finished goods and components that have been purchased since April 2012. Therefore, to the extent that materials expensed prior to April 2012 are used in manufacturing finished goods for sale, the Company s cost of goods sold will be impacted accordingly.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the estimated useful life of the related assets when they are placed into service. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2016 and 2015, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

The Company adheres to ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity s own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.

Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity s own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Revenue Recognition

Revenue from product sales is generally recognized when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; product price is fixed or determinable; and collection of the resulting receivable is reasonably assured. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

Deferred Revenue

Deferred revenue on the accompanying consolidated balance sheets includes payment received for product sales to a distributor. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied.

Selling, General and Administrative

Selling, general and administrative costs include personnel costs and related expenses for the Company s sales, marketing, general management and administrative staff, recruitment, costs related to the Company s commercialization efforts in Europe, professional service fees, professional license fees, business development and certain general legal activities. All such costs are charged to expense when incurred.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

Research and Development

Research and development costs include the costs of materials used for clinical trials and R&D, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, medical science liaisons, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company s proprietary drug delivery system. All such costs are charged to expense when incurred.

Stock Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. The Company expensed its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of Delcath s common stock at the date of the grant. The Company estimates the fair value of stock options using an option pricing model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath s stock over the option s expected term, the risk-free interest rate over the option s expected term, and Delcath s expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with the ASC 740 Income Taxes. Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company applies the accounting guidance issued to address the accounting for uncertain tax positions. This guidance clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements as well as provides guidance on derecognition, measurement, classification, interest and penalties, accounting in

interim periods, disclosure and transition. The Company classifies interest and penalty expense related to uncertain tax positions as a component of income tax expense. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years that the asset is expected to be recovered or the liability settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in its assessment of a valuation allowance. See Note 13 for additional information.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all stock options, unvested restricted stock and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the years ended December 31, 2016 and 2015 are as follows:

(in thousands, except share data)	**2016**	**2015**
Net loss basic and diluted	$ (17,971)	$ (14,704)
Net loss per share basic and diluted	$ 3,707	$ 5,096
Weighted average shares outstanding basic and diluted	4,847	2,887

For the years ended December 31, 2016 and 2015, the following potentially dilutive securities were excluded from the computation of diluted earnings per share (EPS) because their effects would be antidilutive.

Shares excluded from the computation of diluted EPS:

	2016	**2015**
Stock options	118	135
Unvested restricted shares	55	103
Warrants	20,618	3,225
Total	20,791	3,463

All share numbers presented in this footnote reflect a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016 and a one-for-three hundred fifty (1:350) reverse stock split effected on November 6, 2017.

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of CHEMOSAT/Melphalan/HDS. A single management team that reports to the CEO and President comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Foreign Currency and Currency Translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses)/gains in the statement of operations.

The assets and liabilities of the Company s international subsidiaries are translated from their functional currencies into United States dollars at exchange rates prevailing at the balance sheet date. Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates, as well as unrealized foreign exchange gains or losses arising from translation of intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASU 2014-09) that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for the Company beginning in its fiscal year 2018, and may be applied retrospectively to all prior periods presented or through a cumulative adjustment to the opening retained earnings balance in the year of adoption. The Company intends to adopt this standard on January 1, 2018 and does not anticipate that this guidance will materially impact its consolidated financial statements.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements Going Concern, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15). ASU 2014-15 requires management to assess an entity s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the ASU (1) provides a definition of the term substantial doubt, (2) requires an evaluation every reporting period including interim periods, (3) provides principles for considering the mitigating effect of management s plans, (4) requires certain disclosures when substantial doubt is alleviated as a result of consideration of management s plans, (5) requires an express statement and other disclosures when substantial doubt is not alleviated, and (6) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This standard is effective for the fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company has adopted this guidance.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 more closely aligns the measurement of inventory in U.S. GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years. ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company intends to adopt this standard on January 1, 2017 and does not anticipate that this guidance will materially impact its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740). ASU 2015-17 requires deferred tax liabilities and assets to be classified as non-current on the consolidated balance sheet. ASU 2015-17 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years and early application is permitted. ASU 2015-17 may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company intends to adopt this standard on January 1, 2017 and does not anticipate that this guidance will materially impact its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which requires entities to report a right-to-use asset and liability for the obligation to make payments for all leases with the exception of those leases with a term of twelve months or less. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is currently evaluating the impact it may have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. As of December 31, 2016, the Company has early adopted ASU 2016-09. The

cumulative-effect adjustment to equity related to the recognition of excess tax benefits (offset by valuation allowance) is discussed in Note 13.

In June 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including interim periods within those fiscal years. An entity that elects early adoption must adopt all of the amendments in the same period. The guidance requires application using a retrospective transition method. The Company is currently evaluating the effects, if any, that the adoption of this guidance will have on the Company s financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years, and early adoption is permitted. The Company intends to adopt this standard on January 1, 2018 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company s financial statements.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(4) Inventories

Inventories consist of:

(in thousands)	December 31, 2016	December 31, 2015
Raw materials	$ 346	$ 360
Work-in-process	214	251
Finished goods	100	146
Total Inventory	$ 660	$ 757

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

(in thousands)	December 31, 2016	December 31, 2015
Insurance premiums	$ 501	$ 625
Kits for clinical use		162
Other	197	173
Total prepaid expenses and other current assets	$ 698	$ 960

Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% at December 31, 2016 and 2015.

