As filed with the Securities and Exchange Commission on July 2, 2015

No. 333-204979

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No 1
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.)

1301 Avenue of the Americas
43rd Floor
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.
1301 Avenue of the Americas
43rd Floor
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:

Steven A. Navarro
Finnbarr D. Murphy
Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178
(212) 309-6000

James T. Seery
LeClairRyan,
A Professional Corporation
One Riverfront Plaza
1037 Raymond Boulevard, Sixteenth Floor
Newark, New Jersey 07102
(973) 491-3600

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, 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Units, each consisting of one share of common stock, $0.01 par value per share, one Series A Warrant to purchase one share of common stock, and one Series B Warrant to purchase one additional share of common stock and one additional Series B Warrant to purchase one additional share of common stock(2)		
Shares of Common Stock included as part of the Units		
Shares of Common Stock issuable upon exercise of Series A and Series B Warrants(2)		
Series A Warrants included as part of the Units		
Series A Warrants issuable upon exercise of Series B Warrants		
Series B Warrants included as part of the Units		
Total	$10,000,000	$1,162(3)

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended.
(2) The securities being registered also include such indeterminate number of securities as may be issued to prevent dilution resulting from stock splits, stock dividends, recapitalization or other similar transactions or anti-dilution adjustments.
(3) Previously paid.

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 July 2, 2015

Units
Each Unit Consisting of One Share of Common Stock
and
One Series A Warrant to Purchase One Share of Common Stock
and
One Series B Warrant to Purchase One Share of Common Stock and One Series A Warrant

We are offering units, each of which consist of (i) one share of our common stock, (ii) one Series A Warrant to purchase one share of our common stock and (iii) one Series B Warrant to purchase one additional share of common stock and one additional Series A Warrant to purchase one additional share of common stock. The units are being offered at a price of $ per unit.

Units will not be issued or certificated. Purchasers will receive only shares of common stock, Series A Warrants and Series B Warrants. The common stock, the Series A Warrants and the Series B Warrants may be transferred separately immediately upon issuance.

Each Series A Warrant will be immediately exercisable at an initial exercise price of $ per share, which equals % of the last reported sales price of our common stock on The NASDAQ Capital Market. The Series A Warrants will expire on the fifth anniversary of the date of issuance.

Each Series B Warrant will be immediately exercisable at an initial exercise price of $, which equals % of the last reported sales price of our common stock on The NASDAQ Capital Market. The Series B Warrants will expire 90 trading days after the date of issuance.

Our common stock is listed on The NASDAQ Capital Market under the symbol “DCTH.” The last reported sale price of our common stock on July 1, 2015 was $0.92 per share. There is no established public trading market for either series of warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of either series of warrants on any national securities exchange or other nationally recognized trading system.

Investing in our securities involves risks, including those described in the “Risk Factors” section beginning on page 9 of this prospectus.

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

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

(1) See “Underwriting” for more information about total underwriter compensation.
(2) Excludes potential proceeds from the exercise of the warrants through this prospectus.

The underwriter expects to deliver the securities to the purchasers on or about , 2015.

Roth Capital Partners

The date of this prospectus is , 2015

TABLE OF CONTENTS

We have not and the underwriter has not authorized anyone to provide you with any information other than that contained in this prospectus, incorporated by reference into this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where such offers and sales are permitted. The information in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or the time of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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.

PROSPECTUS SUMMARY

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

About Delcath

Delcath Systems, Inc. is a late-stage clinical development company with early commercial activity in Europe focused on cancers of the liver. We are a specialty pharmaceutical and medical device company developing our proprietary product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS). In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT).

Our primary focus is on the execution of our clinical development program in ocular melanoma liver metastases (mOM), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), and certain other cancers that are metastatic to the liver.

Our Market Opportunity

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/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/Melphalan/HDS is uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies. CHEMOSAT/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.

We believe cancers in the liver represent a multi-billion dollar global market opportunity and a clear unmet medical need. Our initial investigational focus for CHEMOSAT/Melphalan/HDS is in the following types of liver cancers:

- Ocular Melanoma, with 8,600 cases diagnosed in the United States and Europe annually.
- Hepatocellular Carcinoma (HCC), with 15,000 cases diagnosed in the United States and Europe annually.
- Intrahepatic Cholangiocarcinoma (ICC), with 6,500 cases diagnosed in the United States and Europe annually.

About Our CHEMOSAT/Melphalan/HDS Product

CHEMOSAT/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), three catheters are placed percutaneously through standard interventional radiology techniques. The ISOFUSE isolation aspiration catheter temporarily isolates the liver

from the body's circulatory system, the CHEMOFUSE hepatic arterial catheter allows administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and a third catheter collect returns the filtered blood exiting the liver for filtration by our proprietary hemofiltration cartridges filters. The filters hemofiltration cartridges 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.

The PHP procedure 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/Melphalan/HDS is repeatable, and a new disposable CHEMOSAT/Melphalan/HDS is used for each treatment. In early clinical trials patients received an average of three procedures in four to eight week intervals. With the current device and procedure, patients treated in both clinical and commercial settings have received up to 6 treatments. In the United States, the plans are for melphalan hydrochloride for injection to 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 phase 3 clinical trial, melphalan hydrochloride for injection will be provided to both European and U.S. clinical trial sites.

Our Clinical Development Program

Our clinical development program for CHEMOSAT/Melphalan/HDS is comprised of:

- a planned Global Phase 3 clinical trial investigating overall survival in ocular melanoma liver metastases (mOM); and
- a Global Phase 2 clinical trial investigating Melphalan/HDS with and without sorafenib in HCC which opened for enrollment in the fall of 2014. We have expanded the Global Phase 2 HCC trial to include a cohort of patients with ICC. Our clinical development program also includes support of select investigator-initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC) and the establishment of a commercial registry for CHEMOSAT commercial cases performed in Europe.

The direction and focus of our clinical development program for CHEMOSAT/Melphalan/HDS is informed by our prior clinical development program, which was conducted between 2004 and 2010. This prior program included:

- a Phase 3 trial in 93 patients with ocular and cutaneous melanoma that demonstrated efficacy for Melphalan/HDS in metastatic melanoma; and
- a Phase 2 multi-histology trial in 56 patients with primary and metastatic liver cancers stratified into four arms; in a cohort of 8 patients an efficacy signal for Melphalan/HDS in HCC was observed.

Our clinical development program is also informed by commercial CHEMOSAT cases performed on over 100 patients in Europe, and prior regulatory experience with the Food and Drug Administration (FDA). Experience gained from this research, development, early European commercial and U.S. regulatory activity has led to the implementation of several safety improvements to both 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 five orphan drug designations, including two orphan designations for the use of the drug melphalan for the treatment of patients with ocular melanoma liver metastases and HCC. 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 where the prospect of securing adequate reimbursement for the procedure is strongest.

The focus of our clinical development program is to generate clinical data for CHEMOSAT/Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment procedure. The program also seeks to address the requirements contained in the FDA's Complete Response Letter (CRL) received in September 2013, which was issued in response to our New Drug Application which we submitted in 2012 seeking an indication in ocular melanoma liver metastases. We believe that the improvements we have made to CHEMOSAT/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 clinical development program 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.

Cancers in the Liver—A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to GLOBOCAN and American Cancer Society (ACS) Facts & Figures 2008, approximately 1.2 million patients globally are diagnosed each year with primary liver cancer or cancer that has metastasized to the liver. According to the American Cancer Society's (ACS) *Cancer Facts & Figures 2013* report, cancer is the second leading cause of death in the United States, with an estimated 580,350 deaths and 1,660,290 new cases expected to be diagnosed in 2013. 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 National Institutes of Health (NIH) estimates that the overall costs of cancer in 2008 were $201 billion: $77 billion for direct medical costs (total of all health expenditures) and $124 billion for indirect mortality costs (cost of lost productivity due to premature death). 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. We estimate that up to 8,600 cases of ocular melanoma are diagnosed in the U.S. 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 development 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 for patients with ocular melanoma liver metastases. As a result, we estimate that up to 4,300 patients with ocular melanoma liver metastases in the U.S. and Europe may be eligible for treatment with our Melphalan/HDS.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers, or cancers affecting the liver, gall bladder and bile ducts,—including HCC and ICC—are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 76,000 new cases of primary liver cancers are diagnosed in the U.S. and Europe annually. Approximately 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 U.S. and Europe may be eligible for treatment with our Melphalan/HDS. We estimate that an additional 6,500 patients diagnosed with ICC may also be eligible for treatment with our Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients in the U.S is approximately 15% compared to 68% for all cancer combined. 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 2013* outlines the treatment options for HCC as follows: "Early stage HCC can sometimes be successfully treated with surgery in patients with sufficient healthy liver tissue; liver transplantation may also be an option. Surgical treatment of early stage HCC is often limited by pre-existing liver disease that has damaged the portion of the liver not affected by cancer. Patients whose tumors cannot be surgically removed may choose ablation (tumor destruction) or embolization, a procedure that cuts off blood flow to the tumor. Fewer treatment options exist for patients diagnosed at an advanced stage of the disease."

Risks of Investing

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

Corporate Information

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 1301 Avenue of the Americas, 43rd Floor, 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	
Securities we are offering	units, each consisting of one share of our common stock, one Series A Warrant to purchase one share of our common stock and one Series B Warrant to purchase one additional share of common stock and one additional Series A Warrant to purchase one additional share of common stock at a price per unit equal to $. The Series A Warrants (including the Series A Warrants issuable upon exercise of the Series B Warrants) will be exercisable immediately and expire on the fifth anniversary of the initial date of issuance at an initial exercise price per share equal to $. See "Description of Securities—Series A Warrants." The Series B Warrants are exercisable immediately at an initial exercise price of $. The Series B Warrants will expire at the close of business on the 90th trading day following the date of issuance. See "Description of Securities—Series B Warrants."
Common stock we are offering	Shares, excluding the shares underlying the Series A Warrants and Series B Warrants.
Common stock to be outstanding after this offering	shares, excluding the shares underlying the Series A Warrants and Series B Warrants.
Use of proceeds	We expect to use the net proceeds from this offering (including any resulting from the exercise of the warrants, if any) to fund the clinical and regulatory development of clinical studies, commercialization of our products, obtaining regulatory approvals, as well as for working capital and other general corporate purposes, including funding the costs of operating as a public company. See "Use of Proceeds."
Dividend policy	We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.
NASDAQ Capital Market symbol for common stock	DCTH
Risk factors	See "Risk Factors" and other information included or incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities
Transfer agent and registrar	American Stock Transfer and Trust Company, LLC

Unless otherwise indicated, all information in this prospectus is based on 12,385,016 shares of common stock outstanding on June 30, 2015 and excludes the following:

- 780,368 shares issuable upon the exercise of stock options at a weighted average exercise price of $7.60 per share;
- 1,696,500 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.35 per share;
- 604,934 unvested restricted shares; and
- the shares of common stock issuable upon the exercise of warrants offered hereby.

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, 2014 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, each of which is incorporated by reference herein. We derived the following summary historical financial statement of operations data and other data for each of the three years in the period ended December 31, 2014 and the summary historical balance sheet data as of December 31, 2014 from our audited financial statements. We derived the summary historical financial data as of and for the three months ended March 31, 2015 and 2014 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.

	Three Months Ended March 31,		Year Ended December 31,		
	2015	2014	2014	2013	2012
	(in thousands, except share and per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenue	$ 444	$ 310	$ 1,069	$ 790	$ 346
Cost of goods sold	133	93	291	464	39
Gross profit	311	217	778	326	307
Operating Expenses:					
Selling, general and administrative	$ 3,040	$ 3,819	$ 15,783	$ 20,657	$ 27,963
Research and development	979	1,457	4,299	12,688	26,215
Total operating expenses	4,019	5,276	20,082	33,345	54,178
Operating loss	(3,708)	(5,059)	(19,304)	(33,019)	(53,871)
Change in fair value of the warrant liability, net	209	(205)	1,942	2,756	2,159
Interest income	2	1	5	20	19
Other income (expense) and interest income (expense)	9	(15)	(24)	(81)	(175)
Net loss	$ (3,488)	$ (5,278)	$ (17,381)	$ (30,324)	$ (51,868)
Common share data:					
Basic loss per share*	$ (0.32)	$ (0.57)	$ (1.84)	$ (4.81)	$ (13.54)
Diluted loss per share*	(0.32)	(0.57)	(1.84)	(5.10)	(13.54)
Weighted average number of basic common shares outstanding*	10,857,142	9,300,078	9,452,050	6,300,614	3,829,721
Weighted average number of diluted common shares outstanding*	10,857,142	9,300,078	9,452,050	6,569,011	3,829,721

* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014

	As of March 31, 2015	As of December 31, 2014
BALANCE SHEET DATA:		
Cash and cash equivalents	$ 18,462	20,469
Total assets	21,650	23,764
Total current liabilities	4,239	4,576
Accumulated deficit	(250,002)	(246,513)
Stockholders' equity	16,424	18,145

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 Melblez Kit system, which precludes approval of our existing New Drug Application, or NDA.

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 September 2013, the FDA issued a complete response letter (CRL) with respect to our NDA seeking an indication for ocular melanoma liver metastases for our Melblez Kit system. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes 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 Melblez Kit using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melblez Kit 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.

As a part of the regulatory process of obtaining marketing clearance for Melphalan/HDS, we will conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. In 2014, we initiated a Phase 2 clinical trial 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. Additionally, we are advancing plans to initiate a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases. Our ability to initiate this trial is subject to FDA clearance of our trial protocol and the satisfaction of certain requirements in the CRL. 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 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.

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/Melphalan/HDS and currently we have only developed this system for the treatment of cancers in the liver. If CHEMOSAT/Melphalan/HDS for the treatment of cancers in the liver fails as a commercial product, 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 Melblez Kit system. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes 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/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 March 31, 2015, we had $18.5 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, 2014, 2013, and 2012, we incurred net losses of approximately $17.4 million, $30.3 million and $51.9 million, respectively, and we expect to continue to incur losses in 2015. To date, we have funded our operations through a combination of private placements and public offerings of our securities. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development, regulatory approval process and commercialization of CHEMOSAT/Melphalan/HDS or any other versions of the system.

If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT/Melphalan/HDS, complete our HCC clinical trial 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/Melphalan/HDS commercially, obtain regulatory approvals or complete our development projects or our clinical trials.

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

- clinical studies, including a Phase 2 clinical trial to establish proof of concept in HCC and ICC and a Phase 3 clinical trial to investigate overall survival in ocular melanoma liver metastases;
- the timing and costs of our various U.S. 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.

In February 2015, we completed the sale of approximately 2.5 million shares of our common stock and the issuance of warrants to purchase approximately 1.1 million shares of our common stock pursuant to an

underwriting agreement. We received proceeds of approximately $2.8 million, with net cash proceeds after related expenses from this transaction of approximately $2.5 million. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. Form S-3 limits the aggregate market value of securities that we are permitted to offer in any 12 month-period under Form S-3 to one-third of our public float. Our ability to raise capital may be impaired and we may not be able to utilize the Form S-3 or access our at the market equity offering program.

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/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 administrative or judicially imposed sanctions.

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act (FFDCA), 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 (CDER) 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 a NDA. A 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 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 Melblez Kit system NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA issued a CRL. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes 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 Melblez Kit using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melblez Kit 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/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.

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/ 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, or 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/Melphalan/HDS may include implementation of a risk evaluation and mitigation strategies (REMS) program to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

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

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

If 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 Melblez Kit system. In September 2013, the FDA 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 precludes approval of the NDA in its current form. The FDA comments in the CRL included a statement that we must perform additional well-controlled randomized trials to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melblez Kit outweigh its risks. Failure to obtain FDA approval will have a material adverse effect on our business, financial condition and results of operations.

Even if we obtain regulatory approval for the Melblez Kit system in the United States, our ability to market the Melblez Kit 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 Melblez Kit, our ability to market and promote the Melblez Kit system would be limited to the approved indication, so even with FDA approval, the Melblez Kit 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 Melblez Kit system, 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 2014, we initiated a Phase 2 clinical trial for HCC in both the United States and Europe. In 2015, we have expanded the Phase 2 clinical trial for HCC to include a cohort of patients with ICC. Additionally, we are advancing plans to initiate a pivotal Phase 3 overall survival clinical trial in ocular melanoma liver metastases, subject to FDA clearance of our trial protocol and the satisfaction of certain requirements contained in the CRL.

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

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase 3 trial, relating to our NDA submissions;
- the FDA or foreign regulatory authorities may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

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

We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT/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 2 HCC clinical trial with an ICC cohort and our planned Phase 3 ocular melanoma 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.

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 approval for Value 4 status reimbursement. Value 4 status does not mandate reimbursement, but allows participating cancer centers to negotiate reimbursement coverage for the CHEMOSAT procedure with all insurers serving their region. Consequently, we may not be able to obtain reimbursement, and any 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 members states of the EEA will reimburse the product's use in the long term or at all. For example, throughout 2014, physicians and patients in Germany submitted and received approvals for Individual Funding Requests (IFRs) granting reimbursement for the treatment of liver metastases with CHEMOSAT. We expect that IFRs will continue to be the main reimbursement vehicle in the German market in 2015. 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. CHEMOSAT/Melphalan/HDS is currently not approved by the FDA or any other regulatory body outside the EEA. 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 were enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. It is uncertain what consequences these provisions will have on our efforts to commercialize CHEMOSAT/Melphalan/HDS.

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

The commercial success of CHEMOSAT/Melphalan/HDS will depend upon their 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/Melphalan/HDS or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, CHEMOSAT/Melphalan/HDS as effective and desirable, our efforts to market CHEMOSAT/Melphalan/HDS may fail, which would have an adverse effect on our business, financial condition and results of operations.

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/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/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/Melphalan/HDS, thereby harming our results of operations.

We may not realize the expected benefits from our restructuring and optimization initiatives; our long-term expense reduction programs may result in an increase in short-term expense; and our efforts may lead to additional unintended consequences.

In early 2013, we announced a plan to increase efficiencies and reduce cash utilization. To achieve the program's goals, we broadened our workforce restructuring actions throughout 2013. As a result of the restructuring program and attrition, we reduced our workforce by approximately 60% in 2013 and an additional 32% in 2014. In addition, we have reduced expenses incurred with outside consultants. In furtherance of our plan, we entered into two sublease agreements to sublease our office space at our corporate headquarters and relocated our corporate headquarters to a new location. The subleases and subsequent relocation represent a significant decrease in total square footage and ongoing facility expenses. These measures could have unintended consequences, such as distraction of our management and employees, business disruption, attrition beyond our planned reduction in workforce and reduced employee productivity. We may be unable to attract or retain key personnel. Attrition beyond our planned reduction in workforce or a material decrease in employee morale or productivity could negatively affect our business and results of operations. In addition, headcount reductions may subject us to the risk of litigation, which could result in substantial cost. These measures, or other expense reduction measures we take in the future, may not result in the expected cost savings.

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

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

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, personnel intellectual property, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our programs and even cease development and commercialization of CHEMOSAT/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.

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

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

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

We purchase components for CHEMOSAT/ Melphalan/HDS from third parties, some of which are sole-source suppliers.

The components of CHEMOSAT/Melphalan/HDS, including catheters, filters, introducers and chemotherapy agents, must be manufactured and assembled in accordance with approved manufacturing and predetermined performance specifications and must meet cGMP and quality systems requirements. Some states also have similar regulations. Many of the components of CHEMOSAT/Melphalan/HDS are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If we or any of our suppliers fails to meet those regulatory obligations, we may be forced to suspend or terminate our clinical trials, and, once a product is approved for marketing, the manufacture, assembly or distribution thereof. Further, if we need to find a new source of supply, we may face long interruptions in obtaining necessary components for CHEMOSAT/Melphalan/HDS, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply CHEMOSAT/Melphalan/HDS to the market.

All of the manufacturers of the components for CHEMOSAT/Melphalan/HDS must comply with a number of FDA and International Organization for Standardization, or ISO, and foreign regulatory agency requirements and regulations. If we or one of our suppliers fails to meet such requirements, we may need to change suppliers. If we are unable to successfully change suppliers, the successful completion of some of our future clinical trials and/or commercialization of CHEMOSAT/Melphalan/HDS could be jeopardized. CHEMOSAT/Melphalan/HDS and its components must be manufactured and sterilized with approved manufacturing and pre-determined performance specifications. Certain components will require sterilization prior to distribution and we rely on third-party vendors to perform the sterilization process. A third-party vendor's failure to properly sterilize a component may cause manufacturing or assembly delays.

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 Phase 2 clinical trial for HCC in the U.S., our planned global Phase 3 in ocular melanoma liver metastases or any future clinical trials.

We have entered into a manufacturing and supply agreement with Synerx Pharma, LLC, or Synerx, and Bioniche Teoranta, or 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 planned Phase 2 clinical trial for HCC and ICC in the United States and our planned global Phase 3 trial for ocular melanoma liver metatases. We may pursue agreements with additional contract manufacturers to produce melphalan and other

chemotherapeutic agents that we will use in the future for our clinical trial program and the commercialization of CHEMOSAT/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/Melphalan/HDS, our ability to develop and commercialize the system would be impaired.

We manufacture CHEMOSAT/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/Melphalan/HDS to purchasers.

In addition to limiting sales opportunities, delays in manufacturing CHEMOSAT/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/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/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/Melphalan/HDS.

We do not have written contracts with all our suppliers for the manufacture of components for CHEMOSAT/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/Melphalan/HDS in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of CHEMOSAT/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/Melphalan/HDS may be delayed.

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

We have not previously sold, marketed or distributed any products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors.

Even though we have obtained the right to affix the CE Mark, we currently have limited sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue our strategy to commercialize CHEMOSAT in the EEA, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If we cannot successfully develop the infrastructure to market and commercialize CHEMOSAT, our ability to generate revenues in the EEA may be harmed, and we may not generate sufficient revenue to sustain our business or we may be required to enter into strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms.

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

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing CHEMOSAT/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/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/Melphalan/HDS or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing CHEMOSAT/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/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/Melphalan/HDS or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We are not able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative

technologies or products that could result in the development of products that compete with CHEMOSAT/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 fulfill 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:

- 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/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/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. In October 2013, the FDA granted us orphan drug designation of the drug melphalan for the treatment of HCC. If CHEMOSAT/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.

We have been named as a party to a purported stockholder class action and stockholder derivative complaint, and we may be named in additional litigation, all of which will require significant management time and attention, result in substantial legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on us.

A purported class action lawsuit has been filed against us on behalf of certain purchasers of our common stock. The complaint includes allegations that we violated federal securities laws by, among other things, knowingly making false and misleading statements or omissions regarding our NDA for our Melblez Kit, thereby artificially inflating the price of our common stock. The complaint seeks compensatory damages, equitable relief, and

reasonable attorneys' fees, expert fees and other costs. In addition, stockholder derivative actions have been initiated against us and certain of our directors and officers. These complaints purport to seek relief on behalf of the Company to remedy alleged breaches of fiduciary duty and other misconduct by the defendants. Our insurance coverage and assets may be insufficient to cover any damage awards or settlement arrangements we may enter into in connection with such claims. Any such payments or settlement arrangements in this current litigation or any future litigation could have material adverse effects on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, this or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, such lawsuits may make it more difficult for us to finance our operations.

Risks Related to Patents, Trade Secrets and Other Proprietary Rights

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 all countries throughout the world would 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 practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection that covers the commercial products to develop their own competing products that are the same or substantially the same as our commercial product and, further, may export otherwise infringing products to territories where we have patent protection, but judicial systems do not adequately enforce patents to cause infringing activities to be ceased.

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

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

Moreover, the United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable

rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies.

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

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

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

Our patent portfolio consists of seven U.S. utility patents, one U.S. design patent, six pending U.S. utility patent applications (one of which has been allowed), two issued foreign counterpart utility patents, six issued foreign counterpart design patents, and nine pending foreign counterpart patent applications (two of which have been allowed). Certain other of our U.S., European and other foreign patents have already expired. Certain of our U.S. and foreign patents will expire in 2016 and 2017.

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

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

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, patents have a

limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our CHEMOSAT/Melphalan/HDS methods and devices, we may be open to competition from generic versions of such methods and devices.

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

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

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

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third-party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third-party patents, it is possible that CHEMOSAT/Melphalan/HDS could be found to infringe these patents. It is also possible that our competitors or potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, import or export our product. If 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 design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline.