(6) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)	December 31, 2016	December 31, 2015

Buildings and land	$	556	$	556
Enterprise hardware and software		1,532		1,520
Leaseholds		1,504		1,305
Equipment		940		902
Furniture		354		355
Property, plant and equipment, gross		4,886		4,638
Accumulated depreciation		(3,803)		(3,506)
Property, plant and equipment, net	$	1,083	$	1,132

Depreciation expense for the years ended December 31, 2016 and 2015 was $0.3 million and $0.6 million, respectively.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(7) Current Accrued Expenses

Current accrued expenses include the following:

(in thousands)	December 31, 2016	December 31, 2015
Clinical trial expenses	$ 1,365	$ 692
Compensation, excluding taxes	933	391
Professional fees	286	220
Short-term portion of lease restructuring	216	219
Other	607	721
Total accrued expenses	$ 3,407	$ 2,243

Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2016 and 2015.

(8) Restructuring Expenses

In order to help reduce operating costs and more appropriately align its office space with the reduced size of its workforce, the Company entered into two sub-leases for office space at its 810 Seventh Avenue office. On May 22, 2014, the Company entered into a sub-lease agreement (Sub-lease #1) for approximately one-half of the office space at this location (Suite 3500), resulting in a lease restructuring reserve of approximately $0.9 million. On August 18, 2014, the Company entered into a sub-lease agreement (Sub-lease #2) for the remaining one-half of office space at its 810 Seventh Avenue office (Suite 3505), resulting in a lease restructuring reserve of approximately $0.7 million. As of December 31, 2016, the total remaining lease restructuring liability for its leased office space was approximately $0.8 million, of which approximately $0.2 million and $0.6 million were included in Accrued expenses and Other non-current liabilities on the consolidated balance sheets, respectively.

The following table provides the year-to-date activity of the Company s restructuring reserves as of December 31, 2016:

(in thousands)	Lease Liability
Reserve balance at December 31, 2015	$ 1,039
Charges	
Payments/Utilizations	(219)

Reserve balance at December 31, 2016	$	820

(9) Convertible Notes Payable

On June 6, 2016, the Company entered into a Securities Purchase Agreement (the SPA) with certain investors named on the Schedule of Buyers attached to the SPA pursuant to which the Company issued $35.0 million in principal face amount of senior secured convertible notes of the Company (the Notes) and related Series C Warrants (the Series C Warrants) to purchase additional shares of the Company s common stock, par value $0.01 per share (Common Stock). $35.0 million of the Notes were issued for cash proceeds of $32.2 million with an original issue discount in the amount of $2.8 million. The Notes are secured pursuant to a Security Agreement which creates a first priority security interest in all of the personal property (other than Excluded Collateral (as defined in the Security Agreement)) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future.

The Notes do not bear any ordinary interest. However, interest shall commence accruing immediately upon the occurrence of, and shall continue accruing during the continuance of, an Event of Default (as defined in the SPA), at 15% per annum and shall be computed on the basis of a 360-day year of twelve 30-day months and shall be payable, if applicable, in arrears for each calendar month on the first (1st) business day of each calendar month after any such interest accrues after an Event of Default.

Under the terms of the Notes, at closing the Company received an initial tranche of $3.0 million for immediate use for general corporate purposes. A second tranche of $3.0 million was released to the Company in December 2016. The remaining cash proceeds of $26.2 million are being held in a restricted account and will be released to the Company in subsequent tranches subject to certain equity conditions.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

As security for the Company s obligations under the Notes, $26.2 million of the total net cash proceeds is subject to a cash covenant restricting its use and requiring it to be held in a Master Restricted Account established in accordance with and pursuant to the terms and conditions of an account control agreement between the Company, the Buyers and Silicon Valley Bank (a Controlled Account Agreement). Subject to certain equity conditions, the $26.2 million of restricted cash will become unrestricted in equal quarterly installments during 2017, such that the balance will become unrestricted by the maturity date of the Notes, December 29, 2017, subject to satisfaction of certain equity conditions contained in the Notes.

In connection with the issuance of the Notes under the SPA, the Company also issued Series C Warrants, exercisable to acquire approximate as 19,000 shares of Common Stock. On December 31, 2017, the number of Warrant Shares issuable upon exercise of the Series C Warrants will be increased by such number of Warrant Shares equal to 75% of the difference of (i) the quotient of (A) the product of (x) the exercise price as of the date of issuance (as adjusted for certain events) multiplied by (y) the number of Warrant Shares as of the date of issuance (as adjusted for certain events), divided by (B) the volume-weighted average price of the Common Stock on the maturity date, less (ii) the number of Warrant Shares as of the date of issuance (as adjusted for certain events).

Each Series C Warrant will be exercisable by the holder beginning June 13, 2017 and continuing for a period of five years thereafter. The Series C Warrants are exercisable at $1,690.50 per share of common stock, subject to adjustments for certain dilutive events. The provisions in the Series C Warrants require the Company to account for the warrants as derivative liabilities. The Company recognized a discount to debt of $27.8 million related to the initial fair value of the Series C Warrants.

The Company has agreed to make amortization payments with respect to the Notes in fourteen (14) equal installments beginning seven (7) months after the original date of issuance of June 13, 2016 (each, an Installment Date). On each installment date, assuming certain equity conditions are met, the installment payment shall, at the election of the Company, automatically be converted into shares of Common Stock at a conversion rate defined in the agreement. If we cannot meet the equity 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. At any time after the issuance of the Notes, the Notes will be convertible at the election of the holder into shares of our Common Stock at a conversion price equal to $1,536.50, subject to adjustment as provided in the Notes.

As a result of the Notes including a feature such that the conversion price is based upon a formula which includes discounts to the market price of the common stock as well as having a lower effective conversion price considering the issuance discount and the value allocated to the Series C Warrants, the Company has recognized a beneficial conversion feature of $4.4 million. The original issue discount, the beneficial conversion feature, and the fair value of the issuance of the Series C Warrants are collectively considered the debt discount. The Company recorded a debt discount in the amount of $35.0 million which is being amortized over the life of the Notes using the effective interest method. As of December 31, 2016, $14.0 million of the debt discount has been amortized to interest expense. In addition to the debt discounts listed above, the Notes also include put options in the event of default and change in control as defined in the Notes. The value of such options was zero as the probability for such events was remote as of

the issuance date and at December 31, 2016.

All debt issuance costs are accounted for as a deferred asset and will be amortized over the life of the Notes. As of December 31, 2016, the Company had incurred approximately $1.0 in debt issuance costs and had amortized approximately $0.3 million of those costs.

The following table summarizes the convertible notes outstanding at December 31, 2016:

(in thousands)	**December 31, 2016**
Convertible notes payable, principal	$ 34,351
Debt discounts	(21,008)
Net convertible note payable	$ 13,343

In 2016, the Company issued approximate 5,000 shares as payment for $0.6 million of convertible notes payable.

(10) Stockholders Equity

Reverse Stock Split

On July 19, 2016, shareholders of the Company approved, through a shareholder vote, an amendment to the Company s Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath s common stock at a ratio within a range of one-for-ten (1:10) to one-for-twenty (1:20). The reverse stock split became effective on July 21, 2016 at which time Delcath s common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(1:16) split-adjusted basis. All owners of record as of the open of the NASDAQ market on July 21, 2016 received one issued and outstanding share of Delcath common stock in exchange for sixteen issued and outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-sixteen exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s consolidated financial statements contained in the Annual Report on Form 10-K and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

In addition, shareholders of the Company also approved an amendment to the Company s Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 170,000,000 to 500,000,000. The previously discussed reverse stock split had no impact on the increase in authorized shares.

Stock and Warrant Issuances

In October 2013, the Company completed the sale of 234 shares of its common stock and the issuance of warrants to purchase approximately 106 common shares (the 2013 Warrants) pursuant to a placement agency agreement. The Company received proceeds of $7.5 million, with net cash proceeds after related expenses from this transaction of approximately $6.9 million. Of those proceeds, the Company allocated an estimated fair value of $1.9 million to the 2013 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At December 31, 2016, the 2013 Warrants were exercisable at $39,424 per share with 105 warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 440 shares of its common stock and the issuance of warrants to purchase 197 common shares (the February 2015 Warrants) pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the February 2015 Warrants. The exercise price is subject to appropriate 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. At December 31, 2016, the February 2015 Warrants were exercisable at $563.50 per share with approximately 87 warrants outstanding. The February 2015 Warrants have a five-year term. There were approximately 114 February 2015 Warrants exercised during the year ended December 31, 2016 for proceeds of approximately $0.1 million.

In July 2015, the Company completed the sale of approximately 1,670 Units consisting of 1,670 shares of its common stock, Series A Warrants to purchase up to approximately 1,253 common shares (Series A Warrants) and Series B Warrants to purchase Units consisting of up to approximately 1,670 common shares (Series B Warrants) and 1,253 Series A Warrants pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated

an estimated fair value of $3.4 million to the Series A and Series B Warrants. During the year ended December 31, 2016, approximately 399 Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 1,272 Series B Warrants expired on January 29, 2016 and the related liability was credited to Change in the fair value of the warrant liability. As a result of the Series B Warrant exercises, an additional 399 Series A Warrants were issued. The exercise price of the Series A Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is 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. At December 31, 2016, the July 2015 Series A Warrants were exercisable at $563.50 with approximately 834 warrants outstanding. The Series A Warrants have a five-year term. There were approximately 718 July 2015 Series A Warrants exercised during the year ended December 31, 2016 for proceeds of $0.4 million.

In June 2016, the Company entered into a Securities Purchase Agreement pursuant to which the Company issued $35.0 million in principal face amount of the Notes and related Series C Warrants to purchase 19,368 additional shares of the Company s common stock. The Company allocated an estimated fair value of $27.8 million to the Series C Warrants. On December 31, 2017, the number of Warrant Shares issuable upon exercise of the Series C Warrants will be increased by such number of Warrant Shares equal to 75% of the difference of (i) the quotient of (A) the product of (x) the exercise price as of the date of issuance (as adjusted for certain events) multiplied by (y) the number of Warrant Shares as of the date of issuance (as adjusted for certain events), divided by (B) the volume-weighted average price of the Common Stock on the maturity date, less (ii) the number of Warrant Shares as of the date of issuance (as adjusted for certain events). The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At December 31, 2016, The Series C Warrants were exercisable at $1,690.50 with approximately 19,368 warrants outstanding. The Series C Warrants will be exercisable by the holder beginning one year after the closing date and continuing for a period of five years thereafter.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

In October 2016, the Company completed the sale of 1,215 shares of its common stock and the issuance of warrants to purchase 425 common shares (the October 2016 Warrants) pursuant to an underwriting agreement. The Company received proceeds of $1.2 million, with net cash proceeds after related expenses from this transaction of $1.1 million. Of those proceeds, the Company allocated an estimated fair value of $0.3 million to the October 2016 Warrants. The exercise price is subject to appropriate 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. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At December 31, 2016, the October 2016 Warrants were exercisable at $563.50 per share with 225 warrants outstanding. The October 2016 Warrants have a five-year term. There were 200 October 2016 Series C Warrants exercised during the year ended December 31, 2016 for proceeds of $0.1 million.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $76.0 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. Pursuant to SEC regulations, so long as the Company s public float remains below $75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our non-affiliated public float during any 12-month period.

Stock Incentive Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the Plans) under which 34 and 573 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In July 2016, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 304 shares, from 269 to 573 shares, upon a favorable vote by the Company s stockholders. The Plans are administered by the Compensation and Stock Option Committee of the Board of Directors which determines the individuals to whom awards shall be granted as well as the type, terms, conditions, option price and the duration of each award. As of December 31, 2016, there were 346 shares available to grant under the 2009 Stock Incentive Plan.