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

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT/Melphalan/HDS or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our U.S. 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 next generation products may be covered by a U.S. patent and U.S. 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 2017, 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, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. 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, or 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. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. 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 (EEA).

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. We presently have issued utility and design patents with claims related to certain features of the current version of CHEMOSAT/Melphalan/HDS in the United States and Japan and a design patent protection in Argentina, Australia, Canada, and China. Other parts of CHEMOSAT/Melphalan/HDS are protected by trade secret in these jurisdictions. In the EEA, we rely on design patent and trade secret protection for CHEMOSAT/Melphalan/HDS. Without utility patent protection in the EEA covering the current version of CHEMOSAT/Melphalan/HDS, CHEMOSAT/

Melphalan/HDS will only be covered by design patent and trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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

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

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

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to 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/Melphalan/HDS. In addition, because CHEMOSAT/Melphalan/HDS is intended for use in patients with cancer, there is an increased risk of death among the patients treated with 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 large claims.

Risks Related to this Offering

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

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

Investors in this offering will experience immediate and substantial dilution.

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

Each of the Series A warrants and Series B warrants are a new issue of securities with no established trading market.

The Series A warrants and Series B 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 warrants issued in our February 2015 offering are subject to an exercise price adjustment upon certain equity issuances below $1.38 per share. 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.

Risks Related to Our Securities

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

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

- 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;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- changes in our pricing policies or the pricing policies of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving our company, our general industry or both;
- recruitment or departure of key personnel;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our common stock by our stockholders; and
- the trading volume of our common stock.

In addition, the stock markets, in general, The NASDAQ Capital Market 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.

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.

Our common stock is listed on The NASDAQ Capital Market and if we do not maintain compliance with NASDAQ Marketplace Rules our common stock may be delisted from the NASDAQ Capital Market.

To keep our listing on The NASDAQ Capital Market, we are required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million. We were automatically provided with a 180-calendar day period within which to regain compliance and we subsequently qualified for an additional 180-day grace period. To regain compliance, our common stock was required to close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ. On February 24, 2014, we obtained shareholder approval of an amendment to our Certificate of Incorporation to effect a reverse stock split of our common stock at a specific ratio within a range from 1-for-8 to 1-for-16, inclusive, on or prior to December 31, 2014. In April 2014, we filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which has effected a reverse stock split of our common stock at a ratio of 1-to-16. Following the completion of the reverse stock split, we resumed compliance with the $1.00 minimum bid threshold; however, we may fail to comply with the requirement in the future.

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ's corporate governance requirements, and we fail to regain compliance within the applicable cure period, our common stock could be delisted from The NASDAQ Capital Market.

If our common stock is delisted, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

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

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.

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 March 31, 2015, we had an aggregate of 158 million shares of common stock authorized but not issued or outstanding. Subject to certain volume limitations imposed by The NASDAQ Capital Market in certain circumstances, we may issue all of these shares without any action or approval by our shareholders. We have established an "at the market" equity offering program, and we may issue shares under this program 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 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.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain certain “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as “anticipates,” “expects,” “intends,” “plans,” “predicts,” “believes,” “seeks,” “estimates,” “could,” “would,” “will,” “may,” “can,” “continue,” “potential,” “should,” and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus and the documents incorporated by reference that are not historical facts are hereby identified as “forward-looking statements” for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 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/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/Melphalan/HDS;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

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

USE OF PROCEEDS

We expect to receive net proceeds from the sale of the securities that we are offering to be approximately $ million, after deduction of underwriting discounts and commissions and estimated expenses payable by us. This amount does not include the proceeds that we may receive in connection with any exercise of the warrants issued in this offering, less a solicitation fee equal to 4.0% we will pay the underwriter upon any exercise of warrants having an expiration equal to or less than 18 months. We cannot predict when or if the warrants will be exercised, however, and it is possible that the warrants may expire and never be exercised.

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

- enrollment and treatment of patients to produce interim results for the Phase 2 Hepatocellular/Intrahepatic cholangiocarcinoma clinical trial;
- initiation of a Phase 3 Ocular Melanoma clinical trial, including necessary start up-costs such as Clinical Research Organization fees, regulatory submission fees and ethics committee fees, and initial enrollment and treatment of patients in the US and EU;
- further support efforts of our NDA submission for Ocular Melanoma and further clinical development of Intrahepatic Cholangiocarcinoma and Hepatocellular Carcinoma as orphan drug designations; and
- the balance, if any, for other general corporate purposes.

Because our business does not generate positive cash flow from operating activities, we will need to raise additional capital in order to fund our clinical development and fully commercialize our product. We continue to believe that we will be able to raise additional capital in the event it is in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling additional shares of our capital stock or other securities, or entering into strategic alliances with appropriate partners. These methods 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. See “Risk Factors.”

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. We conduct an interim and/or futility analysis during each of our clinical trials to determine whether there is a benefit to enrolled patients and whether to continue investing our resources into any such clinical trial. 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.

DILUTION

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

The net tangible book value of our common stock as of March 31, 2015, was approximately $16.4 million, or approximately $1.35 per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities divided by the total number of shares of our common stock outstanding.

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

After giving effect to the sale of units offered by this prospectus and after deducting the estimated underwriting discount and our estimated offering expenses and excluding the proceeds, if any from the exercise of the warrants issued pursuant to this offering, our pro forma net tangible book value as of March 31, 2015 would have been approximately $ million or approximately $ per share. This represents an immediate increase in net tangible book value of approximately $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to purchasers of our common stock in this offering, as illustrated by the following table:

Assumed offering price for one unit consisting of one share of common stock and one Series A Warrant		$
Net tangible book value per share as of March 31, 2015	$1.35	
Increase per share attributable to new investors		$
Pro forma net tangible book value per share as of March 31, 2015 after giving effect to this offering		$
Dilution per share to new investors		$

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

The table above excludes the following potentially dilutive securities as of June 30, 2015:

- 780,368 shares issuable upon the exercise of stock options at a weighted average exercise price of $7.60 per share;
- 1,696,500 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.35 per share;
- 160,956 shares reserved for future issuance under our 2009 Equity Incentive Plan, as amended;
- 604,934 unvested restricted shares; and
- shares issuable upon exercise of the warrants offered hereby.

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

CAPITALIZATION

The following table sets forth our cash and cash equivalents and consolidated capitalization as of March 31, 2015 on: (i) an historical basis; and (ii) an as adjusted basis to give effect to this offering.

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

	March 31, 2015	
	Actual	As Adjusted
	(unaudited)	
Cash and cash equivalents	$ 18,462	$
Warrant liability	836	
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.01 par value; 170,000,000 shares authorized; actual and as adjusted, 12,200,397 shares issued and 12,169,706 shares outstanding, actual, shares issued and shares outstanding, as adjusted	122	
Additional paid-in capital	266,349	
Accumulated deficit	(250,002)	
Treasury stock, at cost; 1,757 shares	(51)	
Accumulated other comprehensive income	6	
Total stockholders' equity	16,424	
Total capitalization	$ 17,260	$

(1) Excludes the following potentially dilutive securities as of June 30, 2015:

- 780,368 shares issuable upon the exercise of stock options at a weighted average exercise price of $7.60 per share;
- 1,696,500 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.35 per share;
- 160,956 shares reserved for future issuance under our 2009 Equity Incentive Plan, as amended;
- 604,934 unvested restricted shares; and
- shares issuable upon exercise of the warrants offered hereby.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is listed on The NASDAQ Capital Market 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 2013. The information in the table below reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

	High	Low
2013:		
First Quarter	$35.04	$19.84
Second Quarter	30.88	5.92
Third Quarter	7.26	4.66
Fourth Quarter	10.56	3.53
2014:		
First Quarter	$ 6.72	$ 4.08
Second Quarter	4.96	2.44
Third Quarter	2.78	1.90
Fourth Quarter	2.03	1.09
2015		
First Quarter	$ 1.63	$ 0.92
Second Quarter	1.92	0.80
Third Quarter (through July 1, 2015)	0.98	0.92

The last reported trading price of our common stock on July 1, 2015 was $0.92. As of June 30, 2015, we had approximately 46 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.

BUSINESS

About Delcath

Delcath Systems, Inc. is a late-stage clinical development company with early commercial activity in Europe focused on cancers of the liver. We are a specialty pharmaceutical and medical device company developing of our proprietary product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS). In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT).

Our primary focus is on the execution of our clinical development program in ocular melanoma liver metastases (mOM), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), and certain other cancers that are metastatic to the liver.

Our Market Opportunity

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/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/Melphalan/HDS is uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies. CHEMOSAT/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.

We believe cancers in the liver represent a multi-billion dollar global market opportunity and a clear unmet medical need. Our initial investigational focus for CHEMOSAT/Melphalan/HDS is in the following types of liver cancers:

- Ocular Melanoma, with 8,600 cases diagnosed in the United States and Europe annually.
- Hepatocellular Carcinoma (HCC), with 15,000 cases diagnosed in the United States and Europe annually.
- Intrahepatic Cholangiocarcinoma (ICC), with 6,500 cases diagnosed in the United States and Europe annually.

About Our CHEMOSAT/Melphalan/HDS Product

CHEMOSAT/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), three catheters are placed percutaneously through standard interventional radiology techniques. The ISOFUSE isolation aspiration catheter temporarily isolates the liver from the body’s circulatory system, the CHEMOFUSE hepatic arterial catheter allows administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and a third catheter collect returns the filtered blood exiting the liver for filtration by our proprietary hemofiltration cartridges filters. The filters hemofiltration cartridges 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.

The PHP procedure 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/Melphalan/HDS is repeatable, and a new disposable CHEMOSAT/Melphalan/HDS is used for each treatment. In early clinical trials patients received an average of three procedures in four to eight week intervals. With the current device and procedure, patients treated in both clinical and commercial settings have received up to 6 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 phase 3 clinical trial, melphalan hydrochloride for injection will be provided to both European and U.S. clinical trial sites.

Our Clinical Development Program

Our clinical development program for CHEMOSAT/Melphalan/HDS is comprised of:

- a planned Global Phase 3 clinical trial investigating overall survival in ocular melanoma liver metastases (mOM); and
- a Global Phase 2 clinical trial investigating Melphalan/HDS with and without sorafenib in HCC which opened for enrollment in the fall of 2014. We have expanded the Global Phase 2 HCC trial to include a cohort of patients with ICC. Our clinical development program also includes sponsorship of select investigator initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC) and the establishment of a commercial registry for CHEMOSAT commercial cases performed in Europe.

The direction and focus of our clinical development program for CHEMOSAT/Melphalan/HDS is informed by our prior clinical development program, which was conducted between 2004 and 2010. This prior program included:

- a Phase 3 trial in 93 patients with ocular and cutaneous melanoma that demonstrated efficacy for Melphalan/HDS in metastatic melanoma; and
- a Phase 2 multi-histology trial in 56 patients with primary and metastatic liver cancers stratified into four arms; in a cohort of 8 patients an efficacy signal for Melphalan/HDS in HCC was observed.

Our clinical development program is also informed by commercial CHEMOSAT cases performed on over 100 patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European commercial and U.S. regulatory activity has led to the implementation of several safety improvements to both 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 five orphan drug designations, including two orphan designations for the use of the drug melphalan for the treatment of patients with ocular melanoma liver metastases and HCC. 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 where the prospect of securing adequate reimbursement for the procedure is strongest.

The focus of our clinical development program is to generate clinical data for the CHEMOSAT/Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment procedure. The program also seeks to address the requirements contained in the FDA's Complete Response Letter (CRL) received in September 2013, which was issued in response to our New Drug Application which we submitted in 2012 seeking an indication in ocular melanoma liver metastases. We believe that the improvements we have made to CHEMOSAT/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 clinical development program 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.

Cancers in the Liver—A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to GLOBOCAN and American Cancer Society (ACS) Facts & Figures 2008, approximately 1.2 million patients globally are diagnosed each year with primary liver cancer or cancer that has metastasized to the liver. According to the American Cancer Society's (ACS) *Cancer Facts & Figures 2013* report, cancer is the second leading cause of death in the United States, with an estimated 580,350 deaths and 1,660,290 new cases expected to be diagnosed in 2013. 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 National Institutes of Health (NIH) estimates that the overall costs of cancer in 2008 were $201 billion: $77 billion for direct medical costs (total of all health expenditures) and $124 billion for indirect mortality costs (cost of lost productivity due to premature death). 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. We estimate that up to 8,600 cases of ocular melanoma are diagnosed in the U.S. 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 development 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 for patients with ocular melanoma liver metastases. As a result, we estimate that up to 4,300 patients with ocular melanoma liver metastases in the U.S. and Europe may be eligible for treatment with our Melphalan/HDS.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers, or cancers affecting the liver, gall bladder and bile ducts—including HCC and ICC—are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 76,000 new cases of primary liver cancers are diagnosed in the U.S. and Europe annually. Approximately 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 U.S. and Europe may be eligible for treatment with our Melphalan/HDS. We estimate that an additional 6,500 patients diagnosed with ICC may also be eligible for treatment with our Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients in the U.S is approximately 15% compared to 68% for all cancer combined. 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 2013* outlines the treatment options for HCC as follows: "Early stage HCC can sometimes be successfully treated with surgery in patients with sufficient healthy liver tissue; liver transplantation may also be an option. Surgical treatment of early stage HCC is often limited by pre-existing liver disease that has damaged the portion of the liver not affected by cancer. Patients whose tumors cannot be surgically removed may choose ablation (tumor destruction) or embolization, a procedure that cuts off blood flow to the tumor. Fewer treatment options exist for patients diagnosed at an advanced stage of the disease." 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 U.S., 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 U.S. and Europe annually. Outside of resection, which is the only cure for ICC, there is currently no standard of care (SOC). Base 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 6,500 ICC patients in the U.S. and Europe annual could be candidates for treatment with Melphalan/HDS, which we believe represents a significant market opportunity.

Prior Clinical Development

Our Phase 3 clinical trial and multi-arm Phase 2 clinical trial of the Melphalan/HDS with melphalan in patients with liver cancers are summarized below. The Phase 3 and Phase 2 clinical trials were subject to the terms and conditions of the Cooperative Research and Development Agreement (CRADA), between the Company and the National Cancer Institute (NCI). The Phase 3 trial was conducted under an FDA Special Protocol Assessment (SPA) and was conducted at centers throughout the United States.

Phase 3—Melanoma Metastases Trial

The most advanced application for which Melphalan/HDS was evaluated is for the treatment of metastatic melanoma in the liver. 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, or hPFS. An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization (ECCO) and the European Society of Medical Oncology (ESMO) 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. Authors of this study submitted these results for publication in February 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 hepatic progression free survival (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.

Risks associated with the CHEMOSAT/Melphalan/HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT/Melphalan/HDS is associated with toxic side effects and certain risks, some of which are potentially life threatening. In our Phase 2 and 3 clinical trials using early versions of CHEMOSAT/Melphalan/HDS and treatment protocol, the integrated safety population of patients treated with CHEMOSAT/Melphalan/HDS showed these risks to include: a 4.1% incidence of deaths due to adverse reactions; 4% incidence of stroke; 2% incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment; a ³ 70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week; and 8% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation. In this integrated safety population, deaths due to certain adverse reactions did not 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 commercial usage in Europe, we have continued to develop and refine both the CHEMOSAT/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 U.S. using the Generation Two CHEMOSAT/Melphalan/HDS in a commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile.

Clinical Development Program

The focus of our clinical development program is to generate clinical data for the CHEMOSAT/Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment

procedure. The program also seeks to address the requirements contained in the FDA's Complete Response Letter (CRL) received in September 2013, which was issued in response to our New Drug Application which we submitted in 2012 seeking an indication in ocular melanoma liver metastases. We believe that the improvements we have made to CHEMOSAT/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 clinical development program is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory approvals in various jurisdictions, including the U.S.

Global Phase 3 Ocular Melanoma Trial

We are advancing plans to initiate a pivotal Phase 3 overall survival (OS) clinical trial in ocular melanoma that is metastatic to the liver for resubmission of our NDA to the FDA. Based on the strength of the efficacy data in this disease observed in our previous Phase 3 clinical trial and the reports of an improved safety profile from over 100 patients treated in a non-clinical trial setting in Europe, we are confident that this program can address the concerns raised by the FDA in its CRL. We are working with the relevant Health Authorities in Europe and the U.S. to initiate this trial. We believe that ocular melanoma liver metastases represent a high unmet medical need, and that pursuit of an indication in this disease state may be the fastest path to potential approval of the Melphalan/HDS in the U.S.

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

In 2014 we initiated a new clinical trial program in Europe and the U.S., 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 U.S., we established separate European and U.S. trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria:

- *Protocol 201*—Conducted in the U.S., this trial will 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 being conducted at the Moffitt Cancer Center in the Tampa, Florida and Montefiore Medical Center in New York, New York.
- *Protocol 202*—conducted in Europe, this trial will 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. Three hospitals in Germany have opened for enrollment—Goethe University Hospital, Hannover Medical School Hospital and Jena University Hospital. We intend to open additional centers in Germany and the U.K., subject to the applicable authorizations and approvals including ethics committee approval at participating hospitals.
- *ICC Cohort*—In 2015 we announced the expansion of *Protocol 202* 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. This cohort is now open for enrollment.

European Clinical Data Generation

We have also initiated a prospective registry in Europe to collect data from cases performed in a commercial setting. This registry will gather data in multiple tumor types, including patient safety and efficacy information, from commercial cases performed by participating cancer centers. 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 support clinical adoption and reimbursement in Europe.

European Investigator Initiated Trials

In addition to the clinical trials in our clinical development program, we are supporting data generation in other areas. We are currently supporting two Investigator Initiated Trials (IITs) in Europe– one in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in The Netherlands, and another in HCC at Goethe University Hospital in Frankfurt Germany. Both of these trials have opened for enrollment. 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.

Recent Data Presentations

In June 2015, data from a study entitled *Single Centre Experience of Chemosaturation Percutaneous Hepatic Perfusion in the Treatment of Metastatic Uveal Melanoma*, were included as an online abstract in the 2015 American Society of Clinical Oncology (ASCO) annual meeting. In this study, 20 patients received 34 treatments with CHEMOSAT (1-3 treatments per patient). Radiologically, 2 patients (10%) demonstrated stable disease for >3 months, 13 patients (65%) had a partial response in the liver with complete responses in 2 patients (10%). Nine deaths from disease progression occurred after a median of 264 days from the first procedure. Eleven patients remain alive after a median of 280 days with one complete response ongoing at >1 year. From the diagnosis of liver metastases, 11 patients (55%) have survived to one year and 3 (15%) for >2 years. No procedure related deaths were seen. Adverse events (AEs) seen were grade 1 (n=12), 2 (n=13), 3 (n=5) and 4 (n=1). The grade 4 complication was pulmonary edema due to fluid overload. Early AEs often expected with percutaneous hepatic perfusion (PHP) were observed including coagulopathy, electrolyte disturbances and transient transaminases (elevated liver enzymes). Rare late AEs (1 patient each) included hair loss, skin rash, myelosuppression and persistent transaminases (elevated liver enzymes). Study authors concluded “that PHP (CHEMOSAT) can be used safely to control hepatic metastases in selected uveal melanoma (also known as ocular melanoma) patients with a high rate of hepatic progression free and excellent overall survival.”

In March 2015, data from a retrospective study entitled *Hepatic Progression Free and Overall Survival after Regional Therapy to the Liver for Metastatic Melanoma* were presented at the *Society of Surgical Oncology (SSO)* annual meeting. Investigators evaluated outcomes from 30 patients with cutaneous or uveal melanoma that metastasized to the liver treated at the Moffitt Cancer Center. Patient outcomes were evaluated on hepatic progression free survival (HPFS), progression free survival (PFS) and overall survival (OS) following treatment with yttrium-90 (Y90), chemoembolization (CE) or percutaneous hepatic perfusion (PHP). In the study six patients received Y90, 10 patients were treated with PHP, 12 patients were treated with CE, one patient received Y90 after PHP and one patient received PHP following treatment with CE. Kaplan-Meier survival estimates, log-rank tests and multivariate time-dependent Cox regression analyses (MVA) were used to relate patient, tumor and treatment variables to HPFS, PFS and OS. The study showed a significant difference in median HPFS with 54 days for patients treated with Y90, 80 days for patients treated with CE and 310 days for those treated with PHP (p=0.002). MVA showed improved HPFS for PHP versus Y90 (p=0.001) and for PHP versus CE (p=0.008), but not for CE versus Y90 (p=0.44). Median OS from time of treatment was longest for PHP at 736 days versus Y90 285 days and CE 265 days; however it did not reach statistical significance. There was a significant difference on MVA of OS for PHP versus Y90 (p = 0.03) but not for PHP versus CE (p=0.37) or CE versus Y90 (0.06). Study authors the study concluded that HPFS and PFS were significantly prolonged in patients treated with PHP versus CE and Y90. Median OS in PHP patients was over double that seen in Y90 or CE patients but was significant on MVA only between PHP and Y90.

In October 2014, three abstracts detailing the clinical experiences at three leading cancer hospitals using CHEMOSAT/Melphalan HDS to perform percutaneous hepatic perfusion (PHP) were presented at the *European Society of Surgical Oncology (ESSO)* congress. The three presentations were:

- *A Single Institution Experience with Percutaneous Hepatic Perfusion for Unresectable Ocular Melanoma and Sarcoma in the Liver*, presented by Dr. Jonathan Zager of the Moffitt Cancer Center in

Tampa, FL. Dr. Zager reported that among 13 patients treated at Moffitt a 67% positive response rate was observed, with one partial response and one complete response.

- *Percutaneous Hepatic Perfusion with Melphalan in Treating Unresectable Liver Metastases from Colorectal Cancer and Uveal (Ocular) Melanoma*, presented by Dr. Neal de Leede of Leiden University Medical Centre (LUMC) in the Netherlands. Dr. de Leede reported that among 11 patients treated at LUMC as 80% response rate was observed.
- *Initial United Kingdom Experience with Melphalan Percutaneous Hepatic Perfusion (PHP) For Treatment of Inoperable Ocular Melanoma Metastases*, presented by Dr. Brian Steadman of the University Hospital Southampton (UHS) in the United Kingdom. Dr. Stedman reported that in 19 patients treated at UHS, a 63% positive response was observed with 47% having a partial response and 16% having a complete response.

These response rates were achieved with a range of one (1) to six (6) treatments. All authors concluded that in their opinion CHEMOSAT or Melphalan/HDS is a safe and effective procedure for selected patients.

Market Access and Commercial Clinical Adoption

European Union

Our immediate market access and clinical adoptions efforts were focused on the key target markets of Germany and the United Kingdom, 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 the Netherlands, Spain, France and Italy. We employ a combination of direct and indirect sales channels to market and sell CHEMOSAT in these markets. Our European Headquarters is in Galway, Ireland.

Since launching CHEMOSAT in Europe, CHEMOSAT has been used to perform 186 commercial treatments on 111 patients. Treatments have been performed at leading cancer centers across Europe. 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 hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, and cutaneous melanoma.

European Reimbursement

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

Germany

In February 2015, we announced that the Institut für das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, again granted Value 4 coverage status for the treatment of patients with liver metastases with CHEMOSAT. The InEk determines three status levels for medical procedures submitted for its review: Value 1 (mandated reimbursement), Value 2 (declined for reimbursement), and Value 4 (negotiated reimbursement). The InEk may also decline to make a determination regarding an application. Under the Neue Untersuchungs und Behandlungsmethoden (NUB) reimbursement scheme, Value 4 Status, while not mandating

reimbursement, allows participating cancer centers to negotiate a budget to fund reimbursement coverage for CHEMOSAT procedure with insurers serving their region. The InEk first established NUB Value 4 status for CHEMOSAT procedures in 2013, and repeated this assessment in 2014. The NUB is an annual process, and participating centers in Germany are required to apply each year for subsequent coverage under the NUB scheme.