A stock option grant allows the holder of the option to purchase a share of the Company s common stock in the future at a stated price. Options and Restricted Stock granted under the Plans vest as determined by the Company s Compensation and Stock Option Committee. Options granted under the Plans expire over varying terms, but not more than ten years from the date of grant.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

Stock option activity for 2016 and 2015 is as follows:

	Stock Option Activity under the Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2014	51	$ 6,944 - $1,372,672	$ 132,328	8.83
Granted	94	6,664	6,664	
Forfeited	(9)	6,664 - 949,760	168,056	
Outstanding at December 31, 2015	136	$ 6,664 - $1,372,672	$ 42,840	8.95
Granted				
Forfeited	(17)	6,664 - 190,848	8382.50	
Outstanding at December 31, 2016	119	$ 6,644 - $1,326,080	$ 47,519.50	7.90
Exercisable at December 31, 2016	77	$ 6,664 - $1,326,080	$ 69,758.50	7.63

For the years ended December 31, 2016 and 2015 the Company recognized compensation expense related to stock option grants of approximately $0.2 million and $0.3 million, respectively.

The estimated fair value of each option award granted was determined on the date of grant using an option pricing model with the following assumptions for option grants during the year ended December 31, 2015. There were no option grants during the year ended December 31, 2016:

	Year ended December 31, 2015
Weighted average risk-free interest rates	1.82%
Weighted average expected volatility	97.70%
Dividend yield	
Weighted average expected option term (in years)	5.15
Weighted average grant date fair value	$ 0.89

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock and does not expect to pay dividends in the foreseeable future. Volatilities were developed using the Company s historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for periods equal to the expected life

of the stock options on the grant date. The expected option term for grants made during 2015, 2014, 2013 and the second half of 2012 is based on actual historical results. The expected option term for grants made prior to that was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under ASC 718. This method of determining the expected holding period was utilized because the Company did not have sufficient historical experience from which to estimate the period.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

A summary of the Company s non-vested options to purchase shares as of December 31, 2016 and changes during the year ended December 31, 2016 and December 31, 2015 are presented below:

	Non-Vested Options	
	Number of Options	Weighted Average Exercise Price
Non-vested at January 1, 2015	41	$ 116,256
Granted	93	9,968
Vested	(28)	147,560
Forfeited	(4)	201,152
Non-vested at December 31, 2015	102	$ 7,892.50
Granted		
Vested	(45)	9,397.50
Forfeited	(15)	6,730.50
Non-vested at December 31, 2016	42	$ 6,688.50

Additional compensation expense of approximately $55,000, relating to the unvested portion of stock options granted, is expected to be recognized over a remaining average period of 1.06 years.

The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2016 is $0. The aggregate intrinsic value represents the total pretax intrinsic value, based on options with an exercise price less than the Company s closing stock price of $0.92 as of December 31, 2016, which would have been received by the option holders had those option holders exercised their options as of that date.

A summary of the Company s restricted stock activity as of December 31, 2016 and changes during the year ended December 31, 2016 and December 31, 2015 are presented below:

	Restricted Stock Activity	
	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at January 1, 2015	6	$ 94,304

Granted	103		14,560
Vested	(6)		76,160
Forfeited			19,040
Non-vested at December 31, 2015	103	$	6,664
Granted	14		1,512
Vested	(55)		5,404
Forfeited	(7)		6,664
Non-vested at December 31, 2016	55	$	6,664

For the years ended December 31, 2016 and 2015 the Company recognized compensation expense related to restricted stock grants of approximately $0.3 million and $0.3 million, respectively. Additional compensation expense of $0.1 million relating to the unvested portion of restricted stock granted is expected to be recognized over a remaining average period of 1.12 years.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

Warrants

The Company issued warrants as part of its offerings in 2013, 2015, and 2016, as well as part of its issuance of convertible notes in 2016. A summary of warrant activity is as follows:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at January 1, 2014	152	$ 9,800-$39,424	$ 30,342	2.78
Issued	3,120		4,480	
Exercised	(39)		4,592	
Expired	(9)		4,592	
Outstanding at December 31, 2015	3,224	$ 4,144-$39,424	$ 5,607	2.16
Issued	20,091		1,680	
Exercised	(1,428)		963	
Expired	(1,271)		1,988	
Outstanding at December 31, 2016	20,616	$ 563.50-$39,424	$ 1,820	5.59

(11) Fair Value Measurements

Derivative Financial Instruments

As disclosed in Note 10 of the Company s consolidated financial statements contained in the Annual Report on Form 10-K, the Company allocated part of the proceeds of public offerings in 2013, 2015 and 2016 of the Company s common stock to warrants issued in connection with those transactions. In addition, the Company recognized a discount to debt related to the initial fair value of warrants issued in connection with the June 2016 Convertible Notes discussed in further detail in Note 9 of the Company s consolidated financial statements contained in the Annual Report on Form 10-K. The valuations of the October 2013, February 2015, July 2015 Series A, June 2016 Series C, and October 2016 Warrants (collectively, the Warrants) were determined using option pricing models. These models use inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the Warrants as a current liability due to certain provisions relating to price adjustments and potential cash payments, as well as the holders ability to exercise the warrants within twelve months of the reporting date and has accounted for them as derivative instruments in accordance with ASC 815, adjusting the fair value at the end of each reporting period. Additionally, the Company has

determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing models against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of Delcath stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath s stock over that term; annual rate of dividends; and the risk-free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company s historical practice of not granting dividends. The closing price of Delcath stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10). The risk-free rate of return is a Level 2 input as defined in ASC 820-10, while the historical volatility is a Level 3 input as defined in ASC 820. Since the lowest level input is a Level 3, Delcath determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