Separately, throughout 2014 physicians and patients in Germany submitted and received approvals for Individual Funding Requests (IFRs) granting reimbursement for the treatment of liver metastases with CHEMOSAT. IFRs are case-by-case appeals for reimbursement made to the patient's insurance carrier ("sickness funds"). While each IFR is evaluated independently, the majority of these applications were approved during the year. Of those IFRs that were initially rejected, subsequent appeals over-ruled most of these rejections and allowed treatments to be funded. IFR approvals have covered a range of sickness funds across a number of regions in Germany including ocular melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, pancreatic cancer and sarcoma; and some were granted for multiple treatments of the same patients. We expect that IFRs will continue to be the main reimbursement vehicle in the German market in 2015.

United Kingdom

In the United Kingdom, though Delcath and our participating cancer centers identified existing Healthcare Resource Groups (HRG) code(s), we have been advised that hospitals have not used it for coverage of CHEMOSAT related costs. We continue to work with the HRG organization that decides on new HRG codes toward receipt of a dedicated and permanent reimbursement code in the future.

We are supporting efforts to seek a block fund grant through the *Commissioning Through Evaluation* (CTE) process, which may ultimately provide funding for up to 50-75 ocular melanoma patients to be treated utilizing CHEMOSAT at two to three centers in the U.K. This process has been driven by our partner centers and their clinical community, with the centers applying for funding for a limited number of patients with ocular melanoma. In the fourth quarter of 2014, Aintree University Hospital in Liverpool was activated with to the intention of it becoming one of these CTE centers. The British healthcare system continues to evolve however, and ongoing changes to the CTE process and funding streams have resulted in delays that made the award and timing of any block grant funding difficult to predict. Our current expectation is for the process to be completed by the end of the second quarter 2015 with the funding, if any, becoming available in the third quarter of 2015. The entire CTE funding mechanism is a new process and these ongoing policy changes in the National Health Service (NHS) make it difficult to predict the likelihood of success in the near term.

In May 2014, the National Institute for Clinical Excellence (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. NICE stated that this research may take the form of observational studies. With UK participation in our Phase 2 HCC trial beginning in 2015, we believe the data generated from these studies will help provide supporting clinical data and address the concerns raised by NICE relative to survival, quality of life and adverse events. NICE may decide to conduct a Technology Appraisal of CHEMOSAT thereafter, the outcome of which could influence the long-term reimbursement status.

Public patients will continue to be treated in the UK through clinical trials and potentially the CTE process. Private patients will continue to be treated through the established private treatment pathway such as private insurance coverage or self-pay.

Other European Markets

Permanent reimbursement coverage in remaining EU markets will require additional time to secure. In the interim period, we are seeking payment through various avenues, including new technology programs. In France, we plan to present our Phase 3 trial data to the French healthcare authorities assuming publication in 2015 to set the foundation for a potential DRG code in 2016.

For France, Spain and the Netherlands, publication of the Phase 3 trial manuscript is a key component of the reimbursement process. The Phase 3 trial manuscript has been submitted and we expect publication in 2015.

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.

Orphan Drug Exclusivity

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

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 European Union 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.

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, we 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.

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. We 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.

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. We currently hold seven U.S. utility patents, one U.S. design patent, six pending U.S. utility patent applications (one of which has been allowed), three issued foreign counterpart utility patents, six issued foreign counterpart design patents, and nine pending foreign counterpart patent applications (two of which have been allowed).

We have developed what we consider to be a strong intellectual property portfolio, including patents, trademarks, copyrights, trade secrets and know-how. We continue to actively pursue a broad array of intellectual property protection in the United States, and in significant markets elsewhere in North America, as well as in Europe, Australia and Asia, including China and Japan. We believe our intellectual property portfolio effectively protects aspects of the products we currently market.

As more fully described below, our patents and patent applications are primarily directed to our chemotherapy blood filtering technology or aspects thereof including the commercialized CHEMOSAT/Melphelan/HDS apparatus.

In addition to patent protection, we rely on materials and manufacturing trade secrets, and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Patents

As of June 14, 2015, we own or exclusively license seven U.S. utility patents, one U.S. design patent, six pending U.S. utility patent applications (one of which has been allowed), two issued foreign counterpart utility patents, six issued foreign counterpart design patents, and nine pending foreign counterpart patent applications (two of which have been allowed).

The following is a summary of our current and pending patents:

U.S. Patent 5,893,841 is directed to Delcath's ISOFUSE isolation aspiration catheter, which is used as part of CHEMOSAT/Melphalan/HDS. This patent is expected to expire in August 2016. A foreign counterpart patent has been granted in Japan.

European Patent No. 0936933, which was filed as a counterpart of U.S. Patent 5,893,841, is directed to an isolation aspiration catheter having port closure means.

U.S. Patent D708749 is a design patent directed to Delcath's dual filter hemofiltration device, which is used as part of CHEMOSAT/Melphalan/HDS. This patent is expected to expire in July of 2028. Foreign counterpart design patents have been granted in Argentina, Australia, Canada, China, Europe, and Japan.

U.S. Patent Application No. 13/671, 549 has pending claims directed to Delcath's hemofiltration cartridges used in CHEMOSAT/Melphalan/HDS. If granted, the issued patent would be expected to expire in November 2032.

U.S. Patent Application No. 13/731,016 has pending claims directed to the CHEMOSAT/Melphalan/HDS system. If granted, the issued patent would be expected to expire in December 2032.

U.S. Patent 8,679,057 is directed to a potential next generation isolation aspiration catheter. This patent is expected to expire in March of 2013. This patent is currently exclusively licensed to Delcath from NFusion Vascular Systems and the license is not expected to terminate before 2017. A U.S. continuation application is currently pending.

U.S. Patent Application No. 13/899,366 has allowed claims directed to a potential next generation isolation aspiration catheter. If granted, this patent is expected to expire in May 2033. This patent is currently exclusively licensed to Delcath from NFusion Vascular Systems and the license is not expected to terminate before 2017. A U.S. continuation application is currently pending.

U.S. Patent 6,186,146 is directed to a method of treating a kidney by isolated perfusion. This patent is expected to expire August of 2016.

U.S. Patent 5,817,046 is directed to an apparatus for isolated perfusion of the pelvic cavity. This patent is expected to expire in July 2017.

U.S. Patent 5,897,533 is directed to sheath introduction for a balloon catheter. This patent is expected to expire in September of 2017.

U.S. Patent 5,919,163 is directed to an apparatus for perfusing blood including a double balloon catheter having a fixed balloon and a slidable balloon**.** This patent is expected to expire in July of 2017.

U.S. Patent 7.022,097 is directed to methods for treating glandular malignancies by isolated perfusion. This patent is expected to expire May of 2023.

U.S. Patent Application No. 13/731,019 has pending claims directed to a telescopically adjustable filter apparatus. If granted, this patent would be expected to expire December 2032.

U.S. Patent Application No. 14/013,005 has pending claims directed to a method of selecting chemotherapeutic agents for regional therapy, such as with the CHEMOSAT/Melphalan/HDS system. If granted, this patent would be expected to expire August 2033.

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. We intend 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, we believe that it will provide us with added protection once commercialization of an orphan drug designated product begins.

Trademarks

When appropriate, we actively pursue protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to make patent improvements that we identify through research and development, manufacturing, and clinical use of the CHEMOSAT/Melphalan/HDS that will enable us to expand our platform beyond the treatment of cancers in the liver. We believe we have protected our trademarks, including CHEMOSAT, ISO-FUSE, CHEMOFUSE and DELCATH, through applications in all major markets worldwide as well as the United States. Our trademark portfolio consists of 38 trademark registrations, seven of which are registered in the United States, including our CHEMOSAT logo. We also have trademark applications pending registration in the United States and in several major markets outside the United States.

Trade Secrets and Know-How

We rely, in some circumstances, on trade secrets and know-how to protect our proprietary manufacturing processes and materials critical to our product. We seek to preserve the integrity and confidentiality of our trade secrets and know-how in part by limiting the employees and third parties who have access to certain information and requiring employees and third parties to execute confidentiality and invention assignment agreements, under which they are bound to assign to us inventions made during the term of their employment. These agreements further require employees to represent that they have no existing obligations and hold no interest that conflicts with any of their obligations under their agreements with us. We also generally require consultants, independent contractors and other third parties to sign agreements providing that any inventions that relate to our business are owned by us, and prohibiting them from disclosing or using our proprietary information except as may be authorized by us. 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.

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/Melphalan/HDS competes with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In the disease states we are

targeting there are also numerous clinical trials sponsored by third-parties, which can compete for potential patients in the near term and may ultimately lead to new competitive therapies.

- For ocular melanoma liver metastases, there are currently no approved or effective treatment options, and patients are generally treated with a variety of focal and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Covidian, Biocompatibles, Merit, CeleNova, SirTex, AngioDynamics, and many others.
- For HCC, sorafenib (Nexavar, Onyx Pharmaceuticals) remains the only targeted drug approved for the treatment of HCC in patients who are not candidates for surgery.
- Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar™, GlaxoSmithKline), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST™, GlaxoSmithKline) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy™, Bristol Myers Squibb) and the B-RAF targeted drug vemurafenib (Zelboraf™, Genentech) may also make up the competitive landscape for the treatment of metastatic liver disease.

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

Manufacturing and Quality Assurance

We manufacture certain components including our proprietary filter media, and assemble and package the CHEMOSAT/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/Melphalan/HDS. The CHEMOSAT/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.

Employees

As of June 30, 2015, the Company 30 had 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 5,818 square feet of office space at 1301 Avenue of the Americas, New York, New York under a license agreement that expires in May 2016. 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 2015 and March 2021 respectively. We have subleased the office space at 810 Seventh Avenue. See Note 12 to our audited financial statements contained in our Annual Report on Form 10-K for more details. Delcath owns a building containing approximately 10,320 square feet at 566 Queensbury Avenue in Queensbury, NY. This facility houses manufacturing, quality assurance and quality control, research and development, and office space. We also own approximately six acres of land at 10, 12 and 14 Park Road in Queensbury, New York. In addition, Delcath Systems Limited 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, but can be terminated after the fifth year (August 2016). We have sublet 5,662 square feet of this facility. We believe substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs.

Legal Proceedings

In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York (Case No. 13-cv-3116)

On May 8, 2013, a purported stockholder of the Company filed a putative class action complaint in the United States District Court for the Southern District of New York, captioned Bryan Green, individually and on behalf of all others similar situated, v. Delcath Systems, Inc., et al. (“Green”), Case No. 1:13-cv-03116-LGS. On June 14, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Joseph Connico, individually and on behalf of all others similarly situated, v. Delcath Systems, Inc., et al. (“Connico”), Case No. 1:13-cv-04131-LGS.

At a hearing on August 2, 2013, the Court consolidated the Green and Connico actions under the caption In re Delcath Systems, Inc. Securities Litigation, No. 13-cv-3116, appointed Lead Plaintiff, Delcath Investor Group, and approved Pomerantz Grossman Hufford Dahlstrom & Gross LLP as Lead Plaintiff’s choice of counsel.

On September 18, 2013, Lead Plaintiff filed a consolidated amended complaint, naming the Company and Eamonn P. Hobbs as defendants (the “Defendants”). The consolidated amended complaint asserts that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by allegedly making false and misleading statements or omissions regarding the Company’s New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma in the liver. The putative class period alleged in the amended complaint is April 21, 2010 through and including May 2, 2013. Lead Plaintiff seeks compensatory damages, equitable relief, and reasonable attorneys’ fees, expert fees and other costs.

The parties have reached a settlement in principle that, if approved by the Court, will fully and finally resolve the claims brought by Lead Plaintiff on behalf of the class it seeks to represent. The proposed settlement establishes a settlement fund of $8,500,000 in return for a release of all claims in this litigation.

On June 24, 2015, the Court granted Lead Plaintiff filed a Motion for Preliminary Approval of Class Action Settlement and set a Final Approval Hearing for October 19, 2015. Pursuant to the Court’s Preliminary Approval

Order, notice and claim forms will be mailed to class members and class members will have an opportunity to submit claims, to opt-out of the settlement, and/or to object to the settlement. At the Final Approval Hearing the Court will consider the notice process and results, any objections, and other relevant information. The Court will then decide whether to finally approve the class settlement. If the settlement is finally approved, the settlement funds will be disbursed as provided in the settlement agreement and the Court's orders.

In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS)

On May 23, 2013, purported stockholders of the Company filed a shareholder derivative lawsuit in the United States District Court for the Southern District of New York, captioned Vincent J. Orlando and Carol Orlando, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Orlando"), Case No. 1:13-cv-03494-LGS. On June 11, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Howard Warsett, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Warsett"), Case No. 1:13-cv-04002-LGS. On July 19, 2013, another substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Patricia Griesi, derivative on behalf of nominal defendant Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Griesi"), Case No. 13 cv 5024. In all three cases, Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung were named as defendants (the "Individual Defendants"), and the Company was named as a nominal defendant.

All three complaints assert claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, and gross mismanagement for making false and misleading statements or failing to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. In addition, the Orlando complaint further asserts claims for contribution and indemnification, abuse of control, and waste of corporate assets, while the Warsett complaint asserts an additional claim for unjust enrichment. The Griesi complaint also asserts additional claims for breach of fiduciary duties for failing to maintain internal controls, unjust enrichment, abuse of control, and violations of Section 14(a) of the Securities Exchange Act of 1934. The relevant time period alleged in the Orlando action is April 21, 2010 through the present, and the relevant time period alleged in the Warsett action is April 10, 2010 through the present. The relevant time period alleged in Griesi is April 21, 2010 through May 2, 2013. The Orlando, Warsett, and Griesi plaintiffs seek damages as well as reasonable costs and attorneys' fees. The Griesi plaintiffs also seek corporate governance reforms and improvements and restitution.

On June 25, 2013, the Court consolidated the Orlando and Warsett actions with the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS ("Consolidated Derivative Case"). On August 1, 2013, the Court consolidated the Griesi action under the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS. At a hearing on August 2, 2013, the Court entered an order approving Federman & Sherwood as lead counsel. The Court stayed the Consolidated Derivative Case, pending resolution of an anticipated motion to dismiss in In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York, No. 13-cv-3116.

On September 12, 2014, Plaintiffs Vincent Orlando and Carol Orlando filed a Verified Amended Consolidated Shareholder Derivative Complaint (the "Amended Complaint") in the Consolidated Derivative Case. The Amended Complaint is brought against the Individual Defendants, and names the Company as a nominal defendant (collectively, the "Defendants"). The Amended Complaint alleges breaches of fiduciary duty against the Individual Defendants for disseminating false and misleading information and for failing to properly oversee and manage the company. In addition, the Amended Complaint alleges claims for gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets. The relevant time period

alleged in the Amended Complaint is April 21, 2010 through the present. The Plaintiffs in the Amended Complaint seek damages as well as reasonable costs and attorneys' fees. On October 27, 2014, Defendants served Plaintiffs with their Motion to Dismiss the Amended Complaint, and the motion is fully briefed. The parties have agreed to a settlement in principle and have requested the Court hold the motion to dismiss in abeyance while parties memorialize the settlement.

The Individual Defendants in the Consolidated Derivative Case deny any wrongdoing, believe the claims are baseless, and if the settlement is not finalized and approved, will defend accordingly.

Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., Supreme Court of the State of New York County of New York (Case No. 652030/2013)

On June 7, 2013, a purported stockholder of the Company filed a shareholder derivative lawsuit in the Supreme Court of the State of New York County of New York, captioned Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., ("Weinstein") Case No. 652030/2013. The action named Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung as individual defendants (the "Individual Defendants"), as well as the Company, as a nominal defendant.

The complaint asserts claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets in connection with allegations that the Individual Defendants made false and misleading statements or failed to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. The relevant time period alleged is April 21, 2010 through the present. The plaintiff seeks damages, as well as reasonable costs and attorneys' fees.

In July 2014, the parties in the Weinstein matter agreed to stipulate to stay the proceeding until the federal district court rules on the anticipated motion to dismiss in In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS). The parties have agreed to a settlement in principle.

The Individual Defendants in the Weinstein matter deny any wrongdoing, believe the claims are baseless, and if the settlement is not finalized, will defend accordingly.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table contains information regarding the beneficial ownership of our Common Stock as of June 30, 2015 (unless otherwise specified), held by: (i) each of our directors; (ii) each of our named executive officers (as defined in Item 402(a)(3) of Regulation S-K under the Securities Exchange Act of 1934); (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. The address of the persons or groups named below is c/o Delcath Systems, Inc., 1301 Avenue of the Americas, 43rd Floor, New York, New York 10019.

	Shares Beneficially Owned(1)	
	Number	Percent
Name of Beneficial Owner:		
Named Executive Officers and Directors:		
Jennifer K. Simpson, Ph.D.(2)	219,337	1.7%
John Purpura, M.S.(3)	124,205	*%
Barbra C. Keck, M.B.A.(4)	86,475	*%
Harold S. Koplewicz, M.D.	45,052	*%
Laura A. Philips, Ph.D., M.B.A.(5)	42,646	*%
Roger G. Stoll, Ph.D.(6)	79,145	*%
Dennis H. Langer, M.D., J.D.	20,000	*%
William D. Rueckert	20,000	*%
Marco Taglietti, M.D.	20,000	*%
Graham Miao(7)	3,186	*%
Peter J. Graham, J.D.(8)	937	*%
All directors and executive officers as a group (9 people)(9):	660,983	5.1%

* 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 June 30, 2015, 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 June 30, 2015; 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 12,385,016 shares of common stock outstanding on June 30, 2015, plus the number of shares of common stock that such person or group has the right to acquire within 60 days of June 30, 2015.

(2) Includes 17,041 shares of common stock which Dr. Simpson has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 30, 2015.

(3) Includes 22,393 shares of common stock which Mr. Purpura has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 30, 2015.

(4) Includes 12,988 shares of common stock which Ms. Keck has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 30, 2015.

(5) Includes 750 shares of common stock owned of record by Dr. Philips' spouse, with respect to which Dr. Philips disclaims beneficial ownership, and 41,896 shares of common stock jointly owned by Dr. Philips and her spouse.

(6) Includes 4,687 shares of common stock which Dr. Stoll has the right to acquire upon exercise of outstanding options exercisable within 60 days of June 30, 2015.

(7) As of September 30, 2014, Dr. Miao is no longer employed by us.

(8) As of March 9, 2015, Mr. Graham is no longer employed by us.

(9) Includes 57,109 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 June 30, 2015.

DESCRIPTION OF CAPITAL STOCK

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

Authorized Capital Stock

Our authorized capital stock consists of 170,000,000 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 June 30, 2015, we had 12,385,016 shares of common stock outstanding and no shares of preferred stock outstanding. As of June 30, 2015, we had 1,696,500 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.35 per share, 780,368 shares issuable upon the exercise of stock options at a weighted average exercise price of $7.60 per share, and 604,934 shares of unvested restricted stock.

Common Stock

Voting

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

Dividends

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

Liquidation and Dissolution

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

Other Rights and Restrictions

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

Listing

Our common stock is listed on The NASDAQ Capital Market 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.

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.

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 SECURITIES WE ARE OFFERING

We are offering units, each unit consisting of one share of our common stock, one Series A Warrant to purchase one share of our common stock and one Series B Warrant to purchase one share of common stock and one Series A Warrant.

The units will not be issued or certificated. The shares of common stock, the Series A Warrants and the Series B Warrants that we are issuing are immediately separable and will be issued separately. The shares of common stock issuable from time to time upon exercise of the Series A Warrants and Series B Warrants, if any, are also being offered pursuant to this prospectus.

Common Stock

The material terms and provisions of our common stock are described under the caption “Description of Capital Stock” starting on page 57 of this prospectus.

Series A Warrants

The following summary of certain terms and provisions of Series A Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the Series A Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series A Warrant for a complete description of the terms and conditions of the Series A Warrants.

Duration and Exercise Price. The Series A Warrants offered hereby will entitle the holders thereof to purchase up to an aggregate of shares of our common stock at an initial exercise price of $ per share, commencing immediately on the date of issuance and will expire on the fifth anniversary of the initial date of issuance. The Series A Warrants will be issued separately from the common stock included in the units, and may be transferred separately immediately thereafter. If the Series B Warrants described below are exercised in full, we will issue additional Series A Warrants to purchase up to an aggregate of shares of our common stock. All Series A Warrants will have the same expiration date.

Anti-Dilution Adjustments: 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 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.

Cashless Exercise. If, at any time during the Series A Warrant exercisability period, the issuance of shares of our common stock upon exercise of the Series A Warrant is not covered by an effective registration statement, we or the holder are permitted to effect a cashless exercise of the Series A Warrants (in whole or in part) by having the holder deliver to us a duly executed exercise notice, canceling a portion of the Series A Warrant in payment of the purchase price payable in respect of the number of shares of our common stock purchased upon such exercise.

Transferability. The Series A Warrants may be transferred at the option of the Series A Warrant holder upon surrender of the Series A Warrants with the appropriate instruments of transfer.

Exchange Listing. We do not plan on making an application to list the Series A Warrants on The NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system.

Rights as a Stockholder. Except by virtue of a holder's ownership of shares of our common stock, the holders of the Series A Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series A Warrants.

Fundamental Transactions. In the event of any fundamental transaction, as described in the Series A Warrants and generally including any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of a majority of our common stock, then the holders of the Series A Warrants will thereafter have the right to receive upon exercise of the Series A Warrants such shares of stock, securities or assets as would have been issuable or payable with respect to or in exchange for a number of shares of our common stock equal to the number of shares of our common stock issuable upon exercise of the Series A Warrants immediately prior to the fundamental transaction, had the fundamental transaction not taken place, and appropriate provision will be made so that the provisions of the Series A Warrants (including, for example, provisions relating to the adjustment of the exercise price) will thereafter be applicable, as nearly equivalent as may be practicable in relation to any share of stock, securities or assets deliverable upon the exercise of the Series A Warrants after the fundamental transaction. In lieu of the right to receive upon exercise the shares of stock, securities or assets as would have been issuable or payable with respect to or in exchange for a number of shares of our common stock, the holders of the Series A Warrants may require us under certain circumstances to redeem the Series A Warrant for a purchase price payable in cash of the Black-Scholes value of the Series A Warrant, as calculated pursuant to the terms of the Series A Warrant.

Limits on Exercise of Series A Warrants. Except upon at least 61 days' prior notice from the holder to us, the holder will not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock (including securities convertible into common stock) outstanding immediately after the exercise.

Series B Warrants

The following summary of certain terms and provisions of the Series B Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the Series B Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the Series B Warrant for a complete description of the terms and conditions of the Series B Warrants.

Duration and Exercise Price. The Series B Warrants offered hereby will entitle the holders thereof to purchase up to an aggregate of additional shares of common stock and an aggregate of Series A Warrants, commencing immediately on the date of issuance and will expire 90 trading days after the date of issuance. The Series B Warrants will be issued separately from the common stock included in the units, and may be transferred separately immediately thereafter. If the Series B Warrants described below are exercised in full, we will issue additional shares of Common Stock and Series A Warrants to purchase up to an aggregate of shares of our common stock.

Transferability. The Series B Warrants may be transferred at the option of the Series B Warrant holder upon surrender of the Series B Warrants with the appropriate instruments of transfer.

Exchange Listing. We do not plan on making an application to list the Series B Warrants on The NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system.

Rights as a Stockholder. Except by virtue of a holder's ownership of shares of our common stock, the holders of the Series B Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series B Warrants.

Fundamental Transactions. In the event of any fundamental transaction, as described in the Series B Warrants and generally including any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our common stock, then the holders of the Series B Warrants will thereafter have the right to receive upon exercise of the Series B Warrants such shares of stock, securities or assets as would have been issuable or payable with respect to or in exchange for a number of shares of our common stock equal to the number of shares of our common stock issuable upon exercise of the Series B Warrants immediately prior to the fundamental transaction, had the fundamental transaction not taken place, and appropriate provision will be made so that the provisions of the Series B Warrants (including, for example, provisions relating to the adjustment of the exercise price) will thereafter be applicable, as nearly equivalent as may be practicable in relation to any share of stock, securities or assets deliverable upon the exercise of the Series B Warrants after the fundamental transaction.

Limits on Exercise of Series B Warrants. The holder will not have the right to exercise any portion of the Series B Warrant if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock (including securities convertible into common stock) outstanding immediately after the exercise.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect the prevailing market price of our common stock. No prediction can be made as to the effect, if any, future sales of shares, or the availability of shares for future sales, will have on the market price of our common stock prevailing from time to time. The number of shares available for future sale in the public market is subject to legal and contractual restrictions, some of which are described below. The expiration of these restrictions will permit sales of substantial amounts of our common stock in the public market, or could create the perception that these sales may occur, which could adversely affect the prevailing market price of our common stock. These factors could also make it more difficult for us to raise funds through future offerings of our securities.

Sale of Restricted Shares

Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. Upon the completion of this offering, we will have issued and outstanding an aggregate of shares of common stock. All of the shares of common stock to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any such shares which may be held or acquired by an "affiliate" of ours, as that term is defined in Rule 144 promulgated under the Securities Act, or "Rule 144," which shares will be subject to the volume limitations and other restrictions of Rule 144 described below.

Rule 144

The shares of our common stock being sold in this offering will generally be freely tradable without restriction or further registration under the Securities Act, except that any shares of our common stock held by an "affiliate" of ours may not be resold publicly except in compliance with the registration requirements of the Securities Act or under an exemption under Rule 144 or otherwise. Rule 144 permits our common stock that has been acquired by a person who is an affiliate of ours, or has been an affiliate of ours within the past three months, to be sold into the market in an amount that does not exceed, during any three-month period, the greater of:

- 1% of the total number of shares of our common stock outstanding which will equal approximately shares after this offering; or
- the average weekly reported trading volume of our common stock on The NASDAQ Capital Market for the four calendar weeks prior to the sale.

Such sales are also subject to specific manner-of-sale provisions, a six-month holding period requirement for restricted securities, notice requirements and the availability of current public information about us.

Rule 144 also provides that a person who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has for at least six months beneficially owned shares of our common stock that are restricted securities, will be entitled to freely sell such shares of our common stock subject only to the availability of current public information about us. A person who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has for at least one year beneficially owned shares of our common stock that are restricted securities, will be entitled to freely sell such shares of common stock under Rule 144 without regard to the public information requirements of Rule 144.

CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS

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

The discussion below of 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 (or any other entity treated as a corporation for U.S. federal income tax purposes) 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 (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.

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, state, local, non-U.S. income and other tax considerations of acquiring, holding and disposing of shares of our common stock and warrants.

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.

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

Allocation of Purchase Price and Characterization of a Unit

There is no authority addressing the treatment, for U.S. federal income tax purposes, of securities with terms substantially the same as the units being offered in this offering, and, therefore, that treatment is not entirely clear. Each unit may be treated for U.S. federal income tax purposes as an investment unit consisting of one shares of our common stock, one Series A Warrant and one Series B Warrant (to purchase one share of our common stock and one Series A Warrant). 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, right or warrant, as the case may be. Similarly, upon the exercise of a Series B Warrant, the holder's tax basis in the Series B Warrant and the exercise price paid on exercise of such Series B Warrant may be required to be allocated amount the common stock and warrant obtainable upon exercise.

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 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.

In general, distributions on shares of our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent any such distributions exceed both our current and our accumulated earnings and profits, they will first be treated as a return of capital reducing a non-U.S. holder's tax basis in our common stock (determined on a share by share basis), but not below zero, and thereafter will be treated as gain from the sale of such stock, the treatment of which is discussed below under "Gain on Disposition of Shares of Common Stock."

As discussed under "Dividend Policy" above, we do not currently expect to pay dividends. In the event that we do pay dividends, dividends paid to a non-U.S. holder generally will be subject to a U.S. federal withholding tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder of shares of our common stock who wishes to claim the benefit of an applicable treaty rate (and avoid backup withholding, as discussed below) for dividends generally will be required (a) to complete IRS Form W-8BEN (or other applicable form) and certify under penalty of perjury that such holder is not a "United States person" as defined under the Code and is eligible for treaty benefits, or (b) if shares of our common stock are held through certain foreign intermediaries (including certain foreign partnerships), satisfy the relevant certification requirements of applicable U.S. Treasury Regulations. This certification must be provided to us or our paying agent prior to the payment to the non-U.S. holder of any dividends, and may be required to be updated periodically.

Gain on Disposition of our Securities

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

- the gain is effectively connected with a trade or business carried on by the non-U.S. holder within the United States (in which case the branch profits tax discussed above may also apply if the non-U.S. holder is a corporation) and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment of the non-U.S. holder maintained in the United States;
- the non-U.S. holder is an individual and is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are satisfied; or
- we are or have been a U.S. real property holding corporation (a "USRPHC") for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held such securities.

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

The tax consequences of a cashless exercise of a warrant are not clear under current tax law. A cashless exercise may be tax-free, either because the exercise is not a gain realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either tax-free situation, a non-U.S. holder's basis in the common stock or warrant received would equal the holder's basis in the warrant. If the cashless exercise were treated as not being a gain realization event, a non-U.S. holder's holding period in the common stock or warrant would be treated as commencing on the date following the date of exercise of the warrant. If the cashless exercise were treated as a recapitalization, the holding period of the common stock or warrant would include the holding period of the warrant being exercised. It is also possible that a cashless exercise could be treated as a taxable exchange in which gain or loss would be recognized. In such event, a non-U.S. holder could be deemed to have surrendered warrants equal to the number of shares of common stock and warrants having a value equal to the exercise price for the total number of warrants to be exercised. The non-U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the common stock or warrants represented by the warrants deemed surrendered and the non-U.S. holder's tax basis in the warrants deemed surrendered. In this case, a non-U.S. holder's tax basis in the common stock received or warrants would equal the sum of the fair market 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 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 Internal Revenue Service (referred to as the "IRS") and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated. Copies of this information also may be made available under the provisions of a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

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

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

- a U.S. person;
- a "controlled foreign corporation" for U.S. federal income tax purposes;
- a foreign person, 50% or more of whose gross income from certain periods is effectively connected with a U.S. trade or business; or
- 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, 2017. Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We have entered into an underwriting agreement with Roth Capital Partners, LLC. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase from us, the units offered hereby. Our common stock trades on the NASDAQ Capital Market under the symbol “DCTH.”

Underwriter	Number of Units
Roth Capital Partners, LLC	

Units sold by the underwriter to the public will be offered at the public offering price set forth on the cover of this prospectus.

Discounts, Commissions and Expenses

We estimate that the total fees and expenses payable by us, excluding underwriting discounts and commissions, will be approximately $300,000. The following table shows the underwriting discounts to be paid to the underwriter by us in connection with this offering:

	Underwriting Discount
Per unit paid by us	$
Total	

We have agreed to reimburse a portion of the expenses of the underwriter in connection with this offering up to a maximum of $50,000.

In addition, upon any exercise of warrants having an expiration equal to or less than 18 months sold in this offering, we will pay the underwriter a solicitation fee equal to 4.0% of the gross proceeds we receive from such exercise. We will provide the underwriter with written notice of each exercise of warrants within three business days of the applicable exercise date. Any such fees will be paid to the underwriter not less than five (5) business days after receipt by us of any cash proceeds from the exercise of warrants.

The offering price and terms of the offering were established through arms-length negotiation between us and the underwriter with consideration given to the trading price of our common stock as reported on the NASDAQ Capital Market.

Indemnification

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

Lock-Up Agreements

We have agreed not to (i) offer, pledge, issue, sell, contract to sell, purchase, contract to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock; (ii) enter into any swap or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of shares of common stock; or (iii) file any registration statement with the SEC relating to the offering of any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, without the prior written consent of the representative for a period of 30 days following the date of this prospectus, subject to an 18-day extension under certain circumstances (the “Lock-up Period”), for a price less than the public offering price per unit. This consent may be given at any time without public notice. These restrictions on future issuances do not apply to the securities to be sold in this offering.

In addition, each of our directors and executive officers has entered into a lock-up agreement with the underwriter. Under the lock-up agreements, the directors and executive officers may not, directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to

otherwise dispose of, any shares of our common stock (including, without limitation, common stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act or securities convertible into or exercisable or exchangeable for our common stock, (ii) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of the beneficially owned shares or securities convertible into or exercisable or exchangeable for common stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or (iii) engage in any short selling of the common stock or securities convertible into or exercisable or exchangeable for common stock. The restrictions on future dispositions by our directors and officers are subject to exceptions for (i) one or more bona fide gift transfers of securities to immediate family members or to a trust, family partnership or family company the beneficiaries of which are exclusively members of immediate family, (ii) by will or intestate succession upon the death or (iii) as a bona fide gift. In addition, these restrictions shall not apply to sales of common stock by our directors and executive officers (i) pursuant to any trading plan established pursuant to Rule 10b5-1 of the Exchange Act, (ii) constituting restricted stock outstanding prior to the date hereof that vests during the Lock-Up Period, solely to the extent necessary to generate proceeds to fund any income taxes resulting from such vesting, and (iii) issued upon the exercise of stock options granted prior to the date hereof and scheduled to expire within six (6) months of the date hereof, solely to the extent necessary to generate proceeds to fund the exercise price thereof and any income taxes resulting from such exercise.

Electronic Distribution

This prospectus may be made available in electronic format on websites or through other online services maintained by the underwriter or by its affiliates. In those cases, prospective investors may view offering terms online and prospective investors may be allowed to place orders online. Other than this prospectus in electronic format, the information on the underwriter's website or our website and any information contained in any other websites maintained by the underwriters or by us 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 underwriter in its capacity as underwriter, and should not be relied upon by investors.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. A naked short position occurs if the underwriter sells more shares than could be covered by the over-allotment option. This position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be discontinued at any time.

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

Selling Restrictions

European Economic Area

This prospectus does not constitute an approved prospectus under Directive 2003/71/EC and no such prospectus is intended to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented Directive 2003/71/EC (each, a "Relevant Member State") an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any shares of common stock may be made at any time under the following exemptions under the Prospectus Directive, if and to the extent that they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives of the underwriter for any such offer; or

(c) in any other circumstances which do not require any person to publish 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 shares of common stock 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 shares of common stock to be offered so as to enable an investor to decide to purchase any shares of common stock, as the expression 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 any amendments thereto including the 2010 PD Amending Directive to the extent implemented in each Relevant Member State) and includes any relevant implementing measure in each Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

This prospectus is not an approved prospectus for purposes of the UK Prospectus Rules, as implemented under the EU Prospectus Directive (2003/71/EC), and have not been approved under section 21 of the Financial Services and Markets Act 2000 (as amended) (the "FSMA") by a person authorized under FSMA. The financial promotions contained in this prospectus are directed at, and this prospectus is only being distributed to, (1) persons who receive this prospectus outside of the United Kingdom, and (2) persons in the United Kingdom who fall within the exemptions under articles 19 (investment professionals) and 49(2)(a) to (d) (high net worth

companies, unincorporated associations, etc.) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (all such persons together being referred to as “Relevant Persons”). This prospectus must not be acted upon or relied upon by any person who is not a Relevant Person. Any investment or investment activity to which this prospectus relates is available only to Relevant Persons and will be engaged in only with Relevant Persons. This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person that is not a Relevant Person.

The underwriter has represented, warranted and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA in connection with the issue or sale of any of the shares of common stock 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 shares of common stock in, from or otherwise involving the United Kingdom.

LEGAL MATTERS

Certain legal matters will be passed upon for us by Morgan, Lewis & Bockius LLP, New York, New York, including the validity of the common stock offered hereby. Certain legal matters will be passed upon for the underwriter by LeClairRyan, A Professional Corporation.

EXPERTS

The consolidated financial statements of Delcath Systems, Inc. at December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014 included in Delcath Systems, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2014, have been audited by Ernst & Young LLP, predecessor independent registered public accounting firm, as set forth in their respective report thereon, included therein, and incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

INFORMATION INCORPORATED BY REFERENCE

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

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2014;
- our Quarterly Report on Form 10-Q for the period ended March 31, 2015;
- our Definitive Proxy Statement on Schedule 14A, filed on April 29, 2015 (solely to the extent incorporated by reference into Part III of our Annual Report on Form 10-K for the year ended December 31, 2014);
- our Current Reports on Form 8-K, filed on February 10, 2015, February 17, 2015, March 11, 2015, March 16, 2015, March 27, 2015, May 26, 2015 and June 11, 2015; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed on September 22, 2000, including all amendments and reports filed for the purpose of updating such description.

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

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus, other than exhibits which are specifically incorporated by reference into such documents. Requests should be directed our Secretary at Delcath Systems, Inc., 1301 Avenue of the Americas, 43rd Floor, New York, New York 10019 or by calling us at 212-489-2100.

Units
Each Unit Consisting of One Share of Common Stock
and
One Series A Warrant to Purchase One Share of Common Stock
and
One Series B Warrant to Purchase One Share of Common Stock and One Series A Warrant

Delcath Systems, Inc.

PRELIMINARY PROSPECTUS

Roth Capital Partners

, 2015

PART II

Item 13. Other expenses of issuance and distribution

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

SEC registration fee	$ 1,162
FINRA filing fee	2,000
Legal fees and expenses	150,000
Accounting fees and expenses	100,000
Printing and engraving expenses	30,000
Transfer agent and registrar fees and expenses	10,000
Other expenses	6,838
Total	$300,000

Item 14. Indemnification of directors and officers

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

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

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

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

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

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

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

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

Item 15. Recent sales of unregistered securities

None.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

The exhibit index attached hereto is incorporated herein by reference.

(b) Financial Statement Schedule

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

Item 17. Undertakings

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

(2) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being

registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(3) The undersigned registrant hereby undertakes that:

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

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, Delcath Systems, Inc., a Delaware corporation, has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on July 2, 2015.

DELCATH SYSTEMS, INC.

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

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

SIGNATURE	TITLE	DATE
/s/ Jennifer K. Simpson, Ph.D. Jennifer K. Simpson, Ph.D.	President and Chief Executive Officer (Principal Executive Officer)	July 2, 2015
/s/ Barbra C. Keck, M.B.A. Barbra C. Keck, M.B.A.	Senior Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	July 2, 2015
* Roger G. Stoll, Ph.D.	Executive Chairman of the Board	July 2, 2015
* Harold S. Koplewicz, M.D.	Director	July 2, 2015
* Dennis H. Langer, M.D., J.D.	Director	July 2, 2015
* Laura A. Philips, Ph.D., M.B.A.	Director	July 2, 2015
* William D. Rueckert	Director	July 2, 2015
* Marco Taglietti, M.D.	Director	July 2, 2015

*By: /s/ Barbra C. Keck, M.B.A.
Attorney-in-Fact

Table of Contents

EXHIBIT INDEX

Exhibit	Description
1.1	Form of Underwriting Agreement*
1.2	Form of Series A Warrant*
1.3	Form of Series B Warant*
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended to June 30, 2005 (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed June 5, 2006 (Commission File No. 001-16133)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective as of April 8, 2014 (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed April 8, 2014 (Commission File No. 001-16133)
3.2	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2 (Registration No. 333-39470))
5.1	Opinion of Morgan, Lewis & Bockius LLP*
23.1	Consent of Ernst & Young LLP*
23.2	Consent of Morgan, Lewis & Bockius LLP (included as part of Exhibit 5.1)*
24.1	Powers of Attorney (included on signature page to this Registration Statement)**

* Filed herewith

** Previously filed

Exhibit 1.1

DELCATH SYSTEMS, INC.

[-] Units

UNDERWRITING AGREEMENT

June [-], 2015

Roth Capital Partners, LLC
888 San Clemente Drive
Newport Beach, CA 92660

Ladies and Gentlemen:

1. *INTRODUCTORY*. Delcath Systems, Inc., a Delaware corporation (the "*Company*"), proposes to sell, pursuant to the terms of this Agreement, to you (the "Underwriter") an aggregate of [-] units (the "Units"), consisting of (i) [-] shares (the *"Stock"*) of common stock, $0.01 par value of the Company (the *"Common Stock"),* (ii) [-] Series A warrants to purchase [-] additional shares of Common Stock (the "Series A Warrants"), and (iii) [-] Series B warrants to purchase [-] additional shares of Common Stock and [-] additional Series A Warrants to purchase [-] additional shares of Common Stock (the "Series B Warrants"). The Series A Warrants, including the Series A Warrants issuable upon exercise of the Series B Warrants, and the Series B Warrants are collectively referred to as the "*Warrants*." The shares of Common Stock underlying the Warrants are collectively referred to as the "*Warrants Shares*." The Stock, the Warrants and the Warrant Shares are collectively referred to as the *"Securities."* The terms of the Series A Warrants and Series B Warrants are set forth in the form of Series A Warrant and Series B Warrant, respectively, attached as Exhibit A and Exhibit B hereto.

2. *REPRESENTATIONS AND WARRANTIES OF THE COMPANY*. The Company represents and warrants to the Underwriter, as of the date hereof and as of the Closing Date (as defined below), and agrees with the Underwriter, that:

(a) *Filing of Registration Statement*. The Company has prepared and filed, in conformity with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the published rules and regulations thereunder (the "*Rules and Regulations*") adopted by the Securities and Exchange Commission (the "Commission"), a registration statement, including a prospectus, covering the Securities on Form S-1 (File No. 333-204979), and such amendments to such registration statement (including post effective amendments) as may have been required to the date of this Agreement. Such registration statement, as amended (including any post effective amendments), has been declared effective by the Commission. Such registration statement, including amendments thereto (including post effective amendments thereto) at the time of effectiveness thereof (the "*Effective Time*"), the exhibits and any schedules thereto at the Effective Time or thereafter during the period of effectiveness and the documents and information otherwise deemed to be a part thereof or included therein by the Securities Act or otherwise pursuant to the Rules and Regulations at the Effective Time or thereafter during the period of effectiveness, is herein called the "Registration Statement." If the Company has filed or files an abbreviated registration statement to register additional Securities pursuant to Rule 462(b)

under the Rules and Regulation (the "*Rule 462(b) Registration Statement*"), then any reference herein to the term "Registration Statement" shall also be deemed to include such Rule 462(b) Registration Statement. Any preliminary prospectus included in the Registration Statement or filed with the Commission pursuant to Rule 424(a) under the Securities Act is hereinafter called a "Preliminary Prospectus." The Preliminary Prospectus relating to the Securities that was included in the Registration Statement immediately prior to the pricing of the offering contemplated hereby is hereinafter called the "Pricing Prospectus."

The Company shall file with the Commission pursuant to Rule 424 under the Securities Act a final prospectus relating to the Securities, which includes the information permitted to be omitted therefrom at the Effective Time by Rule 430A under the Securities Act, and such final prospectus, as filed, is hereinafter called the "Final Prospectus." The Final Prospectus, the Pricing Prospectus and any Preliminary Prospectus in the form in which they were included in the Registration Statement or filed with the Commission pursuant to Rule 424 under the Securities Act is hereinafter called a "Prospectus."

For purposes of this Agreement, all references to the Registration Statement, the Rule 462(b) Registration Statement, the Pricing Prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System ("EDGAR"). All references in this Agreement to amendments or supplements to the Registration Statement, the Rule 462(b) Registration Statement, the Pricing Prospectus or the Prospectus shall be deemed to mean and include the subsequent filing of any document under the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), and which is deemed to be incorporated therein by reference.

(b) *Effectiveness of Registration Statement; Certain Defined Terms*.

i. At each time of effectiveness, at the date hereof and at the Closing Date, the Registration Statement and any post-effective amendment thereto complied or will comply in all material respects with the requirements of the Securities Act and the Rules and Regulations and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Disclosure Package (as defined in Section 1(b)(iii)(A)(1) below) as of the date hereof and at the Closing Date, any roadshow or investor presentations delivered to and approved by the Underwriter for use in connection with the marketing of the offering of the Securities as of the time of their use and at the Closing Date, and the Prospectus, as amended or supplemented, as of its date, at the time of filing pursuant to Rule 424(b) under the Securities Act and at the Closing Date did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences shall not apply to statements in or omissions from the Registration Statement, the Disclosure Package or any Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for use in the preparation thereof, which information

the parties hereto agree is limited to the Underwriter's Information (as defined in Section 17 hereof). The Registration Statement contains all exhibits and schedules required to be filed by the Securities Act or the Rules and Regulations. No order preventing or suspending the effectiveness or use of the Registration Statement or any Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission.

ii. The Company has not distributed any prospectus or other offering material in connection with the offering and sale of the Securities other than the Disclosure Package.

iii. (A) The Company has provided a copy to the Underwriter of each Issuer Free Writing Prospectus (as defined below) used in the sale of the Securities. The Company has filed all Issuer Free Writing Prospectuses required to be so filed with the Commission, and no order preventing or suspending the effectiveness or use of any Issuer Free Writing Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission. When taken together with the rest of the Disclosure Package or the Final Prospectus, since its first use and at all relevant times since then, no Issuer Free Writing Prospectus has, does or will include (1) any untrue statement of a material fact or omission to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or (2) information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Final Prospectus. The representations and warranties set forth in the immediately preceding sentence shall not apply to statements in or omissions from the Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for use in the preparation thereof. As used in this paragraph and elsewhere in this Agreement:

(1) "Disclosure Package" means the Pricing Prospectus, each Issuer Free Writing Prospectus, and the pricing information set forth on Schedule II.

(2) "Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the Rules and Regulations relating to the Securities in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) of the Rules and Regulations.

(3) "Time of Sale" means [-] [a/p.]m., New York city time, on the date of this Agreement.

(B) Each Issuer Free Writing Prospectus satisfied, as of its issue date and at all subsequent times through the Prospectus Delivery Period (as defined below in Section 1(c)), all other conditions as may be applicable to its use as set forth in Rules 164 and 433 of the Rules and Regulations, including any legend, record-keeping or other requirements.

(c) *Contents of Registration Statement*. The Registration Statement complied when it became effective, complies as of the date hereof and, as amended or supplemented, at the Time of Sale and at all times during which a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with any sale of Securities (the "*Prospectus Delivery Period*"), will comply, in all material respects, with the requirements of the Securities Act and the Rules and Regulations; the Registration Statement did not, as of the Effective Time, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading, *provided*, that the Company makes no representation or warranty in this Section 2(c) with respect to statements in or omissions from the Registration Statement in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriter's Information.

(d) *Contents of Prospectus*. The Final Prospectus will comply, as of the date that it is filed with the Commission, the date of its delivery to prospective purchasers and at all times during the Prospectus Delivery Period, in all material respects, with the requirements of the Securities Act; at no time during the period that begins on the date the Final Prospectus is filed with the Commission and ends at the end of the Prospectus Delivery Period will the Prospectus, as then amended or supplemented, include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, *provided*, that the Company makes no representation or warranty with respect to statements in or omissions from the Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriter's Information.

(e) *Incorporated Documents*. Each of the documents incorporated or deemed to be incorporated by reference in the Registration Statement, at the time such document was filed with the Commission or at the time such document became effective, as applicable, complied, in all material respects, with the requirements of the Exchange Act, were filed on a timely basis with the Commission and did not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(f) *Disclosure Package*. The Disclosure Package, as of the Time of Sale, did not, and at the Closing Date will not, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided*, that the Company makes no representations or warranty in this Section 2(f) with respect to statements in or omissions from the Disclosure Package in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriter's Information.

(g) *Distributed Materials; Conflict with Registration Statement*. Other than each Prospectus, the Company has not made, used, prepared, authorized, approved or referred to and will not make, use, prepare, authorize, approve or refer to any "written communication" (as defined in Rule 405 under the Securities Act) that constitutes an offer to sell or a solicitation of an offer to buy the Securities other than (i) any document not constituting a prospectus pursuant to Section 2(a)(10)(a) of the Securities Act or Rule 134 under the Securities Act or (ii) the documents listed on Schedule I hereto and other written communications approved in advance by the Underwriter.

(h) *Issuer Free Writing Prospectuses*. Each Issuer Free Writing Prospectus, if any, conformed or will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations on the date of first use, and the Company has complied or will comply with any filing requirements applicable to such Issuer Free Writing Prospectus pursuant to the Rules and Regulations. Each Issuer Free Writing Prospectus, if any, when considered together with the Disclosure Package, as of its issue date and at all subsequent times through the completion of the Prospectus Delivery Period did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein and any prospectus supplement deemed to be a part thereof that has not been superseded or modified; or includes an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading; *provided*, that the Company makes no representation or warranty with respect to statements in or omissions from any Issuer Free Writing Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriter's Information.

(i) *Not an Ineligible Issuer*. (1) At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) under the Securities Act) of the Securities and (2) at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 ("*Rule 405*") under the Securities Act.