For the year ended December 31, 2016, the Company recorded pre-tax derivative instrument income of $12.8 million. The resulting derivative instrument liabilities totaled $18.8 million at December 31, 2016. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at December 31, 2016 was determined by using option pricing models assuming the following:

	October 2016 Warrants	June 2016 Series C Warrants	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	95.03%	94.19%	95.51%	95.52%	152.70%
Risk free interest rates	1.93%	2.01%	1.59%	1.47%	1.20%
Expected life (in years)	4.80	5.50	3.60	3.10	1.80

The table below presents the Company s assets and liabilities measured at fair value on a recurring basis as of December 31, 2016 and 2015, aggregated by the level in the fair value hierarchy within which those measurements fall.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Balance at December 31,	
(in thousands)	2016	2015	2016	2015	2016	2015	2016	2015
Liabilities								
Derivative instrument liabilities	$	$	$	$	$ 18,751	$ 3,785	$ 18,751	$ 3,785

Fair Value Measurements Using Significant Unobservable

Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at January 1, 2015	$ 225
Total change in the liability included in earnings	(564)
Fair value of warrants issued	4,247

Fair value of warrants exercised		(123)
Balance at December 31, 2015		3,785
Total change in the liability included in earnings		(12,780)
Fair value of warrants issued		28,472
Fair value of warrants exercised		(726)
Balance at December 31, 2016	$	18,751

(12) Commitments

Operating Leases

In February 2010, the Company entered into an agreement to lease (Initial Lease) 8,629 square feet of office space at 810 Seventh Avenue, New York, NY with an option to expand an additional 8,629 square feet. The term of the Initial Lease began in March, 2010. In September 2010, the Company exercised its option right under the Initial Lease and entered into an agreement to lease (Lease Amendment) an additional 8,629 square feet of office space. The term of the Lease Amendment began in January 2011 and will expire in March 2021. In addition, the Lease Amendment extends the term of the Initial Lease to March 2021. The Initial Lease and the Lease Amendment provide for annual rent of $996,000 in 2015, $1.0 million in 2016, and $1.1 million in 2017-2020. As discussed in Note 8, the Company has sub-leased this office space.

In August 2011, Delcath Systems Limited entered into an agreement of lease for an office and manufacturing facility located in the city of Galway, Ireland. This facility is approximately 19,200 square feet and is intended to be the location of Delcath s European headquarters. The Lease is for a term of ten years, commencing August 2, 2011. The Lease provides for fixed annual lease amounts payable in advance in equal quarterly installments. The annual lease amounts, which escalate annually, are as follows (USD conversions are based on the December 31, 2016 conversion rate): Year 1 106,051 ($115,458), Year 2

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

134,974 ($146,946), Year 3 159,077 ($173,187) and Years 4 and 5 183,179 ($199,427). Annual lease amounts in years 6 through 10 are to be paid at a fixed amount of 187,209 ($197,377). Delcath Limited is also required to pay for customary building operating expenses. Delcath Limited s payment obligations and performance of the Lease are guaranteed by Delcath. The Company has sub-leased a portion of this facility.

In March 2016, the Company entered into a sub-lease agreement to lease approximately 6,877 square feet of office space at 1633 Broadway, New York, NY. The term began in April 2016 and is effective through March 2019. The agreement provides for total annual base rent of $522,652.

In October 2016, the Company entered into a lease agreement for 95-97 Park Road in Queensbury, NY, agreeing to lease the 6,000 square feet at that location. The term began on November 1, 2016 and was effective for a two year period. The agreement provides for total annual base rent of $48,223 and will expire October 2018.

Future minimum lease payments, net of receipts due under the terms of subleases, under all operating leases at December 31, 2016 are as follows:

(in thousands)	**Future Lease Payment**
2017	$ 952
2018	946
2019	529
2020	428
2021	254
2022	
	$ 3,109

Rent expense totaled approximately $0.5 million and $0.4 million, for the years ended December 31, 2016 and 2015, respectively.

Letters of Credit

Under the terms of the lease agreement for office space at 810 Seventh Avenue, New York, NY, the Company is required to maintain a letter of credit in the amount of $881,297 which will expire in February 2017 if not renewed by the Company. Under the terms of a sub-lease agreement for office space at 1633 Broadway, New York, NY, the Company is required to maintain a letter of credit in the amount of $130,663 which will expire with the sublease in March 2019.

(13) Income Taxes

There is no income tax provision for the years ended December 31, 2016 and 2015. Income before income taxes consists of:

(in thousands)	Year Ended December 31, 2016	2015
Domestic	$ (13,930)	$ (11,276)
Foreign	(4,040)	(3,428)
Income before taxes	$ (17,970)	$ (14,704)

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

The provision for income taxes differs from the amount computed by applying the statutory rate as follows:

(in thousands)	Year Ended December 31, 2016	2015
Income taxes using U.S federal statutory rate	$ (6,110)	$ (4,999)
Loss of tax benefit of net operating loss carryforwards	68,795	
Loss of tax benefit of state net operating loss carryforwards	13,891	
Loss of tax benefit of tax credit carryforwards	4,023	
Amortization of gain on IP migration	767	767
State income taxes, net of federal benefit	(2,576)	380
Foreign rate differential	1,141	920
Valuation allowance	(75,407)	2,649
Derivative charge	(4,345)	(192)
Stock option exercises and cancellations	53	674
Research and development costs	(250)	(199)
Other	18	
	$	$

Significant components of the Company s deferred tax assets are as follows:

(in thousands)	December 31, 2016	December 31, 2015
Deferred tax assets:		
Employee compensation accruals	$ 1,386	$ 1,279
Accrued liabilities	343	633
Research tax credits	22	3,796
Other	55	66
Net operating losses	6,194	77,906
Total deferred tax assets	$ 8,000	$ 83,680
Deferred tax liabilities:		
Beneficial conversion feature	906	