(j) *Due Incorporation*. The Company and each Subsidiary (defined below) has been duly organized and is validly existing as a corporation in good standing under the laws of its jurisdiction of organization, with the corporate power and authority to own its properties and to conduct its business as currently being conducted and as described in the Registration Statement, the Final Prospectus and the Disclosure Package. The Company and each Subsidiary is duly qualified to transact business and is in good standing as a foreign corporation or other legal entity in each other jurisdiction in which its ownership or leasing of property or the conduct of its business requires such qualification, except where the failure to be so qualified and in good standing or have such power or authority (i) would not have, individually or in the aggregate, a material adverse effect upon, the general affairs, business, operations, prospects, properties, financial condition, or results of operations of the Company, taken as a whole, or (ii) impair in any material respect the power or ability of the Company to perform its obligations under this Agreement or to consummate any transactions contemplated by this Agreement, including the issuance and sale of the Securities (any such effect as described in clauses (i) or (ii), a "*Material Adverse Effect*").

(k) *Subsidiaries*. The Company has no subsidiaries (as defined in Rule 405 of the Securities Act) other than those entities listed on Schedule V hereto (each a "Subsidiary" and collectively, the "Subsidiaries"). The Company, directly or indirectly, owns all of the issued and outstanding capital stock or other equity interests of each Subsidiary and, except as otherwise described in the Disclosure Package, does not own any beneficial interest, directly or indirectly, in any other corporation, partnership, joint venture or other business entity.

(l) *Due Authorization and Enforceability*. The Company has the full right, power and authority to enter into this Agreement and the Warrants and to perform and discharge its obligations hereunder and thereunder; and this Agreement and the Warrants have been duly authorized, executed and delivered by the Company, and each constitutes the valid, legal and binding obligation of the Company, enforceable against the Company in accordance with their respective terms, except as rights to indemnity hereunder may be limited by federal or state securities laws and except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and subject to general principles of equity.

(m) *The Stock*. The issuance of the Stock has been duly and validly authorized by the Company and when issued, delivered and paid for in accordance with the terms of this Agreement, will have been duly and validly issued and will be fully paid and nonassessable, will not be subject to any statutory or contractual preemptive rights or other rights to subscribe for or purchase or acquire any shares of Common Stock of the Company, which have not been waived or complied with and will conform in all material respects to the description thereof contained in the Disclosure Package and the Final Prospectus and such description conforms in all material respects to the rights set forth in the instruments defining the same. The Warrant Shares have been duly authorized and reserved for issuance pursuant to the terms of the Warrants, and when issued by the Company upon valid exercise of the Warrants and payment of the exercise price, will be duly and validly issued, fully paid and nonassessable and free of any preemptive or similar rights and will conform to the description thereof and contained in the Disclosure Package and the Final Prospectus.

(n) *Capitalization*. The information set forth under the caption "Capitalization" in the Registration Statement, Disclosure Package and the Final Prospectus is fairly presented on a basis consistent with the Company's financial statements. The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in the Final Prospectus under the captions "Description of Capital Stock" and "Description of the Securities We Are Offering" and in the Disclosure Package. The issued and outstanding shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and nonassessable, and have been issued in compliance with all federal and state securities laws. None of the outstanding shares of Common Stock was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase or acquire any securities of the Company. There are no authorized or outstanding shares of capital stock, options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable for, any capital stock of the Company other than those described in the Registration Statement, Disclosure Package, and the Final Prospectus. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, as described in the Registration Statement, Disclosure Package, and the Final Prospectus, accurately and fairly present the information required to be shown with respect to such plans, arrangements, options and rights.

(o) *No Conflict*. The execution, delivery and performance by the Company of this Agreement and the Warrants and the consummation of the transactions contemplated hereby, and thereby including the issuance and sale by the Company of the Securities, will not conflict with or result in a breach or violation of, or constitute a default under (nor constitute any event which with notice, lapse of time or both would result in any breach or violation of or constitute a default under), give rise to any right of termination or other right or the cancellation or acceleration of any right or obligation or loss of a benefit under, or give rise to the creation or imposition of any lien, encumbrance, security interest, claim or charge upon any property or assets of the Company or any Subsidiary pursuant to (i) any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any Subsidiary is a party or by which any of them or any of their respective properties may be bound or to which any of the property or assets of the Company or any Subsidiary is subject, (ii) result in any violation of the provisions of the charter or by-laws of the Company or any Subsidiary, or (iii) result in any violation of any law, statute, rule, regulation, judgment, order or decree of any court or governmental agency or body, domestic or foreign, having jurisdiction over the Company or any Subsidiary or any of their properties or assets.

(p) *No Consents Required*. No approval, authorization, consent or order of or filing, qualification or registration with, any court or governmental agency or body, foreign or domestic, which has not been made, obtained or taken and is not in full force and effect, is required in connection with the execution, delivery and performance of this Agreement or the Warrants by the Company, the issuance and sale of the Securities or the consummation by the Company of the transactions contemplated hereby or thereby other than (i) as may be required under the Securities Act, (ii) any necessary qualification of the Securities under the securities or blue sky laws of the various jurisdictions in which the Securities are being offered, (iii) under the rules and regulations of the Financial Industry Regulatory Authority ("*FINRA*") or (iv) the NASDAQ Capital Market in connection with the distribution of the Securities.

(q) *Preemptive Rights*. Except as otherwise described in the Registration Statement, the Final Prospectus and the Disclosure Package, there are no preemptive rights or other rights (other than rights which have been waived in writing in connection with the transactions contemplated by this Agreement or otherwise satisfied) to subscribe for or to purchase any shares of Common Stock or shares of any other capital stock or other equity interests of the Company, or any agreement or arrangement between the Company and any of the Company's stockholders, or to the Company's knowledge, between or among any of the Company's stockholders, which grant special rights with respect to any shares of the Company's capital stock or which in any way affect any stockholder's ability or right freely to alienate or vote such shares.

(r) *Registration Rights*. Except as otherwise described in the Registration Statement, Final Prospectus and the Disclosure Package, there are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights which have been waived in writing in connection with the transactions contemplated by this Agreement or otherwise satisfied) to require the Company to register any securities with the Commission.

(s) *Lock-Up Agreements*. The Company has received copies of the executed Lock-Up Agreements, substantially in the form of Exhibit B hereto (the "*Lock-Up Agreements*") executed by each person listed on Schedule III hereto, and such Lock-Up Agreements shall be in full force and effect on the Closing Date.

(t) *Independent Accountants*. Each of Ernst & Young LLP ("*E&Y LLP*"), whose reports on the consolidated financial statements of the Company are incorporated by reference in the Registration Statement, the Final Prospectus and the Disclosure Package, and Grant Thornton LLP ("*GT LLP*") is (A) an independent public accounting firm within the meaning of the Securities Act, (B) a registered public accounting firm (as defined in Section 2(a)(12) of the Sarbanes-Oxley Act of 2002 (the "*Sarbanes-Oxley Act*")), and (C) to the Company's knowledge, not in violation of the auditor independence requirements of the Sarbanes-Oxley Act.

(u) *Financial Statements*. The financial statements of the Company, together with the related schedules and notes thereto, included or incorporated by reference in the Registration Statement, Final Prospectus and the Disclosure Package, comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly in all material respects (i) the financial condition of the Company as of the dates indicated and (ii) the consolidated results of operations, stockholders' equity and changes in cash flows of the Company for the periods therein specified; and such financial statements and related schedules and notes thereto have been prepared in conformity with United States generally accepted accounting principles, consistently applied throughout the periods involved (except as otherwise stated therein and subject, in the case of unaudited financial statements, to the absence of footnotes and normal year-end adjustments). There are no other financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement, the Final Prospectus or the Disclosure Package; and all disclosures contained in the Registration Statement, the Disclosure Package and the Final Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act and Item 10(e) of Regulation S-K under the Securities Act, to the extent applicable, and present fairly the information shown therein and the Company's basis for using such measures.

(v) *Absence of Material Changes*. Subsequent to the respective dates as of which information is given in the Registration Statement, the Final Prospectus and the Disclosure Package, and except as may be otherwise stated or incorporated by reference in the Registration Statement, the Final Prospectus and the Disclosure Package, there has not been (i) any Material Adverse Effect, (ii) any transaction which is material to the Company or any Subsidiary, (iii) any obligation, direct or contingent (including any off-balance sheet obligations), incurred by the Company or any Subsidiary, which is material to the Company, (iv) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company, (v) any change in the capital stock (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants or the conversion of convertible indebtedness), or material change in the short-term debt or long-term debt of the Company or any Subsidiary (other than upon conversion of convertible indebtedness) or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock (other than grants of stock options under the Company's stock option plans existing on the date hereof) of the Company or any Subsidiary.

(w) *Legal Proceedings*. There are no legal or governmental actions, suits, claims or proceedings pending or, to the Company's knowledge, threatened or contemplated to which the Company or any Subsidiary is or would be a party or of which any of their respective properties is or would be subject at law or in equity, before or by any federal, state, local or foreign governmental or regulatory commission, board, body, authority or agency, or before or by any self-regulatory organization or other non-governmental regulatory authority (including, without limitation, the Food and Drug Administration of the U.S. Department of Health and Human Services (the "*FDA*")) which are required to be described in the Registration Statement, the Disclosure Package or the Final Prospectus and are not so described therein, or which, singularly or in the aggregate, if resolved adversely to the Company or any Subsidiary, would reasonably be likely to result in a Material Adverse Effect or prevent or materially and adversely affect the ability of the Company to consummate the transactions contemplated hereby.

(x) *No Violation*. Neither the Company nor any Subsidiary is in breach or violation of or in default (nor has any event occurred which with notice, lapse of time or both would result in any breach or violation of, or constitute a default) (i) under the provisions of its charter or bylaws (or analogous governing instrument, as applicable) or (ii) in the performance or observance of any term, covenant, obligation, agreement or condition contained in any indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any license, lease, contract or other agreement or instrument to which the Company or any Subsidiary is a party or by which it or any of its properties may be bound or affected, or (iii) in the performance or observance of any statute, law, rule, regulation, ordinance, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any Subsidiary or any of its properties, as applicable (including, without limitation, those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), except, with respect to clauses (ii) and (iii) above, to the extent any such contravention has been waived or would not result in a Material Adverse Effect.

(y) *Permits*. The Company and each Subsidiary has made all filings, applications and submissions required by, and owns or possesses all approvals, licenses, certificates, certifications, clearances, consents, exemptions, marks, notifications, orders, permits and other authorizations issued by, the appropriate federal, state or foreign regulatory authorities (including, without limitation, the FDA, and any other foreign, federal state or local government or regulatory authorities performing functions similar to those performed by the FDA) necessary to conduct its business as described in the Disclosure Package and the Final Prospectus (collectively, "*Permits*"), except for such Permits which the failure to obtain would not have a Material Adverse Effect (the "*Immaterial Permits*"), and is in compliance in all material respects with the terms and conditions of all such Permits other than the Immaterial Permits (the "*Required Permits*"). All such Required Permits held by the Company or any Subsidiary are valid and in full force and effect. Neither the Company nor any Subsidiary has received any notice of any proceedings relating to revocation or modification of, any such Required Permit, which, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect.

(z) *Not an Investment Company*. Neither the Company nor any Subsidiary is or, after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Disclosure Package and the Final Prospectus, will be (i) required to register as

an "investment company" as defined in the Investment Company Act of 1940, as amended (the "*Investment Company Act*"), and the rules and regulations of the Commission thereunder or (ii) a "business development company" (as defined in Section 2(a)(48) of the Investment Company Act).

(aa) *No Price Stabilization*. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any of the Company's or any Subsidiary's officers, directors, affiliates or controlling persons has taken or will take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in, or which has constituted or which might reasonably be expected to constitute the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(bb) *Good Title to Property*. The Company and each Subsidiary has good and marketable title to all property (whether real or personal) described in the Registration Statement, the Disclosure Package and the Final Prospectus as being owned by it, in each case free and clear of all liens, claims, security interests, other encumbrances or defects (collectively, "*Liens*"), except such as are described in the Registration Statement, the Disclosure Package and the Final Prospectus and those that would not, individually or in the aggregate materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or any Subsidiary. All of the property described in Disclosure Package and the Final Prospectus as being held under lease by the Company or any Subsidiary is held thereby under leases that are in full force and effect.

(cc) *Intellectual Property Rights*. The Company and each Subsidiary owns or possesses the right to use all patents, trademarks, trademark registrations, service marks, service mark registrations, trade names, copyrights, licenses, inventions, software, databases, know-how, Internet domain names, trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures, and other intellectual property (collectively, "*Intellectual Property*") necessary to carry on their respective businesses as currently conducted, and as proposed to be conducted and described in the Disclosure Package and the Final Prospectus, and neither the Company nor any Subsidiary is aware of any claim to the contrary or any challenge by any other person to the rights of the Company or any Subsidiary with respect to the foregoing except for those that could not have a Material Adverse Effect. The Intellectual Property licenses described in the Disclosure Package and the Final Prospectus are, to the knowledge of the Company, valid, binding upon, and enforceable by or against the parties thereto in accordance to their terms. The Company and each Subsidiary has complied in all material respects with, and is not in breach nor has received any asserted or threatened claim of breach of, any Intellectual Property license, and neither the Company nor any Subsidiary has knowledge of any breach or anticipated breach by any other person to any Intellectual Property license. The Company's and each Subsidiary's businesses as now conducted and as proposed to be conducted, to the knowledge of the Company, do not and will not infringe or conflict with any patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses or other Intellectual Property or franchise right of any person. Neither the Company nor any Subsidiary has received notice of any material claim against the Company or any Subsidiary alleging the infringement by the Company or any Subsidiary of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. The Company and each Subsidiary has taken all reasonable steps to protect, maintain and safeguard its rights in all Intellectual Property, including the execution of appropriate

intellectual property assignment, nondisclosure and confidentiality agreements, and no current or former employee or contractor is in violation of any such agreement or has retained any rights in such Intellectual Property. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's or any Subsidiary's right to own, use, or hold for use any of the Intellectual Property as owned, used or held for use in the conduct of the businesses as currently conducted. Neither the Company nor any Subsidiary has entered into any agreement to indemnify any third party against a claim of intellectual property infringement. The Company and each Subsidiary has duly and properly filed or caused to be filed with the United States Patent and Trademark Office (the "*PTO*") and applicable foreign and international patent authorities all patent applications owned by the Company or any Subsidiary (collectively, the "*Company Patent Applications*"). To the knowledge of the Company, the Company each Subsidiary has complied with the PTO's duty of candor and disclosure for the Company Patent Applications and has made no material misrepresentation in the Company Patent Applications. Neither the Company nor any Subsidiary is aware of any information material to a determination of patentability regarding the Company Patent Applications not called to the attention of the PTO or similar foreign authority. Neither the Company nor any Subsidiary is aware of any information not called to the attention of the PTO or similar foreign authority that would preclude the grant of a patent for the Company Patent Applications. Neither the Company nor any Subsidiary has knowledge of any information that would preclude the Company or any Subsidiary, as applicable, from having clear title to the Company Patent Applications. Neither the Company nor any Subsidiary has used any open source software in any Company product. The Company and each Subsidiary is in compliance with all relevant local, state, federal, and foreign laws related to the collection, storage and distribution of personally identifiable information and with all Company and any Subsidiary privacy policies and all applicable agreements. The consummation of the transactions contemplated by this Agreement will not violate any Company or any Subsidiary privacy obligations nor require the Company or any Subsidiary to provide any notice to, or seek any consent from, any employee, customer, supplier, service provide or other third party.

(dd) *No Labor Disputes*. No labor problem or dispute with the employees of the Company or any Subsidiary exists, or, to the Company's knowledge, is threatened or imminent, which would reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary is aware that any key employee or significant group of employees of the Company or any Subsidiary plans to terminate employment with the Company or any Subsidiary. Neither the Company nor any Subsidiary has engaged in any unfair labor practice; except for matters which would not, individually or in the aggregate, result in a Material Adverse Effect, (i) there is (A) no unfair labor practice complaint pending or, to the Company's knowledge, threatened against the Company or any Subsidiary before the National Labor Relations Board, and no grievance or arbitration proceeding arising out of or under collective bargaining agreements is pending or to the Company's knowledge, threatened, (B) no strike, labor dispute, slowdown or stoppage pending or, to the Company's knowledge, threatened against the Company and (C) no union representation dispute currently existing concerning the employees of the Company or any Subsidiary and (ii) to the Company's knowledge, (A) no union organizing activities are currently taking place concerning the employees of the Company and (B) there has been no violation of any federal, state, local or foreign law relating to discrimination in the hiring, promotion or pay of employees, any applicable wage or hour laws or any provision of the Employee Retirement Income Security Act of 1974 ("*ERISA*") or the rules and regulations promulgated thereunder concerning the employees of the Company or any Subsidiary.

(ee) *Taxes*. The Company and each Subsidiary has (i) timely filed all necessary federal, state, local and foreign income and franchise tax returns (or timely filed applicable extensions therefore) that have been required to be filed and (ii) is not in default in the payment of any taxes which were payable pursuant to said returns or any assessments with respect thereto, other than any which the Company or any Subsidiary is contesting in good faith and for which adequate reserves have been provided and reflected in the Company's financial statements included in the Registration Statement, the Disclosure Package and the Final Prospectus. Neither the Company nor any Subsidiary has any tax deficiency that has been or, to the knowledge of the Company, is reasonably likely to be asserted or threatened against it that would result in a Material Adverse Effect.

(ff) *ERISA*. The Company and each Subsidiary is in compliance in all material respects with all presently applicable provisions of ERISA; no "reportable event" (as defined in ERISA) has occurred with respect to any "pension plan" (as defined in ERISA) for which the Company or any Subsidiary would have any liability; neither the Company nor any Subsidiary has incurred and does not expect to incur liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "pension plan" or (ii) Sections 412 or 4971 of the Internal Revenue Code of 1986, as amended, including the regulations and published interpretations thereunder (the "*Code*"); and each "pension plan" for which the Company or any Subsidiary would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified in all material respects and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(gg) *Compliance with Environmental Laws*. The Company and each Subsidiary (i) is in compliance with any and all applicable foreign, federal, state and local laws, orders, rules, regulations, directives, decrees and judgments relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of human health and safety or the environment which are applicable to their businesses ("*Environmental Laws*"), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business; and (iii) is in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, individually or in the aggregate, result in a Material Adverse Effect. There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, individually or in the aggregate, result in a Material Adverse Effect.

(hh) *Insurance*. The Company and each Subsidiary maintains or is covered by insurance provided by recognized, financially sound and reputable institutions with insurance policies in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries. All such insurance is fully in force on the date hereof and will be fully in

force as of the Closing Date. Neither the Company nor any Subsidiary has reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect.

(ii) *Accounting Controls*. The Company and each Subsidiary maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(jj) *Disclosure Controls*. The Company and each Subsidiary has established, maintains and evaluates "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act), which (i) are designed to ensure that material information relating to the Company is made known to the Company's and any Subsidiary's principal executive officer and its principal financial officer by others within those entities, (ii) have been evaluated for effectiveness as of the end of the last fiscal period covered by the Registration Statement; and (iii) such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established. There are no significant deficiencies and material weaknesses in the design or operation of internal controls which could adversely affect the Company's or any Subsidiary's ability to record, process, summarize, and report financial data to management and the Board of Directors of the Company. The Company is not aware of any fraud, whether or not material, that involves management or other employees who have a role in the Company's or any Subsidiary's internal controls; and since the date of the most recent evaluation of such disclosure controls and procedures, there have been no significant changes in internal controls or in other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

(kk) *Contracts; Off-Balance Sheet Interests*. There is no document, contract, permit or instrument, or off-balance sheet transaction (including without limitation, any "variable interests" in "variable interest entities," as such terms are defined in Financial Accounting Standards Board Interpretation No. 46) of a character required by the Securities Act or the Rules and Regulations to be described in the Registration Statement, the Disclosure Package or the Final Prospectus or to be filed as an exhibit to the Registration Statement or document incorporated by reference therein, which is not described or filed as required. The contracts described in the immediately preceding sentence to which the Company or any Subsidiary is a party have been duly authorized, executed and delivered by the Company or such Subsidiary, constitute valid and binding agreements of the Company or such Subsidiary, are enforceable against and by the Company or such Subsidiary in accordance with the terms thereof and are in full force and effect on the date hereof.

(ll) *No Undisclosed Relationships*. No relationship, direct or indirect, exists between or among the Company on the one hand and the directors, officers, stockholders, customers or suppliers of the Company or any of their affiliates on the other hand, which is required to be described in the Registration Statement, Disclosure Package and the Final Prospectus or a document incorporated by reference therein and which has not been so described.

(mm) *Brokers Fees*. There are no contracts, agreements or understandings between the Company and any person (other than this Agreement) that would give rise to a valid claim against the Company or the Underwriter for a brokerage commission, finder's fee or other like payment in connection with the offering and sale of the Securities.

(nn) *Forward-Looking Statements*. No forward-looking statements (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Registration Statement, Disclosure Package, or the Final Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(oo) *NASDAQ; Exchange Act Registration*. The Common Stock is registered pursuant to Section 12(b) and/or 12(g) of the Exchange Act and is listed on the NASDAQ Capital Market, and the Company has taken no action designed to, or reasonably likely to have the effect of, termination the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NASDAQ Capital Market, nor has the Company received any notification that the Commission or the NASDAQ Capital Market is contemplating terminating such registration or listing. The Company has complied in all material respects with the applicable requirements of the NASDAQ Capital Market for maintenance of inclusion of the Common Stock thereon. The Company will file a notification of the listing of the Stock and the Warrant Shares on the NASDAQ Capital Market.

(pp) *Sarbanes-Oxley Act*. The Company, each Subsidiary, and to the Company's knowledge, all of the Company's and each Subsidiary's directors or officers, in their capacities as such, are in compliance in all material respects with all applicable effective provisions of the Sarbanes-Oxley Act and any related rules and regulations promulgated by the Commission. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it with the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(qq) *Corporate Records*. The minute books of the Company and each Subsidiary, representing all existing records of all meetings and actions of the board of directors (including, Audit, Compensation and Stock Option, and Nominating Committees) and stockholders of the Company and each Subsidiary (collectively, the "*Corporate Records*") through the date of the latest meeting and action have been made available to the Underwriter and counsel for the Underwriter. All such Corporate Records are complete and accurately reflect, in all material respects, all transactions referred to in such Corporate Records. There are no material transactions, agreements or other actions that have been consummated by the Company or any Subsidiary that are not properly approved and/or recorded in the Corporate Records of the Company and the Subsidiaries.

(rr) *Foreign Corrupt Practices*. Neither the Company, any Subsidiary, nor, to the Company's knowledge, any other person associated with or acting on behalf of the Company or any Subsidiary, including without limitation any director, officer, agent or employee of the Company or any Subsidiary, has, directly or indirectly, while acting on behalf of the Company or any Subsidiary (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity or failed to disclose fully any contribution in violation of law, (ii) made any payment to any federal or state governmental officer or official, or other person charged with similar public or quasi-public duties, other than payments required or permitted by the laws of the United States or any jurisdiction thereof, (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment.

(ss) *Statistical or Market-Related Data*. Any statistical, industry-related and market-related data included or incorporated by reference in the Registration Statement, the Final Prospectus or the Disclosure Package are based on or derived from sources that the Company reasonably and in good faith believes to be reliable and accurate, and such data agree with the sources from which they are derived.

(tt) *Money Laundering Laws*. The operations of the Company and each Subsidiary are and have been conducted at all times in compliance in all material respects with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "*Money Laundering Laws*") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending, or to the knowledge of the Company, threatened against the Company or any Subsidiary.

(uu) *OFAC*. Neither the Company, the Subsidiaries, nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("*OFAC*"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any affiliate, joint venture partner or other person or entity, which, to the Company's knowledge, will use such proceeds for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(vv) *Margin Securities*. The Company does not own any "margin securities" as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the "*Federal Reserve Board*"), and none of the proceeds of the sale of the Securities will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the Securities to be considered a "purpose credit" within the meanings of Regulation T, U or X of the Federal Reserve Board.

(ww) *Rated Securities*. At the Time of Sale there were, and as of the Closing Date there will be, no securities of or guaranteed by the Company that are rated by a "nationally recognized statistical rating organization," as that term is defined in Rule 436(g)(2) promulgated under the Securities Act.

(xx) *FINRA*. There are no affiliations or associations between (i) any member of FINRA and (ii) the Company or any of the Company's officers, directors or 5% or greater securityholders or any beneficial owner of the Company's unregistered equity securities that were acquired at any time on or after the one hundred eightieth (180th) day immediately preceding the date the Registration Statement was initially filed with the Commission, except as set forth in the Registration Statement, the Disclosure Package and the Final Prospectus.

(yy) *Exchange Act Requirements*. The Company has filed in a timely manner all reports required to be filed pursuant to Sections 13(a), 13(e), 14 and 15(d) of the Exchange Act during the preceding 12 months (except to the extent that Section 15(d) requires reports to be filed pursuant to Sections 13(d) and 13(g) of the Exchange Act, which shall be governed by the next clause of this sentence); and the Company has filed in a timely manner all reports required to be filed pursuant to Sections 13(d) and 13(g) of the Exchange Act since January 1, 2012, except where the failure to timely file could not reasonably be expected individually or in the aggregate to have a Material Adverse Effect.

(zz) *Trading Market*. No approval of the shareholders of the Company under the rules and regulations of any trading market (including Rule 5635 of the NASDAQ Marketplace Rules) is required for the Company to issue and deliver the Securities to prospective purchasers.

(aaa) *Form S-1*. The conditions for the use of Form S-1 to register the offering and sale of the Securities under the Securities Act, as set forth in the general instructions to such form, have been satisfied.

(bbb) *Regulatory Compliance*.

a. The clinical, pre-clinical and other studies and tests conducted by or on behalf of or sponsored by the Company or any Subsidiary or in which the Company or any Subsidiary or products or product candidates have participated that are described in the Registration Statement, the Disclosure Package and the Final Prospectus were and, if still pending, are being conducted in accordance in all material respects with all applicable federal, state or foreign statutes, laws, rules and regulations, as applicable (including, without limitation, those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA and current Good Laboratory and Good Clinical Practices) and in accordance in all material respects with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards. The descriptions in the Registration Statement, the Final Prospectus and the Disclosure Package of the results of such studies, tests and trials are accurate and complete in all material respects and fairly present the published data derived from such studies, tests and trials. Neither the Company nor any Subsidiary has received any notices or other correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those

performed by the FDA with respect to any ongoing clinical or pre-clinical studies or tests requiring the termination, suspension or material modification of such studies, tests or preclinical or clinical trials, which termination, suspension or material modification would reasonably be expected to result in a Material Adverse Effect. To the Company's knowledge, no filing or submission to the FDA or any other federal, state or foreign regulatory body, that is intended to be the basis for any approval, contains any material misstatement or omission. The Company and each Subsidiary is in compliance with all applicable federal, state, local and foreign laws, regulations, orders and decrees governing their business as prescribed by the FDA, or any other federal, state or foreign agencies or bodies, including those bodies and agencies engaged in the regulation of pharmaceuticals or biohazardous substances or materials, except where noncompliance would not, singly or in the aggregate, result in a Material Adverse Effect.

b. Neither the Company nor any Subsidiary has received any written notice or other communication from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA regarding non-compliance with the Federal Food, Drug, and Cosmetic Act ("*FDCA*") and applicable FDA regulations or similar laws, statutes, ordinances, rules, or regulations of any other foreign, federal, state or local governmental or regulatory authority, including, but not limited to, any regulatory or warning letter, untitled letter, adverse inspection finding, finding of deficiency, any other compliance or enforcement action. To the Company's knowledge, there has not been any non-compliance with or violation of any statute, law, rule, regulation, ordinance, judgment, injunction, writ, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company, any Subsidiary or any of their properties, as applicable (including, without limitation, the Public Health Service Act, the FDCA and those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), that could reasonably be expected to require the issuance of any such communication, or an investigation, corrective action or enforcement action by the FDA or similar governmental or regulatory authorities. To the Company's knowledge, no review or investigation by governmental or regulatory authorities is pending and no such review or investigation has been threatened.

c. Neither the Company, any Subsidiary nor, to the Company's knowledge, any of their respective directors, officers, employees or agents has been convicted of any crime or has been the subject of an FDA debarment proceeding. Neither the Company nor any Subsidiary has been nor is now subject to FDA's Applications Integrity Policy. To the Company's knowledge, neither the Company, any Subsidiary nor any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any applications, approvals, reports or other submissions to the FDA or any other governmental or regulatory authority, or made any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental or regulatory authority.

d. Neither the Company, any Subsidiary nor, to the Company's knowledge, any of their respective directors, officers, employees or agents, have with respect to each of the following statutes, or regulations promulgated thereto: (i) engaged in activities under 42 U.S.C. §§ 1320a-7 or 1395nn; (ii) knowingly engaged in any activities under 42 U.S.C. § 1320a-7a or the Federal False Claims Act, 31 U.S.C. § 3729; or (iii) knowingly and willfully engaged in any activities under 42 U.S.C. § 1320a-7b, which are, as applicable, prohibited, cause for civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other State Health Care Program or Federal Health Care Program.

Any certificate signed by any officer of the Company and delivered to the Underwriter or to counsel for the Underwriter in connection with the Offering shall be deemed a representation and warranty by the Company to the Underwriter as to the matters covered thereby.

3. *PURCHASE, SALE AND DELIVERY OF OFFERED SECURITIES*. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to sell to the Underwriter, and the Underwriter agrees to purchase from the Company the number of Units set forth opposite the name of the Underwriter on Schedule IV hereto.

The purchase price per Unit to be paid by the Underwriter to the Company for the combination of Stock, Series A Warrants, and Series B Warrants will be $[-] per Unit (the *"Purchase Price"*).

The Company will deliver to the Underwriter, (i) the Stock through the facilities of The Depository Trust Company and (ii) the Warrants in physical, certificated form, in each such case, issued in such names and in such denominations as the Underwriter may direct by notice in writing to the Company given at or prior to 12:00 Noon, New York time, on the second (2nd) full business day preceding the Closing Date against payment of the aggregate Purchase Price therefor by wire transfer in federal (same day) funds to an account at a bank acceptable to the Underwriter payable to the order of the Company all at the offices of LeClairRyan, A Professional Corporation, 885 Third Avenue, New York, New York 10022. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligations of the Underwriter hereunder. The time and date of the delivery and closing shall be at 10:00 A.M., New York time, on July , 2015. The time and date of such payment and delivery are herein referred to as the "Closing Date". The Closing Date and the location of delivery of, and the form of payment for, the Stock and the Warrants may be varied by agreement among the Company and the Underwriter.

The Company is advised by the Underwriter that the Underwriter intends (i) to make a public offering of the Stock and the Warrants as soon after the effectiveness of this Agreement as in the Underwriter's judgment is advisable and (ii) initially offer the Stock and the Warrants upon the terms set forth in the Prospectus. The Underwriter may from time to time increase or decrease the public offering price after the initial public offering to such extent as the Underwriter may determine.

4. *FURTHER AGREEMENTS OF THE COMPANY.* The Company agrees with the Underwriter:

(a) To prepare the Rule 462(b) Registration Statement, if necessary, in a form approved by the Underwriter and file such Rule 462(b) Registration Statement with the Commission by 10:00 p.m., New York time, on the date hereof, and the Company shall at the time of filing either pay to the Commission the filing fee for the Rule 462(b) Registration Statement or give irrevocable instructions for the payment of such fee pursuant to Rule 111(b) under the Rules and Regulations; to prepare the Prospectus in a form approved by the Underwriter containing information previously omitted at the time of effectiveness of the Registration Statement in reliance on Rules 430A, 430B or 430C of the Rules and Regulations and to file such Prospectus pursuant to Rule 424(b) of the Rules and Regulations not later than the second business (2nd) day following the execution and delivery of this Agreement or, if applicable, such earlier time as may be required by Rule 430A of the Rules and Regulations; prior to the termination of the Offering, to notify the Underwriter immediately of the Company's intention to file or prepare any supplement or amendment to any Registration Statement or to the Final Prospectus and to make no amendment or supplement to the Registration Statement, the Disclosure Package or to the Final Prospectus to which the Underwriter shall reasonably object by notice to the Company after a reasonable period to review; prior to the termination of the Offering, to advise the Underwriter, promptly after it receives notice thereof, of the time when any amendment to any Registration Statement has been filed or becomes effective or any supplement to the Disclosure Package or the Final Prospectus or any amended Prospectus has been filed and to furnish the Underwriter with copies thereof; to timely file all material required to be filed by the Company with the Commission pursuant to Rules 433(d) or 163(b)(2) of the Rules and Regulations, as the case may be; to file promptly all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of a prospectus covering the sale or resale of the Warrant Shares pursuant to Section 5(r) hereto; to advise the Underwriter, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any Issuer Free Writing Prospectus or the Prospectus, of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement, the Disclosure Package or the Final Prospectus or for additional information; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of any Issuer Free Writing Prospectus or the Prospectus or suspending any such qualification, and promptly to use its best efforts to obtain the withdrawal of such order.

(b) The Company represents and agrees that, unless it obtains the prior consent of the Underwriter, and the Underwriter represents and agrees that, unless the Underwriter obtains the prior consent of the Company, no party has made nor will make any offer relating to the Securities that would constitute a "free writing prospectus" as defined in Rule 405 of the Rules and Regulations (each, a "*Permitted Free Writing Prospectus*"). The Company represents that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, comply with the requirements of Rules 164 and 433 of the Rules and Regulations applicable to any Issuer Free Writing Prospectus, including the requirements relating to timely filing with the Commission, legending and record keeping and will not take any action that would result in the Underwriter or the Company being required to file with the Commission

pursuant to Rule 433(d) of the Rules and Regulations a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder.

(c) If at any time prior to the expiration of nine (9) months after the later of (i) the latest effective date of the Registration Statement or (ii) the date of the Prospectus, when a prospectus relating to the Securities is required to be delivered (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations) any event occurs or condition exists as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact, or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made when the Prospectus is delivered (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations), not misleading, or if it is necessary at any time to amend or supplement any Registration Statement or the Prospectus (or to file under the Exchange Act any document incorporated by reference in a prospectus covering the sale or resale of the Warrant Shares pursuant to Section 4(r) hereto) to comply with the Securities Act or the Exchange Act, that the Company will promptly notify the Underwriter thereof and upon its request will prepare an appropriate amendment or supplement or upon its request make an appropriate filing pursuant to Section 13 or 14 of the Exchange Act in form and substance satisfactory to the Underwriter which will correct such statement or omission or effect such compliance and will use its best efforts to have any amendment to any Registration Statement declared effective as soon as possible. The Company will furnish without charge to the Underwriter and to any dealer in securities as many copies as the Underwriter may from time to time reasonably request of such amendment or supplement. In case the Underwriter is required to deliver a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations) relating to the Securities nine (9) months or more after the later of (i) the latest effective date of the Registration Statement or (ii) the date of the Prospectus, the Company upon the request of the Underwriter will prepare promptly an amended or supplemented Prospectus as may be necessary to permit compliance with the requirements of Section 10(a)(3) of the Securities Act and deliver to such Underwriter as many copies as such Underwriter may reasonably request of such amended or supplemented Prospectus complying with Section 10(a)(3) of the Securities Act.

(d) If the Disclosure Package is being used to solicit offers to buy the Securities at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur as a result of which, in the judgment of the Company or in the reasonable opinion of the Underwriter, it becomes necessary to amend or supplement the Disclosure Package in order to make the statements therein, in the light of the circumstances then prevailing, not misleading, or to make the statements therein not conflict with the information contained or incorporated by reference in the Registration Statement then on file and not superseded or modified, or if it is necessary at any time to amend or supplement the Disclosure Package to comply with any law, the Company promptly will prepare, file with the Commission (if required) and furnish to the Underwriter and any dealers an appropriate amendment or supplement to the Disclosure Package so that the Disclosure Package will comply with law.

(e) If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or will conflict with the information contained in the Registration Statement or Prospectus, including any document incorporated by reference therein and any

prospectus supplement deemed to be a part thereof and not superseded or modified or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company has promptly notified or will promptly notify the Underwriter so that any use of the Issuer Free Writing Prospectus may cease until it is amended or supplemented and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(f) For so long as delivery of a prospectus by the Underwriter or a dealer may be required under the Act, to deliver promptly to the Underwriter in New York City such number of the following documents as the Underwriter shall reasonably request: (i) any Issuer Free Writing Prospectus, (ii) the Prospectus (the delivery of the documents referred to in clauses (i) and (ii) of this Section 4(f) to be made not later than 10:00 a.m., New York time, on the business day following the execution and delivery of this Agreement), (iii) conformed copies of any amendment to the Registration Statement (excluding exhibits), (iv) any amendment or supplement to the Disclosure Package or the Prospectus (the delivery of the documents referred to in clauses (iii) and (iv) of this Section 4(f) to be made not later than 10:00 a.m., New York time, on the business day following the date of such amendment or supplement), and (v) any document incorporated by reference in the Disclosure Package or the Final Prospectus (excluding exhibits thereto) after the date hereof (the delivery of the documents referred to in clause (v) of this Section 4(f) to be made not later than 10:00 a.m., New York time, on the business day following the date of such document); provided that filing with the Commission on EDGAR any document specified in Section 4(f)(iii) or (v) shall constitute delivery to the Underwriter.

(g) To make generally available to its shareholders as soon as practicable, but in any event not later than sixteen (16) months after the effective date of each Registration Statement (as defined in Rule 158(c) of the Rules and Regulations), an earnings statement of the Company (which need not be audited) complying with Section 11(a) of the Securities Act and the Rules and Regulations (including, at the option of the Company, Rule 158).

(h) To take promptly from time to time such actions as the Underwriter may reasonably request to qualify the Securities for offering and sale under the securities or Blue Sky laws of such jurisdictions (domestic or foreign) as the Underwriter may designate and to continue such qualifications in effect, and to comply with such laws, for so long as required to permit the offer and sale of the Securities in such jurisdictions; *provided* that the Company shall not be obligated to qualify as a foreign corporation in any jurisdiction in which it is not so qualified or to file a general consent to service of process in any jurisdiction.

(i) Upon request, during the period of five (5) years from the date hereof, to deliver to the Underwriter, (i) as soon as they are available, copies of all reports or other communications furnished to shareholders, and (ii) as soon as they are available, copies of any reports and financial statements furnished or filed with the Commission or any national securities exchange on which the Common Stock is listed. However, so long as the Company is subject to the reporting requirements of either Section 13 or Section 15(d) of the Exchange Act and is timely filing reports with the Commission on EDGAR, it is not required to furnish such reports or statements to the Underwriter.

(j) That the Company will not for a period of thirty (30) days from the date of this Agreement (the "*Lock-Up Period*"), without the prior written consent of the Underwriter, directly or indirectly offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock for less than the Purchase Price, other than the Company's sale of the Securities hereunder and the issuance of restricted Common Stock or options to acquire Common Stock pursuant to the Company's employee benefit plans, qualified stock option plans or other employee compensation plans as such plans are in existence on the date hereof and described in the Prospectus and the issuance of Common Stock pursuant to the valid exercises of options, warrants or rights outstanding on the date hereof and upon exercise of the Warrants. The Company will cause each person listed in Schedule III to furnish to the Underwriter, on or prior to the date hereof, the Lock-Up Agreement substantially in the form of Exhibit C hereto. The Company also agrees that during such period, other than for the sale of the Securities hereunder, the Company will not file any registration statement, preliminary prospectus or prospectus, or any amendment or supplement thereto, under the Securities Act for any such transaction or which registers, or offers for sale, Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, except for (i) a registration statement on Form S-8 relating to employee benefit plans or (ii) a resale registration statement on Form S-3 relating to Common Stock issuable upon valid exercises of warrants outstanding on the date hereof to the extent such shares of Common Stock are not otherwise registered under an existing and effective shelf registration statement on Form S-3. The Company hereby agrees that (i) if it issues an earnings release or material news, or if a material event relating to the Company occurs, during the last seventeen (17) days of the Lock-Up Period, or (ii) if prior to the expiration of the Lock-Up Period, the Company announces that it will release earnings results during the sixteen (16)-day period beginning on the last day of the Lock-Up Period, the restrictions imposed by this Section 4(j) or the letter shall continue to apply until the expiration of the eighteen (18)-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. The Company will provide the Underwriter (in accordance with Section 13 herein) notice of any such announcement that gives rise to an extension of the Lock-Up Period.

(k) To supply the Underwriter with copies of all correspondence to and from, and all documents issued to and by, the Commission in connection with the registration of the Stock, Warrants, and Warrant Shares under the Securities Act or any of the Registration Statement, the Prospectus, or any amendment or supplement thereto or document incorporated by reference therein.

(l) Prior to the Closing Date, not to issue any press release or other communication directly or indirectly or hold any press conference with respect to the Company, its condition, financial or otherwise, or earnings, business affairs or business prospects (except for routine oral marketing communications in the ordinary course of business and consistent with the past practices of the Company and of which the Underwriter is notified), without the prior written consent of the Underwriter, unless in the judgment of the Company and its counsel, and after notification to the Underwriter, such press release or communication is required by law.

(m) Until the Underwriter shall have notified the Company of the completion of the resale of the Stock and Warrants, that the Company will not, and will cause its affiliated

purchasers (as defined in Regulation M under the Exchange Act) not to, either alone or with one or more other persons, bid for or purchase, for any account in which it or any of its affiliated purchasers has a beneficial interest, any Stock and Warrants, or attempt to induce any person to purchase any Stock and Warrants, and not to, and to cause its affiliated purchasers not to, make bids or purchase for the purpose of creating actual, or apparent, active trading in or of raising the price of the Stock and Warrants.

(n) To at all times comply in all material respects with all applicable provisions of the Sarbanes-Oxley Act in effect from time to time.

(o) To maintain, at its expense, a registrar and transfer agent for the Stock and Warrant Shares.

(p) To apply the net proceeds from the sale of the Units as set forth in the Registration Statement, the Disclosure Package and the Final Prospectus under the heading "Use of Proceeds," and except as disclosed in the Disclosure Package, the Company does not intend to use any of the proceeds from the sale of the Units hereunder to repay any outstanding debt owed to any affiliate of the Underwriter. The Company shall not invest, or otherwise use the proceeds of the Offering in such a manner as would require the Company to be or become an "investment company" within the meaning of the Investment Company Act and the rules and regulations thereunder.

(q) To use its best efforts to list, subject to notice of issuance, and to maintain the listing of the Stock and Warrant Shares on the NASDAQ Capital Market.

(r) For a period commencing on the Closing Date and ending on the earlier of (i) the five (5) year anniversary of the Closing Date or (ii) the date that the Warrants are no longer outstanding, to use commercially reasonable efforts to (A) cause the Registration Statement to remain effective with a current prospectus under the Securities Act and the Rules and Regulations (including by post effective amendment) or (B) file a post effective amendment on Form S-3 to the previously filed and effective Registration Statement to convert such Registration Statement from a Form S-1 to a Form S-3, and thereafter cause such registration statement to remain effective with a current prospectus covering the sale or resale of the Warrant Shares under the Securities Act and the Rules and Regulations.

(s) If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant is exercised via cashless exercise at a time when such Warrant Shares would be eligible for resale under Rule 144 by a non-affiliate of the Company, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends.

(t) Upon any exercise of Series B Warrants solicited by the Underwriter (the effective date of any such exercise, a "Series B Exercise Date"), the Company shall pay to the applicable Underwriter a financial advisory fee equal to 7.0% of the gross proceeds received by the Company from such exercise (the "Advisory Fee"). The Company shall provide the Underwriter with written notice of each exercise of Series B Warrants within three business days of the applicable Series B Exercise Date. Any such Advisory Fee shall be paid to the Underwriter not more than five (5) business days after notice of the Series B Exercise Date giving rise to such Advisory Fee and shall be paid by wire transfer of immediately available funds to an account previously specified by the Underwriter.

5. *PAYMENT OF EXPENSES*. The Company agrees to pay, or reimburse if paid by the Underwriter, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated: (a) the costs incident to the authorization, issuance, sale, preparation and delivery of the Securities and any taxes payable in that connection; (b) the costs incident to the registration of the Securities under the Securities Act; (c) the costs incident to the preparation, printing and distribution of the Registration Statement, any Issuer Free Writing Prospectus, the Disclosure Package, the Final Prospectus, any amendments, supplements and exhibits thereto or any document incorporated by reference therein and the costs of printing, reproducing and distributing this Agreement and any closing documents by mail, telex or other means of communications; (d) the fees and expenses (including related fees and expenses of counsel for the Underwriter) incurred in connection with securing any required review by FINRA of the terms of the sale of the Securities and any filings made with FINRA; (e) any applicable listing or other fees in connection with listing the Stock and the Warrant Shares on the NASDAQ Capital Market; (f) the fees and expenses (including related fees and expenses of counsel to the Underwriter) of qualifying the Securities under the securities laws of the several jurisdictions as provided in Section 4(h) and of preparing, printing and distributing wrappers, Blue Sky Memoranda and Legal Investment Surveys; (g) the cost of preparing and printing stock certificates; (h) all fees and expenses of the registrar and transfer agent of the Common Stock; (i) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Securities, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the officers of the Company and such consultants, including the cost of any aircraft chartered in connection with the road show; (k) the fees and disbursements of counsel to the Underwriter; and (l) all other costs and expenses incident to the offering of the Securities or the performance of the obligations of the Company under this Agreement (including, without limitation, the fees and expenses of the Company's counsel and the Company's independent accountants). Notwithstanding the foregoing, the maximum amount of fees and expenses that shall be included in the expense reimbursement to the Underwriter shall not exceed $50,000 without the prior approval of the Company, which approval shall not be unreasonably withheld.

6. *CONDITIONS OF UNDERWRITER'S OBLIGATIONS*. The obligations of the Underwriter hereunder are subject to the accuracy, when made and as of the Time of Sale and on the Closing Date, of the representations and warranties of the Company contained herein, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions:

(a) The Registration Statement has become effective under the Securities Act, and no stop order suspending the effectiveness of the Registration Statement or any part thereof, preventing or suspending the use of any Prospectus or any Permitted Free Writing Prospectus or any part thereof shall have been issued and no proceedings for that purpose or pursuant to Section 8A under the Securities Act shall have been initiated or threatened by the Commission,

and all requests for additional information on the part of the Commission (to be included or incorporated by reference in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the reasonable satisfaction of the Underwriter; the Rule 462(b) Registration Statement, if any, each Issuer Free Writing Prospectus and the Prospectus shall have been filed with the Commission within the applicable time period prescribed for such filing by, and in compliance with, the Rules and Regulations and in accordance with Section 4(a), and the Rule 462(b) Registration Statement, if any, shall have become effective immediately upon its filing with the Commission; and FINRA shall have raised no objection to the fairness and reasonableness of the terms of this Agreement or the transactions contemplated hereby.

(b) The Underwriter shall not have discovered and disclosed to the Company on or prior to the Closing Date that the Registration Statement or any amendment or supplement thereto contains an untrue statement of a fact which, in the opinion of counsel for the Underwriter, is material or omits to state any fact which, in the opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading, or that the Disclosure Package, any Issuer Free Writing Prospectus or the Final Prospectus or any amendment or supplement thereto contains an untrue statement of fact which, in the opinion of such counsel, is material or omits to state any fact which, in the opinion of such counsel, is material and is necessary in order to make the statements, in the light of the circumstances in which they were made, not misleading.

(c) All corporate action incident to the authorization, form and validity of each of this Agreement, the Stock, the Warrants, the Warrant Shares, the Registration Statement, the Disclosure Package, each Issuer Free Writing Prospectus and the Final Prospectus and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to counsel for the Underwriter, and the Company shall have furnished to such counsel all Company documents and information that it may reasonably request to enable it to pass upon such matters.

(d) Morgan, Lewis & Bockius LLP shall have furnished to the Underwriter such counsel’s written opinion and a negative assurance letter, as counsel to the Company, addressed to the Underwriter and dated as of the Closing Date, in form and substance satisfactory to the Underwriter.

(e) [Reserved.]

(f) The Underwriter shall have received from LeClairRyan, A Professional Corporation, counsel for the Underwriter, such opinion or opinions, dated as of the Closing Date, with respect to such matters as the Underwriter may reasonably require, and the Company shall have furnished to such counsel such documents as it requests for enabling it to pass upon such matters.