Total deferred tax liabilities	$ 906	$
Valuation allowance	7,094	83,680
Net deferred tax assets	$	$

As of December 31, 2016 and 2015, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $209.3 million and $184.5 million, respectively. A significant portion of the federal amount, $201.0 million, is subject to an annual limitation of approximately $72,500 as a result of a change in the Company s ownership in May 2003 and November 2016, as defined by Federal Internal Revenue Code Section 382 and the related income tax regulations. As a result of the limitations caused by the May 2003 and November 2016 ownership changes, approximately $205.7 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $3.6 million of net operating loss carryforwards remains available to offset future federal taxable income which will expire between 2018 and 2036. In addition, the Company s state net operating losses are also subject to annual limitations that generally follow the federal Section 382 provisions, adjusted for each state s respective income apportionment percentages. As of December 31, 2016 and 2015, the Company had net operating loss carryforwards for state and city income tax purposes between approximately $27.3 million and $153.0 million and between approximately $27.3 million and $109.7, respectively, which expire through 2036. As a result of the 382 limitations, approximately $150.2 million and $130.5 million of New York State and New York City net operating losses are expected to expire unutilized and will be unavailable to offset future taxable income. Approximately $2.8 million and $2.7 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2016 and 2015, the Company had a net operating loss

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

carryforward for foreign income tax purposes of $21.1 million and $22.1 million, respectively, which have indefinite carryforward periods. As of December 31, 2016 and 2015, the Company had federal research and development tax credit carryforwards of approximately $4.0 million and $3.8 million, respectively, which expire through 2036. As a result of the section 382 limitation, the entire tax credit carryforward is expected to expire unutilized.

The Company has a tax benefit of approximately $1.0 million related to the exercise of non-qualified stock options. As a result of the adoption of ASU 2016-09, the $1.0 million tax benefit was recognized as a cumulative adjustment to retained earnings, offset by a $1 million valuation allowance against retained earnings.

Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company s valuation allowance decreased by approximately $76.6 million and increased by approximately $2.6 million in 2016 and 2015, respectively. The primary reason for the significant decrease in the valuation allowance during the current year is due to the reduction of recognizable deferred tax assets related net operating loss and credit carryforwards resulting from the Sec. 382 ownership change. The change in valuation allowance is as follows:

(in thousands)	**December 31, 2016**	**December 31, 2015**
Beginning balance	$ 83,680	$ 81,223
Charged to costs and expenses	(75,407)	2,649
Charged to additional paid-in capital	(1,854)	
Charged to retained earnings	1,010	
Charged to other comprehensive income	(335)	(192)
Ending balance	$ 7,094	$ 83,680

The Company complies with the provisions of ASC 740-10 in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The Company is currently under examination by the Internal Revenue Service for the period ending December 31, 2013. The examination commenced in the third quarter of 2015 and as of December 31, 2016, there have been no adjustments proposed. The Company has not recorded an uncertain tax position and therefore a table of unrecognized tax benefits has not been presented, and no interest or penalties have been accrued as of December 31, 2016. The

Company s total amount of unrecognized tax benefits could increase within the next twelve months as a result of the exam. However, the effect of the outcome cannot be reasonably estimated as the IRS examination is ongoing. The Company has not been audited by any state tax authorities in connection with income taxes. The Company has not been audited by international tax authorities or any states in connection with income taxes. The Company s New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company is no longer subject to federal and state examination for tax years ending prior to December 31, 2013; tax years ending December 31, 2013 through December 31, 2016 remain open to examination. However, the Company s tax years December 31, 1998 through December 31, 2016 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization, and the applicable statutes of limitation have expired in the utilization year. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

Delcath recognizes interest accrued related to unrecognized tax benefits and penalties, if incurred, as a component of income tax expense.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to Consolidated Financial Statements

for the Years Ended December 31, 2016 and 2015

(14) Subsequent Events
NASDAQ Notification Letter

On February 13, 2017, the Company received a notification letter (the Notice) from The NASDAQ Stock Market (NASDAQ) advising the Company that for 30 consecutive trading days preceding the date of the Notice, the bid price of the Company s common stock had closed below the $1.00 per share minimum required for continued listing on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 5550(a)(2) (the Minimum Bid Price Rule). The Notice stated that the Company will be provided 180 calendar days, or until August 14, 2017, to regain compliance with the Minimum Bid Price Rule. To do so, the bid price of the Company s common stock must close at or above $1.00 per share for a minimum of ten consecutive business days prior to that date. If, by August 14, 2017 the Company cannot demonstrate compliance with Marketplace Rule 5550(a)(2), then the NASDAQ staff will determine whether or not the Company meets The NASDAQ Capital Market initial listing criteria set forth in NASDAQ Marketplace Rule 5550, except for the bid price requirement. If the Company meets the initial listing criteria (with the exception of the bid price requirement) and provides written notice of its intention to cure the deficiency during an additional 180 calendar day compliance period, the NASDAQ staff will notify the Company that it has been granted such an additional compliance period (the second compliance period). If the Company is not eligible for the second compliance period, the NASDAQ staff will provide written notice that the Company s securities will be delisted. At that time, the Company may appeal the NASDAQ staff s determination to delist its securities to a Listing Qualifications Panel.

From January 1, 2017 through March 28, 2017, the Company issued 312,415 shares of Common Stock to the holders of the Notes as payment on the convertible notes payable.

From January 1, 2017 through March 28, 2017, the holders of Notes released an aggregate of approximately $6.6 million in cash previously funded to the Company and authorized the release of those funds from the restricted accounts of the Company in accordance with the Master Control Account Agreement.