(g) At the time of the execution of this Agreement, the Underwriter shall have received from each of GT LLP and E&Y LLP, a letter, addressed to the Underwriter, executed and dated such date, in form and substance satisfactory to the Underwriter (A) confirming that they are an independent registered accounting firm with respect to the Company within the meaning of the Securities Act and the Rules and Regulations and PCAOB and (B) stating the conclusions and findings of such firm, of the type ordinarily included in accountants' "comfort letters" to underwriters, with respect to the financial statements and certain financial information contained or incorporated by reference in the Registration Statement, the Disclosure Package and the Final Prospectus.

(h) On the effective date of any post-effective amendment to the Registration Statement and on the Closing Date, the Underwriter shall have received a letter (the "*bring-down letter*") from each of GT LLP and E&Y LLP, addressed to the Underwriter and dated as of the Closing Date confirming, as of the date of the bring-down letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Disclosure Package and the Final Prospectus, as the case may be, as of a date not more than three (3) business days prior to the date of the bring-down letter), the conclusions and findings of such firm, of the type ordinarily included in accountants' "comfort letters" to underwriters, with respect to the financial information and other matters covered by its letter delivered to the Underwriter concurrently with the execution of this Agreement pursuant to Section 6(g).

(i) The Company shall have furnished to the Underwriter a certificate, dated as of the Closing Date, of its President and Chief Executive Officer and its Senior Vice President, Finance stating that (i) such officers have carefully examined the Registration Statement, the Disclosure Package, any Permitted Free Writing Prospectus and the Final Prospectus, (ii) to the best of their knowledge after reasonable investigation, as of the Closing Date, the representations and warranties of the Company in this Agreement are true and correct and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date, and (iii) there has not been, subsequent to the date of the most recent audited financial statements included or incorporated by reference in the Disclosure Package, any material adverse change in the financial position or results of operations of the Company, or any change or development that, singularly or in the aggregate, would involve a material adverse change or a prospective material adverse change, in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company taken as a whole, except as set forth in the Final Prospectus.

(j) Since the date of the latest audited financial statements included in the Disclosure Package or incorporated by reference in the Disclosure Package as of the date hereof, (i) the Company shall not have sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth in the Disclosure Package, and (ii) there shall not have been any change in the capital stock (other than a change in number of Common Stock shares outstanding due to the issuance of shares upon exercise of options or warrants) or long-term debt of the Company, or any change, or any development involving a prospective change, in or affecting the business, general affairs, management, financial position, stockholders' equity or results of operations of the Company, otherwise than as set forth in the Disclosure Package, the effect of which, in any such case described in clause (i) or (ii) of this

Section 6(j), is, in the judgment of the Underwriter, so material and adverse as to make it impracticable or inadvisable to proceed with the sale or delivery of the Stock and the Warrants on the terms and in the manner contemplated in the Disclosure Package.

(k) No action shall have been taken and no law, statute, rule, regulation or order shall have been enacted, adopted or issued by any governmental agency or body which would prevent the issuance or sale of the Securities or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company; and no injunction, restraining order or order of any other nature by any federal or state court of competent jurisdiction shall have been issued which would prevent the issuance or sale of the Securities or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company.

(l) Subsequent to the execution and delivery of this Agreement there shall not have occurred any of the following: (i) trading in securities generally on the New York Stock Exchange, NASDAQ Global Market or NASDAQ Capital Market or in the over-the-counter market, or trading in the Common Stock of the Company on any exchange or in the over-the-counter market, shall have been suspended or materially limited, (ii) a banking moratorium shall have been declared by Federal or state authorities or a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States, (iii) the United States shall have been the subject of an act of terrorism or there shall have been an outbreak of or escalation in hostilities involving the United States, or there shall have been a declaration of a national emergency or war by the United States or (iv) there shall have occurred such a material adverse change in general economic, political or financial conditions (or the effect of international conditions on the financial markets in the United States shall be such) as to make it, in the judgment of the Underwriter, impracticable or inadvisable to proceed with the sale or delivery of the Stock and Warrants on the terms and in the manner contemplated in the Disclosure Package and the Final Prospectus.

(m) The NASDAQ Capital Market shall have approved the Stock and the Warrant Shares for listing therein, subject only to official notice of issuance.

(n) The Underwriter shall have received on and as of the Closing Date satisfactory evidence of the good standing of the Company in its jurisdiction of incorporation and its good standing as a foreign corporation in such other jurisdictions as the Underwriter may reasonably request, in each case in writing or any standard form of telecommunication from the appropriate governmental authorities of such jurisdictions.

(o) The Underwriter shall have received the written Lock-Up Agreements, substantially in the form of Exhibit C hereto, of the persons listed in Schedule III to this Agreement.

(p) The Underwriter shall have received on the Closing Date a Secretary's Certificate of the Company.

(q) On or prior to the Closing Date, the Company shall have furnished to the Underwriter such further certificates and documents as the Underwriter may reasonably request.

All opinions, letters, evidence and certificates mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriter.

7. *INDEMNIFICATION AND CONTRIBUTION.*

(a) The Company agrees to indemnify, defend and hold harmless the Underwriter, its partners, directors and officers, any person who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, and the successors and assigns of all of the foregoing persons, from and against any loss, damage, expense, liability or claim (including the reasonable cost of investigation) which, jointly or severally, such Underwriter or any such person may incur under the Securities Act, the Exchange Act, the common law or otherwise, insofar as such loss, damage, expense, liability or claim arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or in the Registration Statement as amended by any post-effective amendment thereof by the Company) or arises out of or is based upon any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as any such loss, damage, expense, liability or claim arises out of or is based upon any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning the Underwriter furnished in writing by or on behalf of the Underwriter to the Company expressly for use in, the Registration Statement or arises out of or is based upon any omission or alleged omission to state a material fact in the Registration Statement in connection with such information, which material fact was not contained in such information and which material fact was required to be stated in such Registration Statement or was necessary to make such information not misleading or (ii) any untrue statement or alleged untrue statement of a material fact included in any Prospectus (including for the purpose of this Section 7 any amendments or supplements to the foregoing), in any Permitted Free Writing Prospectus, in any "issuer information" (as defined in Rule 433 under the Securities Act) of the Company or in any Prospectus together with any combination of one or more of the Permitted Free Writing Prospectuses, if any, or arises out of or is based upon any omission or alleged omission to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, except, with respect to such Prospectus or Permitted Free Writing Prospectus, insofar as any such loss, damage, expense, liability or claim arises out of or is based upon any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning the Underwriter furnished in writing by or on behalf of the Underwriter to the Company expressly for use in, such Prospectus or Permitted Free Writing Prospectus or arises out of or is based upon any omission or alleged omission to state a material fact in such Prospectus or Permitted Free Writing Prospectus in connection with such information, which material fact was not contained in such information and which material fact was necessary in order to make the statements in such information, in the light of the circumstances under which they were made, not misleading.

(b) The Underwriter agrees to indemnify, defend and hold harmless the Company, its directors and officers, and any person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, and the successors and assigns of all of the foregoing persons, from and against any loss, damage, expense, liability or claim (including the reasonable cost of investigation) which, jointly or severally, the Company or any

such person may incur under the Securities Act, the Exchange Act, the common law or otherwise, insofar as such loss, damage, expense, liability or claim arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning the Underwriter furnished in writing by or on behalf of the Underwriter to the Company expressly for use in, the Registration Statement (or in the Registration Statement as amended by any post-effective amendment thereof by the Company), or arises out of or is based upon any omission or alleged omission to state a material fact in such Registration Statement in connection with such information, which material fact was not contained in such information and which material fact was required to be stated in such Registration Statement or was necessary to make such information not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning the Underwriter furnished in writing by or on behalf of the Underwriter to the Company expressly for use in, a Prospectus or a Permitted Free Writing Prospectus, or arises out of or is based upon any omission or alleged omission to state a material fact in such Prospectus or Permitted Free Writing Prospectus in connection with such information, which material fact was not contained in such information and which material fact was necessary in order to make the statements in such information, in the light of the circumstances under which they were made, not misleading.

(c) If any action, suit or proceeding (each, a "*Proceeding*") is brought against a person (an "*indemnified party*") in respect of which indemnity may be sought against the Company or the Underwriter (as applicable, the "*indemnifying party*") pursuant to subsection (a) or (b), respectively, of this Section 7, such indemnified party shall promptly notify such indemnifying party in writing of the institution of such Proceeding and such indemnifying party shall assume the defense of such Proceeding, including the employment of counsel reasonably satisfactory to such indemnified party and payment of all fees and expenses; provided, however, that the omission to so notify such indemnifying party shall not relieve such indemnifying party from any liability which such indemnifying party may have to any indemnified party or otherwise. The indemnified party or parties shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such indemnified party or parties unless the employment of such counsel shall have been authorized in writing by the indemnifying party in connection with the defense of such Proceeding or the indemnifying party shall not have, within a reasonable period of time in light of the circumstances, employed counsel to defend such Proceeding or such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from, additional to or in conflict with those available to such indemnifying party (in which case such indemnifying party shall not have the right to direct the defense of such Proceeding on behalf of the indemnified party or parties), in any of which events such fees and expenses shall be borne by such indemnifying party and paid as incurred (it being understood, however, that such indemnifying party shall not be liable for the expenses of more than one separate counsel (in addition to any local counsel) in any one Proceeding or series of related Proceedings in the same jurisdiction representing the indemnified parties who are parties to such Proceeding). The indemnifying party shall not be liable for any settlement of any Proceeding effected without its written consent, such consent not to be unreasonably withheld, but, if settled with its written consent, such indemnifying party agrees to indemnify and hold harmless the indemnified party or parties from and against any loss or liability by reason of such settlement. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as

contemplated by the second sentence of this Section 7(c), then the indemnifying party agrees that it shall be liable for any settlement of any Proceeding effected without its written consent if (i) such settlement is entered into more than 60 business days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall not have fully reimbursed the indemnified party in accordance with such request prior to the date of such settlement and (iii) such indemnified party shall have given the indemnifying party at least 30 days' prior notice of its intention to settle. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened Proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such Proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

(d) If the indemnification provided for in this Section 7 is unavailable to an indemnified party under subsections (a) and (b) of this Section 7 or insufficient to hold an indemnified party harmless in respect of any losses, damages, expenses, liabilities or claims referred to therein, then each applicable indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, damages, expenses, liabilities or claims (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriter on the other hand from the offering of the Securities or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and of the Underwriter on the other in connection with the statements or omissions which resulted in such losses, damages, expenses, liabilities or claims, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriter on the other shall be deemed to be in the same respective proportions as the total proceeds from the offering (net of underwriting discounts and commissions but before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriter, bear to the aggregate public offering price of the Securities. The relative fault of the Company on the one hand and of the Underwriter on the other shall be determined by reference to, among other things, whether the untrue statement or alleged untrue statement of a material fact or omission or alleged omission relates to information supplied by the Company or by the Underwriter and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The amount paid or payable by a party as a result of the losses, damages, expenses, liabilities and claims referred to in this subsection shall be deemed to include any legal or other fees or expenses reasonably incurred by such party in connection with investigating, preparing to defend or defending any Proceeding.

(e) The Company and the Underwriter agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in subsection (d) above. Notwithstanding the provisions of this Section 7, the Underwriter shall not be required to contribute any amount in excess of the amount by which the total price at which the Securities underwritten by the Underwriter and distributed to the public were offered to the public exceeds the amount of any damage which the Underwriter has otherwise been required to pay by reason of such untrue statement or alleged untrue statement or omission or alleged

omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

(f) The indemnity and contribution agreements contained in this Section 7 and the covenants, warranties and representations of the Company contained in this Agreement shall remain in full force and effect regardless of any investigation made by or on behalf of the Underwriter, its respective partners, directors or officers or any person (including each partner, director or officer of such person) who controls the Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or by or on behalf of the Company, its directors or officers or any person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, and shall survive any termination of this Agreement or the issuance and delivery of the Stock and Warrants. The Company and the Underwriter agree promptly to notify each other of the commencement of any Proceeding against them and, in the case of the Company, against any of the Company's officers or directors in connection with the issuance and sale of the Stock and Warrants, or in connection with the Registration Statement, any Prospectus or any Permitted Free Writing Prospectus.

8. *TERMINATION*. The obligations of the Underwriter hereunder may be terminated by the Underwriter, in the Underwriter's absolute discretion, by notice given to the Company prior to delivery of and payment for the Stock and the Warrants if, prior to that time, any of the events described in Sections 6(j), 6(k) or 6(l) have occurred or if the Underwriter shall decline to purchase the Securities for any reason permitted under this Agreement.

9. *REIMBURSEMENT OF UNDERWRITER'S EXPENSES*. Notwithstanding anything to the contrary in this Agreement, if the sale of the Securities is not consummated because any condition to the obligations of the Underwriter set forth in Section 6 is not satisfied or because of the refusal, inability or failure on the part of the Company to perform any agreement herein or to satisfy any condition or to comply with the provisions hereof, then in addition to the payment of amounts in accordance with Section 5, the Company shall reimburse the Underwriter for the fees and expenses of Underwriter's counsel and for such other out-of-pocket expenses as shall have been reasonably incurred by it in connection with this Agreement and the proposed purchase of the Securities, including, without limitation, travel and lodging expenses of the Underwriter, and upon demand the Company shall pay the full amount thereof to the Underwriter.

10. *ABSENCE OF FIDUCIARY RELATIONSHIP*. The Company acknowledges and agrees that:

(a) the Underwriter's responsibility to the Company is solely contractual in nature, the Underwriter have been retained solely to act as an underwriter in connection with the sale of the Securities and no fiduciary, advisory or agency relationship between the Company and the Underwriter has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Underwriter has advised or is advising the Company on other matters;

(b) the price of the Stock and the terms of the Warrants set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Underwriter, and the Company is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) it has been advised that the Underwriter and their respective affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Underwriter have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) it waives, to the fullest extent permitted by law, any claims it may have against the Underwriter for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that the Underwriter shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, employees or creditors of the Company.

11. *SUCCESSORS; PERSONS ENTITLED TO BENEFIT OF AGREEMENT*. This Agreement shall inure to the benefit of and be binding upon the Underwriter, the Company and their respective successors and assigns. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, other than the persons mentioned in the preceding sentence, any legal or equitable right, remedy or claim under or in respect of this Agreement, or any provisions herein contained, this Agreement and all conditions and provisions hereof being intended to be and being for the sole and exclusive benefit of such persons and for the benefit of no other person; except that the representations, warranties, covenants, agreements and indemnities of the Company contained in this Agreement shall also be for the benefit of the Underwriter indemnified parties, and the indemnities of the Underwriter shall be for the benefit of the Company indemnified parties. It is understood that the Underwriter's responsibility to the Company is solely contractual in nature and the Underwriter does not owe the Company, or any other party, any fiduciary duty as a result of this Agreement. No purchaser of any of the Stock or Warrants from the Underwriter shall be deemed to be a successor or assign by reason merely of such purchase.

12. *SURVIVAL OF INDEMNITIES, REPRESENTATIONS, WARRANTIES, ETC.* The respective indemnities, covenants, agreements, representations, warranties and other statements of the Company and the Underwriter, as set forth in this Agreement or made by them respectively, pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation made by or on behalf of the Underwriter, the Company or any person controlling any of them and shall survive delivery of and payment for the Stock and the Warrants. Notwithstanding any termination of this Agreement, including without limitation any termination pursuant to Section 8, the indemnities, covenants, agreements, representations, warranties and other statements forth in Sections 2, 5, 7 and 9 and Sections 10 through 19, inclusive, of this Agreement shall not terminate and shall remain in full force and effect at all times.

13. *NOTICES.* All statements, requests, notices and agreements hereunder shall be in writing, and:

(a) if to the Underwriter, shall be delivered or sent by mail, telex, facsimile transmission or email to Roth Capital Partners, LLC, 888 San Clemente Drive, Newport Beach, California 92660, Attention: Aaron Gurewitz, Managing Director and Head of Equity Capital Markets, Fax: (858) 720-7227, with a copy (which shall not constitute notice) to LeClairRyan, A Professional Corporation, 885 Third Avenue, New York, New York 10022, Attention: James T. Seery, E-mail: james.seery@leclairryan.com; and

(b) if to the Company shall be delivered or sent by mail, telex, facsimile transmission or email to Delcath Systems, Inc., 1301 Avenue of the Americas, 43rd Floor, New York, New York 10019, Attention: Barbra Keck, Fax: 212-489-2102, with a copy (which shall not constitute notice) to Morgan, Lewis & Bockius LLP, 101 Park Avenue, New York, New York 10178, Attention: Anna Tomczyk, Esq., Fax: 212-309-6001.

14. *DEFINITION OF CERTAIN TERMS*. For purposes of this Agreement, "*business day*" means any day on which the New York Stock Exchange, Inc. is open for trading.

15. ***GOVERNING LAW AND JURISDICTION***. **This Agreement shall be governed by and construed in accordance with the laws of the State of New York, including without limitation Section 5-1401 of the New York General Obligations.** The Company and the Underwriter irrevocably (a) submit to the non-exclusive jurisdiction of the Federal and state courts in the Borough of Manhattan in The City of New York for the purpose of any suit, action or other proceeding arising out of this Agreement or the transactions contemplated by this Agreement, the Registration Statement and the Final Prospectus, (b) agree that all claims in respect of any such suit, action or proceeding may be heard and determined by any such court, (c) waive to the fullest extent permitted by applicable law, any immunity from the jurisdiction of any such court or from any legal process, (d) agree not to commence any such suit, action or proceeding other than in such courts, and (e) waive, to the fullest extent permitted by applicable law, any claim that any such suit, action or proceeding is brought in an inconvenient forum.

16. *UNDERWRITER'S INFORMATION.* The parties hereto acknowledge and agree that, for all purposes of this Agreement, the Underwriter's Information consists solely of the statements concerning the Underwriter contained in the eleventh and twelfth paragraphs in the "Underwriting" section of the Prospectus.

17. *PARTIAL UNENFORCEABILITY*. The invalidity or unenforceability of any section, paragraph, clause or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph, clause or provision hereof. If any section, paragraph, clause or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

18. *GENERAL*. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. In this Agreement, the masculine, feminine and neuter genders and the singular and the plural include one another. The section headings in this Agreement are for the convenience of the parties only and will not affect the construction or interpretation of this Agreement. This Agreement may be amended or modified, and the observance of any term of this Agreement may be waived, only by a writing signed by the Company and the Underwriter.

19. *COUNTERPARTS*. This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

If the foregoing is in accordance with your understanding of the agreement between the Company and the Underwriter, kindly indicate your acceptance in the space provided for that purpose below.

Very truly yours,
DELCATH SYSTEMS, INC.

By: _____
Name:
Title:

Accepted as of the date first above written:
ROTH CAPITAL PARTNERS, LLC

By: _____
Name: Aaron M. Gurewitz
Title: Head of Equity Capital Markets

SCHEDULE I

General Use Free Writing Prospectuses

None.

SCHEDULE II
Pricing Information

Stock to be sold: [-]

Series A Warrants to be sold: [-]
Warrant Shares underlying the Series A Warrants: [-]

Series B Warrants to be sold: [-]
Warrants Shares underlying the Series B Warrants: [-]
Series A Warrants issuable upon exercise of Series B Warrant Shares: [-]
Warrant Shares underlying Series A Warrants issuable upon exercise of Series B Warrant Shares: [-]

Purchase Price Per Unit: $[-]
Underwriting Discounts and Commissions per Unit: $[-]
Estimated Net Proceeds to the Company, before expenses: $[-]
Exercise Price of the Series A Warrants: $[-]
Series A Warrant Term: 5 years
Exercise Price of the Series B Warrants: $[-]
Series B Warrant Term: 90 days

SCHEDULE III

Persons Executing Lock-Up Agreements

Jennifer Simpson
John Purpura
Barbra C. Keck
Roger G. Stoll
Harold S. Koplewicz
Dennis H. Langer
Laura A. Philips
William D. Rueckert
Marco Taglietti

SCHEDULE IV

Underwriter	Number of Units to be Purchased
Roth Capital Partners, LLC	
Total	

SCHEDULE V

Subsidiaries

Delcath Holdings Limited, an Irish non-resident company permitted and residing in Bermuda.
Delcath Systems Limited, an Irish company.
Delcath Systems UK Limited, a company organized under the laws of England and Wales.
Delcath Systems GmbH, a German Company.
Delcath Systems B.V., a Dutch company.

EXHIBIT A

Form of Series A Warrant

EXHIBIT B

Form of Series B Warrant

EXHIBIT C
Form of Lock-Up Agreement

_____
Name

_____, 2015

Roth Capital Partners, LLC
888 San Clemente Drive
Newport Beach, CA 92660

Re: Proposed Public Offering by Delcath Systems, Inc.

Dear Sirs:

This Agreement is being delivered to you in connection with the proposed Underwriting Agreement (the "*Underwriting Agreement*") between Delcath Systems, Inc., a Delaware corporation (the "*Company*"), and Roth Capital Partners, LLC (the "*Underwriter*"), relating to the proposed public offering comprised of shares of Common Stock, par value $0.01 per share (the "Common Stock") and warrants, of the Company.

In order to induce the Underwriter to enter into the Underwriting Agreement, and in light of the benefits that the offering will confer upon the undersigned in its capacity as a security holder and/or an officer, director or employee of the Company, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with the Underwriter that, during the period beginning on the date hereof through and including the date that is the 30th day after the date of the Underwriting Agreement (the "*Lock-Up Period*"), the undersigned will not, without the prior written consent of Roth Capital Partners, LLC, directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any shares of Common Stock (including, without limitation, Common Stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act of 1933, as the same may be amended or supplemented from time to time (such shares, the "*Beneficially Owned Shares*")) or securities convertible into or exercisable or exchangeable for Common Stock, (ii) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of the Beneficially Owned Shares or securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or (iii) engage in any short selling of the Common Stock or securities convertible into or exercisable or exchangeable for Common Stock, for a price less than $[-] per share of Common Stock. If (i) the Company issues an earnings release or material news or a material event relating to the Company occurs during the last 17 days of the Lock-Up Period, or (ii) prior to the expiration of the Lock-Up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the Lock-Up Period, the Lock-Up Period shall be extended and the restrictions imposed by this Agreement shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

The restrictions set forth in the immediately preceding paragraph shall not apply to:

(1) if the undersigned is a natural person, any transfers made by the undersigned (a) as a bona fide gift to any member of the immediate family (as defined below) of the undersigned or to a trust, family partnership or family company the beneficiaries of which are exclusively the undersigned or members of the undersigned's immediate family, (b) by will or intestate succession upon the death of the undersigned or (c) as a bona fide gift,

(2) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfers to any shareholder, partner or member of, or owner of a similar equity interest in, the undersigned, as the case may be, if, in any such case, such transfer is not for value, and

(3) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfer made by the undersigned (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by this Agreement or (b) to another corporation, partnership, limited liability company or other business entity so long as the transferee is an affiliate (as defined below) of the undersigned and such transfer is not for value;

provided, however, that in the case of any transfer described in clause (1), (2) or (3) above, it shall be a condition to the transfer that (A) the transferee executes and delivers to the Underwriter, not later than one business day prior to such transfer (which period shall not apply in connection with a transfer pursuant to Section (1)(b)), a written agreement, in substantially the form of this Agreement (it being understood that any references to "immediate family" in the agreement executed by such transferee shall expressly refer only to the immediate family of the undersigned and not to the immediate family of the transferee), and (B) if the undersigned is required to file a report under Section 16(a) of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), reporting a reduction in beneficial ownership of shares of Common Stock or Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or Beneficially Owned Shares during the Lock-Up Period (as the same may be extended as described above), the undersigned shall include a statement in such report to the effect that, in the case of any transfer pursuant to clause (1) above, such transfer is being made as a gift or by will or intestate succession or, in the case of any transfer pursuant to clause (2) above, such transfer is being made to a shareholder, partner or member of, or owner of a similar equity interest in, the undersigned and is not a transfer for value or, in the case of any transfer pursuant to clause (3) above, such transfer is being made either (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets or (b) to another corporation, partnership, limited liability company or other business entity that is an affiliate of the undersigned and such transfer is not for value. For purposes of this paragraph, "immediate family" shall mean a spouse, child, grandchild or other lineal descendant (including by adoption), father, mother, brother or sister of the undersigned; and "affiliate" shall have the meaning set forth in Rule 405 under the Securities Act of 1933, as amended. This Agreement shall not apply to the entering into a written trading plan designed to comply with Section 10b5-1 of the Exchange Act, provided no sales are made pursuant to such plan during the Lock-Up Period.