(15) Reverse Stock Split
On November 6, 2017, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-three hundred and fifty (1:350) split-adjusted basis. All owners of record as of the open of the OTCQB market on November 6, 2017 received one issued and outstanding share of Delcath common stock in exchange for three hundred and fifty issued and outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-three hundred and fifty exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in these financial statements and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

Table of Contents

DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 2,495	$ 4,409
Restricted cash	8,362	27,287
Accounts receivables, net	298	403
Inventories	1,164	660
Prepaid expenses and other current assets	385	698
Deferred financing costs	529	699
Total current assets	13,233	34,156
Property, plant and equipment, net	1,253	1,083
Total assets	$ 14,486	$ 35,239
Liabilities and Stockholders Deficit		
Current liabilities		
Accounts payable	$ 1,891	$ 594
Accrued expenses	3,755	3,407
Series C preferred shares	494	
Convertible notes payable, net of debt discount	9,736	13,343
Warrant liability	16	18,751
Total current liabilities	15,892	36,095
Deferred revenue		30
Other non-current liabilities	444	604
Total liabilities	16,336	36,729
Commitments and Contingencies		
Stockholders deficit		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively		
Common stock, $.01 par value; 500,000,000 shares authorized; 1,426,153 and 11,805 shares issued and 1,425,862 and 11,750 shares outstanding at September 30, 2017 and December 31, 2016, respectively*	14	
Additional paid-in capital	303,808	277,790

Accumulated deficit	(305,587)	(279,188)
Treasury stock, at cost; 1 share at September 30, 2017 and December 31, 2016, respectively*	(51)	(51)
Accumulated other comprehensive income	(34)	(41)
Total stockholders deficit	(1,850)	(1,490)
Total liabilities and stockholders deficit	$ 14,486	$ 35,239

* reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016 and a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017

See accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenue	$ 684	$ 435	$ 2,011	$ 1,316
Cost of goods sold	172	112	527	373
Gross profit	512	323	1,484	943
Operating expenses:				
Selling, general and administrative	2,860	2,361	7,807	7,025
Research and development	2,279	2,686	7,119	5,975
Total operating expenses	5,139	5,047	14,926	13,000
Operating loss	(4,627)	(4,724)	(13,442)	(12,057)
Change in fair value of the warrant liability, net	27	8,680	1,227	9,171
Gain on warrant extinguishment			9,613	
Loss on debt settlements	(2,952)		(2,952)	
Interest expense	(5,042)	(4,963)	(20,324)	(6,584)
Other income (expense)	(2)	3	5	(15)
Net loss	$ (12,596)	$ (1,004)	$ (25,873)	$ (9,485)
Other comprehensive loss:				
Foreign currency translation adjustments	(15)	(2)	7	(12)
Comprehensive loss	$ (12,611)	$ (1,006)	$ (25,866)	$ (9,497)
Common share data:				
Basic and diluted loss per share*	$ (9.36)	$ (230.99)	$ (34.99)	$ (2,232.30)
Weighted average number of basic and diluted common shares outstanding*	1,401,413	4,349	754,421	4,249

* reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016 and a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017

See accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Stockholders Deficit)

(Unaudited)

(in thousands, except share data)

	Common Stock Issued $0.01 Par Value		Treasury Stock				
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive loss	Total
Balance at January 1, 2017	11,805	$	(1)	$ (51)	$ 277,790	$ (279,188)	$ (41)	$ (1,490)
Compensation expense for issuance of stock options					48			48
Compensation expense for issuance of restricted stock	261				84			84
Issuance of common stock for payments made in shares on convertible note payable	1,413,790	14			25,852			25,866
Series B preferred stock dividend						(526)		(526)
Warrants exercised	297				15			15
Fair value of warrants exercised					19			19
Net loss						(25,873)		(25,873)
Total comprehensive loss							7	7
Balance at September 30, 2017	1,426,153	$ 14	(1)	$ (51)	$ 303,808	$ (305,587)	$ (34)	$ (1,850)

* reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016 and a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017

See accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine months ended September 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (25,873)	$ (9,485)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	48	138
Restricted stock compensation expense	84	228
Depreciation expense	198	232
Loss on disposal of equipment	20	1
Warrant liability fair value adjustment	(1,227)	(9,171)
Gain on warrant extinguishment	(9,613)	
Non-cash interest income	16	(1)
Deferred revenue	(30)	31
Debt discount and deferred finance costs amortization	20,315	6,567
Loss on debt settlements	2,952	
Changes in assets and liabilities:		
Decrease in prepaid expenses and other assets	276	610
Increase in accounts receivable	(94)	(94)
Decrease (increase) in inventories	(338)	190
Increase in accounts payable and accrued expenses	1,767	312
Decrease in other non-current liabilities	(160)	(155)
Net cash used in operating activities	(11,659)	(10,597)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(372)	(245)
Increase in restricted cash		(1,087)
Net cash used in investing activities	(372)	(1,332)
Cash flows from financing activities:		
Increase in restricted cash		(29,200)
Net proceeds from the release of restricted cash	7,901	
Release of restricted cash for extinguishment of Series C Warrants	7,876	
Cash paid to extinguish of Series C Warrants	(7,876)	
Net proceeds from sale of Series B and Series C preferred shares	2,278	
Release of restricted cash for redemption of Series A and Series B preferred shares	2,360	

Redemption of Series A and Series B preferred shares		(2,360)		
Net proceeds from convertible debt financing				31,436
Net proceeds from sale of stock and exercise of warrants		15		704
Net cash provided by financing activities		10,194		2,940
Foreign currency effects on cash and cash equivalents		(77)		71
Net decrease in cash and cash equivalents		(1,914)		(8,918)
Cash and cash equivalents:				
Beginning of period		4,409		12,607
End of period	$	2,495		3,689
Supplemental non-cash activities:				
Conversion of convertible notes to common stock	$	26,199	$	
Fair value of warrants issued	$		$	28,133
Fair value of warrants exercised	$	19	$	245

See accompanying Notes to Condensed Consolidated Financial Statements.

Table of Contents

DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

(Unaudited)

(1) General

The interim condensed consolidated financial statements of Delcath Systems, Inc. (Delcath or the Company) as of and for the three and nine months ended September 30, 2017 and 2016 should be read in conjunction with the consolidated financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2016 (Annual Report), which has been filed with the Securities Exchange Commission (SEC), as amended by that certain Amendment No. 1 to Form 10-K for the year ended December 31, 2016, filed with the SEC on July 14, 2017 and can also be found on the Company s website (www.delcath.com). In these notes the terms us , we or our refer to Delcath and its consolidated subsidiaries.

On November 6, 2017, the Company effected a reverse stock split at which time Delcath s common stock began trading on the OTCQB on a one-for-three hundred and fifty (1:350) split-adjusted basis. All owners of record as of the open of the OTCQB market on November 6, 2017 received one issued and outstanding share of Delcath common stock in exchange for three hundred and fifty issued and outstanding shares of Delcath common stock. No fractional shares were issued in connected with the reverse stock split. All fractional shares created by the one-for-three hundred and fifty exchange were rounded up to the next whole share. The reverse stock split had no impact on the par value per share of Delcath common stock, which remains at $0.01. All current and prior period amounts related to shares, share prices and earnings per share, presented in the Company s interim condensed consolidated financial statements contained in the Quarterly Report on Form 10-Q and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

Description of Business

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.

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 in 2017. 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.

Liquidity and Operating Matters

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and has an accumulated deficit of $305.6 million at September 30, 2017. As shown in the accompanying financial statements during the three and nine months ended September 30, 2017, the Company incurred net losses of $12.6 million and $25.9 million, respectively and during the nine months ended September 30, 2017 used $11.7 million of cash for its operating activities. These factors among others raise substantial doubt about the Company s ability to continue as a going concern for a reasonable period of time.

The Company s existence is dependent upon management s ability to obtain additional funding sources or to enter into strategic alliances. There can be no assurance that the Company s efforts will result in the resolution of the Company s liquidity needs. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

Table of Contents

The Company has incurred losses since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. As a result of issuing $35.0 million in senior secured convertible notes in June 2016 and effecting a reverse stock split on November 6, 2017 management believes that in its current reduced operating mode its capital resources will be adequate to fund operations through at least January 2018. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainties and risks related to clinical research, product development; regulatory approvals; technology; patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing; marketing and sales experience; and dependence on key personnel.

Basis of Presentation

These interim condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the SEC s instructions to Form 10-Q and Article 10 of Regulation S-X. They include the accounts of all entities controlled by Delcath and all significant inter-company accounts and transactions have been eliminated in consolidation.

The preparation of interim financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company s results of operations, financial position and cash flows for the interim periods ended September 30, 2017 and 2016; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company s results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year or any interim period.

Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 *Summary of Significant Accounting Policies* to the Consolidated Financial Statements included in the Company s Annual Report on Form 10-K filed for the period ended December 31, 2016.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASU 2014-09) that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for the Company beginning in its fiscal year 2018, and may be applied retrospectively to all prior periods presented or through a cumulative adjustment to the opening retained earnings balance in the year of adoption. The Company intends to adopt this standard on January 1, 2018. Due to the nature of the Company s revenue generating activities and the small number of customer contracts, the Company does not anticipate that this guidance will materially impact its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which requires entities to report a right-to-use asset and liability for the obligation to make payments for all leases with the exception of those leases with a term of twelve

months or less. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is currently evaluating the impact it may have on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including interim periods within those fiscal years. An entity that elects early adoption must adopt all of the amendments in the same period. The guidance requires application using a retrospective transition method. The Company is currently evaluating the effects, if any, that the adoption of this guidance will have on the Company s financial statements.

Table of Contents

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years, and early adoption is permitted. The Company intends to adopt this standard on January 1, 2018 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company s financial statements.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815). The new guidance intends to reduce the complexity associated with the issuer s accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the Board determined that a down round feature would no longer cause a freestanding equity-linked financial instrument (or an embedded conversion option) to be accounted for as a derivative liability at fair value with changes in fair value recognized in current earnings. In addition, the Board re-characterized the indefinite deferral of certain provisions of Topic 480 to a scope exception. The re-characterization has no accounting effect. ASU 2017-11 is effective for public entities for fiscal years beginning after December 15, 2018. The Company intends to adopt this standard on January 1, 2019 and is evaluating the effects, if any, that the adoption of this guidance will have on the Company s financial statements.

(2) Inventories

Inventories consist of the following:

(in thousands)	**September 30, 2017**	**December 31, 2016**
Raw materials	$ 328	$ 346
Work-in-process	660	214
Finished goods	176	100
Total inventories	$ 1,164	$ 660

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	**September 30, 2017**	**December 31, 2016**
Insurance premiums	$ 61	$ 501
Taxes	53	
Security Deposit	50	50
Other[1]	221	147
Total prepaid expenses and other current assets	$ 385	$ 698

1 Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% of prepaid expenses and other current assets at September 30, 2017 and December 31, 2016.

(4) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	**September 30, 2017**	**December 31, 2016**
Buildings and land	$ 574	$ 556
Enterprise hardware and software	1,648	1,532
Leaseholds	1,659	1,504
Equipment	960	940
Furniture	182	354
Property, plant and equipment, gross	5,023	4,886
Accumulated depreciation	(3,770)	(3,803)
Property, plant and equipment, net		