In addition, the restrictions set forth herein shall not apply to sales of Common Stock:

(1) pursuant to any Rule 10b5-1 plan, a copy of which has been provided to the Underwriter prior to the date hereof,

(2) constituting restricted stock outstanding prior to the date hereof that vests during the Lock-Up Period, solely to the extent necessary to generate proceeds to fund any income taxes resulting from such vesting, and

(3) issued upon the exercise of stock options granted prior to the date hereof and scheduled to expire within six (6) months of the date hereof, solely to the extent necessary to generate proceeds to fund the exercise price thereof and any income taxes resulting from such exercise.

The undersigned further agrees that (i) it will not, during the Lock-Up Period (as the same may be extended as described above), make any demand or request for or exercise any right with respect to the registration under the Securities Act of 1933, as amended, of any shares of Common Stock or other Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or other Beneficially Owned Shares, and (ii) the Company may, with respect to any Common Stock or other Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or other Beneficially Owned Shares owned or held (of record or beneficially) by the undersigned, cause the transfer agent or other registrar to enter stop transfer instructions and implement stop transfer procedures with respect to such securities during the Lock-Up Period (as the same may be extended as described above).

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that this Agreement has been duly authorized (if the undersigned is not a natural person), executed and delivered by the undersigned and is a valid and binding agreement of the undersigned. This Agreement and all authority herein conferred are irrevocable and shall survive the death or incapacity of the undersigned (if a natural person) and shall be binding upon the heirs, personal representatives, successors and assigns of the undersigned.

The undersigned acknowledges and agrees that whether or not any public offering of Common Stock actually occurs depends on a number of factors, including market conditions.

Very truly yours,

_____

(Name of Stockholder - Please Print)

_____

(Signature)

_____

(Name of Signatory if Stockholder is an entity - Please Print)

_____

(Title of Signatory if Stockholder is an entity - Please Print)

Address: _____

_____

_____

Exhibit 1.2

DELCATH SYSTEMS, INC.

SERIES A WARRANT (the "Warrant")

Warrant No. [●] Original Issue Date: [●], 2015

DELCATH SYSTEMS, INC., a Delaware corporation (the "**Company**"), hereby certifies that, for value received, [●] or its permitted registered assigns (the "**Holder**"), is entitled to purchase from the Company up to a total of [●] shares of common stock, $0.01 par value (the "**Common Stock**"), of the Company (each such share, a "**Warrant Share**" and all such shares, the "**Warrant Shares**") at an exercise price equal to $[●] per share (as adjusted from time to time as provided herein, the "**Exercise Price**"), at any time and from time to time on or after the Closing Date (the "**Trigger Date**") and through and including 5:00 P.M., New York City time, on [●], 2020 (the "**Expiration Date**"), and subject to the following terms and conditions:

The original issuance of the Warrants and the Warrant Shares by the Company has been registered pursuant to a Registration Statement on Form S-1 (File No. 333-204979) (together with any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act, the "**Registration Statement**").

1. Definitions.

"**Affiliate**" of a person means a person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the person specified.

"**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

"**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

"**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

"**Trading Day**" means any day on which trading of the Common Stock occurs on the applicable Trading Market.

"**Trading Market**" means the NASDAQ Capital Market or, if the Company's Common Stock is not then listed on the NASDAQ Capital Market, then such exchange or quotation system on which the Common Stock then primarily trades.

"**VWAP**" means, for any security as of any date, the dollar volume-weighted average price for such security on the applicable Trading Market during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg through its "Volume at Price" function or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg, or, if no dollar

volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in the "pink sheets" by Pink Sheets LLC (formerly the National Quotation Bureau, Inc.). If the VWAP cannot be calculated for such security on such date on any of the foregoing bases, the VWAP of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved pursuant to Section 15(b) hereof. All such determinations shall be appropriately adjusted for any share dividend, share split or other similar transaction during such period.

2. List of Warrant Holders. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder from time to time). The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. List of Transfers.

(a) This Warrant and the Warrant Shares are transferable.

(b) The Company shall register any such transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, with the Form of Assignment attached hereto duly completed and signed, to the Company at its address specified herein. Upon any such registration or transfer, a new Warrant to purchase Common Stock, in substantially the form of this Warrant (any such new Warrant, a "**New Warrant**"), evidencing the portion of this Warrant so transferred shall be issued to the transferee and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Holder is responsible for any transfer taxes, fees or expenses payable upon such transfer.

4. Exercise and Duration of Warrants.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 hereof at any time and from time to time on or after the Trigger Date and through and including the Expiration Date. Subject to Section 11 hereof, at 5:00 p.m., New York City time, on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value and this Warrant shall be terminated and no longer outstanding. In addition, if cashless exercise would be permitted under Section 10(b) hereof, then all or part of this Warrant may be exercised by the registered Holder utilizing such cashless exercise provisions at any time, or from time to time, on or after the Trigger Date and through and including the Expiration Date.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached hereto (the "**Exercise Notice**"), completed and duly signed, and (ii) if such Holder is not utilizing the cashless exercise provisions set forth in this Warrant, payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being

exercised. The date the Exercise Notice is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "**Exercise Date**;" provided that the Exercise Price is paid by Holder to Company within two Trading Days of such Exercise Date. For the avoidance of doubt, the Exercise Notice does not need to be notarized or contain a medallion guarantee or any other guarantee of any nature. The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares. On or before the first (1st) business day following the date on which the Company has received the Exercise Notice, the Company shall transmit a confirmation of receipt of the Exercise Notice to the Holder and also will notify the Company's transfer agent.

5. Delivery of Warrant Shares.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than three Trading Days after the Exercise Date) issue or cause to be issued and cause to be delivered to or upon the written order of the Holder and in such name or names as the Holder may designate (provided that, if the Registration Statement is not then effective and the Holder directs the Company to deliver a certificate for the Warrant Shares in a name other than that of the Holder or an Affiliate of the Holder, it shall deliver to the Company on the Exercise Date an opinion of counsel reasonably satisfactory to the Company to the effect that the issuance of such Warrant Shares in such other name may be made pursuant to an available exemption from the registration requirements of the Securities Act of 1933, as amended (the "**Securities Act**") and all applicable state securities or blue sky laws), a certificate for the Warrant Shares issuable upon such exercise, free of restrictive legends unless the Registration Statement is not then effective or the Warrant Shares are not freely transferable without volume restrictions pursuant to Rule 144 under the Securities Act. The Holder, or any Person permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date. If the Warrant Shares can be issued without restrictive legends, the Company shall, upon the written request of the Holder, use its best efforts to deliver, or cause to be delivered, Warrant Shares hereunder electronically through the Depository Trust and Clearing Corporation ("**DTC**") or another established clearing corporation performing similar functions, if available; provided, that, the Company may, but will not be required to, change its transfer agent if its current transfer agent cannot deliver Warrant Shares electronically through DTC.

(b) If by the close of the third Trading Day after delivery of an Exercise Notice, duly completed and executed by the Holder, the Company fails to deliver to the Holder a certificate representing the required number of Warrant Shares in the manner required pursuant to Section 5(a) hereof, and if after such third Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "**Buy-In**"), then the Company shall, within three Trading Days after the Holder's request, and in the Holder's sole discretion, either (i) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "**Buy-In Price**"), at which point the Company's obligation to deliver such certificate (and to issue such Warrant Shares) shall terminate or (ii) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of Warrant Shares, times (B) the closing bid price on the date of the event giving rise to the Company's obligation to deliver such certificate.

(c) To the extent permitted by law, the Company's obligations to issue and deliver Warrant Shares in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, withholding tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided*, *however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any certificates for Warrant Shares or Warrants in a name other than that of the Holder. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction and customary and reasonable indemnity (which shall not include a surety bond), if requested. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are then issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9 hereof). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable.

9. Certain Adjustments. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on

any class of capital stock that is payable in shares of Common Stock, (ii) subdivides outstanding shares of Common Stock into a larger number of shares, or (iii) combines outstanding shares of Common Stock into a smaller number of shares, then in each such case the Exercise Price shall be adjusted by multiplying the Exercise Price by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph), (iii) rights or warrants to subscribe for or purchase any security, or (iv) any other asset (including cash) (in each case, "**Distributed Property**"), then the Holder shall receive with respect to all Warrant Shares the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to the record date for such Distributed Property.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, (ii) the Company effects any sale of all or substantially all of its assets in one or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of a majority of the outstanding shares of Common Stock tender or exchange their shares for other securities, cash or property, or (iv) the Company effects any reclassification of its outstanding Common Stock or any compulsory share exchange pursuant to which outstanding Common Stock is effectively converted into or exchanged for other securities, cash or property (each, a "**Fundamental Transaction**"), then the Holder shall have the right thereafter to receive, upon any subsequent exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant (the "**Alternate Consideration**"). The Company shall not effect any such Fundamental Transaction unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or the corporation purchasing or otherwise acquiring such assets or other appropriate corporation or entity shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to purchase, and the other obligations under this Warrant. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any successor entity shall pay in exchange for this Warrant at the Holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the Fundamental Transaction, an amount of cash equal to the value of this Warrant as determined in accordance with the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg L.P. using (i) a price per share of Common Stock equal to the VWAP of the Common Stock for the Trading Day immediately preceding the date of consummation of the applicable Fundamental Transaction, (ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of this Warrant as of the date of consummation of the applicable Fundamental Transaction and (iii) an expected volatility equal to the greater of 100% and the 60 day volatility obtained from the "HVT" function on Bloomberg L.P. determined as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction. The provisions of this paragraph (c) shall similarly apply to subsequent Fundamental Transactions.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to paragraph (a) of this Section 9, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Subsequent Equity Sales.

(i) If the Company shall at any time issue shares of Common Stock, Options or Convertible Securities entitling any Person to acquire shares of Common Stock, at a price per share less than the Exercise Price in effect immediately prior to the time of such issuance (if the holder of the Common Stock, Options or Convertible Securities so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights issued in connection with such issuance, be entitled to receive shares of Common Stock at a price less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price), then, the Exercise Price shall be reduced to equal such lower price, but the number of Warrant Shares which the Holder may acquire under this Warrant will not be affected thereby. Such adjustment shall be made whenever such Common Stock, Options or Convertible Securities are issued. The Company shall notify the Holder in writing, no later than the Trading Day following the issuance of any Common Stock, Options or Convertible Securities subject to this Section, indicating therein the applicable issuance price, or the applicable reset price, exchange price, conversion price and other pricing terms.

(ii) For purposes of this subsection 9(e), the following subsections (e)(ii)(l) to (e)(ii)(7) shall also be applicable:

(1) Issuance of Rights or Options. In case at any time the Company shall in any manner grant (directly and not by assumption in a merger or otherwise) any Options or Convertible Securities, whether or not such Options or the right to convert or exchange any such Convertible Securities are immediately exercisable, and the price per share for which Common Stock is issuable upon the exercise of such Options or upon the conversion or exchange of such Convertible Securities (determined by dividing (i) the sum (which sum shall constitute the applicable consideration) of (x) the total amount, if any, received or receivable by the Company as consideration for the granting of such Options, plus (y) the aggregate amount of additional consideration payable to the Company upon the exercise of all such Options, plus (z), in the case of such Options that relate to Convertible Securities, the aggregate amount of additional consideration, if any, payable upon the issue or sale of such Convertible Securities and upon the conversion or exchange thereof, by (ii) the total maximum number of shares of Common Stock issuable upon the exercise of such Options or upon the conversion or exchange of all such Convertible Securities issuable upon the exercise of such Options) shall be less than the Exercise Price in effect immediately prior to the time of the granting of such Options, then the total number of shares of Common

Stock issuable upon the exercise of such Options or upon conversion or exchange of the total amount of such Convertible Securities issuable upon the exercise of such Options shall be deemed to have been issued for such price per share as of the date of granting of such Options or the issuance of such Convertible Securities and thereafter shall be deemed to be outstanding for purposes of adjusting the Exercise Price. Except as otherwise provided in subsections 9(e)(i) and 9(e)(ii)(3), no adjustment of the Exercise Price shall be made upon the actual issue of such Common Stock or of such Convertible Securities upon exercise of such Options or upon the actual issue of such Common Stock upon conversion or exchange of such Convertible Securities.

(2) Issuance of Convertible Securities. In case the Company shall in any manner issue (directly and not by assumption in a merger or otherwise) or sell any Convertible Securities, whether or not the rights to exchange or convert any such Convertible Securities are immediately exercisable, and the price per share for which Common Stock is issuable upon such conversion or exchange (determined by dividing (i) the sum (which sum shall constitute the applicable consideration) of (x) the total amount received or receivable by the Company as consideration for the issue or sale of such Convertible Securities, plus (y) the aggregate amount of additional consideration, if any, payable to the Company upon the conversion or exchange thereof, by (ii) the total number of shares of Common Stock issuable upon the conversion or exchange of all such Convertible Securities) shall be less than the Exercise Price in effect immediately prior to the time of such issue or sale, then the total maximum number of shares of Common Stock issuable upon conversion or exchange of all such Convertible Securities shall be deemed to have been issued for such price per share as of the date of the issue or sale of such Convertible Securities and thereafter shall be deemed to be outstanding for purposes of adjusting the Exercise Price, provided that (a) except as otherwise provided in subsection 9(e)(ii)(3), no adjustment of the Exercise Price shall be made upon the actual issuance of such Common Stock upon conversion or exchange of such Convertible Securities and (b) no further adjustment of the Exercise Price shall be made by reason of the issue or sale of Convertible Securities upon exercise of any Options to purchase any such Convertible Securities for which adjustments of the Exercise Price have been made pursuant to the other provisions of subsection 9(e). No adjustment pursuant to this Section 9 shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(3) Change in Option Price or Conversion Rate. Upon the happening of any of the following events, namely, if the purchase price provided for in any Option referred to in subsection 9(e)(ii)(l) hereof, the additional consideration, if any, payable upon the conversion or exchange of any Convertible Securities referred to in subsections 9(e)(ii)(l) or 9(e)(ii)(2), or the rate at which Convertible Securities referred to in subsections 9(e)(ii)(l) or 9(e)(ii)(2) are convertible into or exchangeable for Common Stock shall change at any time (including, but not limited to, changes under or by reason of provisions designed to protect against dilution), the

Exercise Price in effect at the time of such event shall forthwith be readjusted to the Exercise Price that would have been in effect at such time had such Options or Convertible Securities still outstanding provided for such changed purchase price, additional consideration or conversion rate, as the case may be, at the time initially granted, issued or sold.

(4) Stock Dividends. Subject to the provisions of this Section 9(e), in case the Company shall declare a dividend or make any other distribution upon any stock of the Company (other than the Common Stock) payable in Common Stock, Options or Convertible Securities, then any Common Stock, Options or Convertible Securities, as the case may be, issuable in payment of such dividend or distribution shall be deemed to have been issued or sold without consideration.

(5) Calculation of Consideration Received. In case any Option is issued in connection with the issue or sale of other securities of the Company, together comprising one integrated transaction in which no specific consideration is allocated to such Options by the parties thereto, the Options will be deemed to have been issued for a consideration of $0.01. If any shares of Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount received by the Company therefor. If any shares of Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of securities, in which case the amount of consideration received by the Company will be the VWAP of such security on the date of receipt. If any shares of Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities, as the case may be. The fair value of any consideration other than cash or securities will be determined by the Company.

(6) Record Date. In case the Company shall take a record of the holders of its Common Stock for the purpose of entitling them (i) to receive a dividend or other distribution payable in Common Stock, Options or Convertible Securities or (ii) to subscribe for or purchase Common Stock, Options or Convertible Securities, then such record date shall be deemed to be the date of the issue or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase, as the case may be.

(7) Treasury Shares. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company or any of its wholly-owned subsidiaries, and the

disposition of any such shares (other than the cancellation or retirement thereof) shall be considered an issue or sale of Common Stock for the purpose of this subsection (e).

(iii) Notwithstanding the foregoing, no adjustment will be made under this paragraph (e) in respect of: (i) the issuance of securities upon the exercise or conversion of any Common Stock or Convertible Securities issued by the Company prior to the date hereof; provided that neither the conversion price, exercise price nor number of shares issuable under such Convertible Securities (excluding any Convertible Securities covered by clause (ii) below) is amended, modified or changed after the date hereof, (ii) the grant of options, warrants, Common Stock or other Convertible Securities (but not including any amendments to such instruments) under any duly authorized Company stock option, restricted stock plan or stock purchase plan whether now existing or hereafter approved by the Company and its stockholders in the future, and the issuance of Common Stock in respect thereof, (iii) the issuance of securities in connection with a Strategic Transaction, or (iv) the issuance of securities in a transaction described in Section 9(a) or 9(b) (collectively, "**Excluded Issuances**"). For purposes of this paragraph, a "**Strategic Transaction**" means a transaction or relationship in which (1) the Company issues shares of Common Stock to a Person that the Board of Directors determined in good faith is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company (or a shareholder thereof) and (2) the Company expects to receive benefits in addition to the investment of funds.

(f) Calculations. All calculations under this Section 9 shall be made to the nearest cent or the nearest 1/100th of a share, as applicable. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company, and the disposition of any such shares shall be considered an issue or sale of Common Stock.

(g) De Minimis Adjustments. No adjustment in the Exercise Price shall be required unless such adjustment would require an increase or decrease of at least $0.01 in such price; provided, however, that any adjustment which by reason of this Section 9(g) is not required to be made shall be carried forward and taken into account in any subsequent adjustments under this Section 9. All calculations under this Section 9 shall be made by the Company in good faith and shall be made to the nearest cent or to the nearest one hundredth of a share, as applicable. No adjustment need be made for a change in the par value or no par value of the Company's Common Stock.

(h) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, notify the Holder in writing of the occurrence of such adjustment and, at the written request of the Holder, promptly compute such adjustment in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the American Stock Transfer & Trust Company, the transfer agent of the Company.

(i) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including without limitation any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any Subsidiary, (ii) authorizes or approves,

enters into any definitive agreement for or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice describing the material terms and conditions of such transaction at least 10 Trading Days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction, and the Company will take all reasonable steps to give Holder the practical opportunity to exercise this Warrant prior to such time; *provided*, *however*, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

10. Payment of Exercise Price. The Holder may pay the Exercise Price in one of the following manners:

(a) Cash Exercise. The Holder may deliver immediately available funds; or

(b) Cashless Exercise. If an Exercise Notice is delivered at a time when the Registration Statement is not then effective, then the Holder may notify the Company in an Exercise Notice of its election to utilize cashless exercise, in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

X = Y [(A-B)/A]

Where

X = the number of Warrant Shares to be issued to the Holder

Y = the number of Warrant Shares with respect to which this Warrant is being exercised

A = the VWAP for the five Trading Days immediately prior to (but not including) the Exercise Date

B = the Exercise Price

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a cashless exercise transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued.

After the Trigger Date, the Company shall use commercially reasonable efforts to maintain an effective Registration Statement registering the Warrant Shares.

(c) Company-Elected Conversion. (i) The Company shall provide to the Holder prompt written notice of any time that the Company is unable to issue the Warrant Shares via DTC transfer (or otherwise without restrictive legend), because (A) the Securities and Exchange Commission (the "**Commission**") has issued a stop order with respect to the Registration Statement, (B) the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, (C) the Company has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, or (D) otherwise (each a "**Restrictive Legend Event**"). To the extent that a Restrictive Legend Event occurs after the Holder has exercised this Warrant in accordance with Section 4(b) but prior to the delivery of the Warrant Shares, the Company shall (i) if the VWAP (as calculated above) of the Warrant Shares is greater than the Exercise Price, provide written notice to the Holder that the Company will deliver that number of Warrant Shares to the Holder as should be delivered in a cashless exercise transaction in accordance with Section 10(b), and return to the Holder all consideration paid to the Company in connection with the Holder's attempted exercise

of this Warrant pursuant to Section 4(b) (a "**Company-Elected Conversion**"), or (ii) at the election of the Holder to be given within five (5) days of receipt of notice of a Company-Elected Conversion, the Holder shall be entitled to rescind the previously submitted Exercise Notice and the Company shall return all consideration paid by Holder for such shares upon such rescission. The Company shall provide to the Holder prompt written notice of the termination of the Restrictive Legend Event. If a Restrictive Legend Event is occurring as of the Expiration Date, the term of this Warrant shall be extended until the fifth (5th) business day after the termination of such Restrictive Legend Event.

11. Limitations on Exercise. Notwithstanding anything to the contrary contained herein, the number of Warrant Shares that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), does not exceed 9.99% of the total number of issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise). For such purposes, beneficial ownership shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. Each delivery of an Exercise Notice by the Holder will constitute a representation by the Holder that it has evaluated the limitation set forth in this Section and determined that issuance of the full number of Warrant Shares requested in such Exercise Notice is permitted under this Section. The Company's obligation to issue shares of Common Stock in excess of the limitation referred to in this Section shall be suspended (and, except as provided below, shall not terminate or expire notwithstanding any contrary provisions hereof) until such time, if any, as such shares of Common Stock may be issued in compliance with such limitation; provided, that, if, as of 5:30 p.m., New York City time, on the Expiration Date, the Company has not received written notice that the shares of Common Stock may be issued in compliance with such limitation, the Company's obligation to issue such shares shall terminate. This provision shall not restrict the number of shares of Common Stock which a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant. By written notice to the Company, which will not be effective until the 61st day after such notice is delivered to the Company, the Holder may waive the provisions of this Section to change the beneficial ownership limitation to 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant, and the provisions of this Section 11 shall continue to apply. Upon such a change by a Holder of the beneficial ownership limitation from such 9.99% limitation to such 4.99% limitation, the beneficial ownership limitation may not be further waived by such Holder.

12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the closing price of one Warrant Share as reported by the applicable Trading Market on the Exercise Date.

13. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address, respectively, specified in this Section 13 at or prior to 5:00 p.m. (New York City time) on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section 13 on a day that is not a Trading Day or later than 5:00 p.m. (New York City time) on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized

overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. The addresses for such notices or communications shall be: (a) if to the Company, to Delcath Systems, Inc., 1301 Avenue of the Americas, 43rd Floor, New York, New York 10019, Attention: Senior Vice President, Finance, Facsimile No.: (212) 489-2102, email: warrants@delcath.com (or such other address as the Company shall indicate in writing in accordance with this Section 13) or (b) if to the Holder, to the address or facsimile number appearing on the Warrant Register (or such other address as the Company shall indicate in writing in accordance with this Section 13). The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

14. Warrant Agent. The Company shall serve as warrant agent under this Warrant. Upon 30 days' notice to the Holder, the Company may appoint a new warrant agent provided any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. Miscellaneous.

(a) This Warrant shall be binding on and inure to the benefit of the parties hereto and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(b) All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of this Warrant and the transactions herein contemplated ("**Proceedings**") (whether brought against a party hereto or its respective Affiliates, employees or agents) shall be commenced exclusively in the courts of the State of New York located in the City and County of New York or in the United States District Court for the Southern District of New York (the "**New York Courts**"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any Proceeding, any claim that it is not personally subject to the jurisdiction of any New York Court, or that such Proceeding has been commenced in an improper or inconvenient forum. Each party hereto hereby irrevocably waives personal service of process and consents to process being served in any such Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Warrant or the transactions contemplated hereby. If either party shall commence a Proceeding to enforce

any provisions of this Warrant, then the prevailing party in such Proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Proceeding.

(c) The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(d) In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefore, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

(e) Prior to exercise of this Warrant, the Holder hereof shall not, by reason of by being a Holder, be entitled to any rights of a stockholder with respect to the Warrant Shares.

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

DELCATH SYSTEMS, INC.

By: _____
Name: Barbra C. Keck
Title: Senior Vice President, Finance

EXERCISE NOTICE

DELCATH SYSTEMS, INC.

WARRANT NO. DATED , 20

Ladies and Gentlemen:

(1) The undersigned hereby elects to exercise the above-referenced Warrant with respect to shares of Common Stock. Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The Holder intends that payment of the Exercise Price shall be made as (check one):

☐ Cash Exercise under Section 10(a)

☐ Cashless Exercise under Section 10(b)

(3) If the Holder has elected a Cash Exercise, the holder shall pay the sum of $ to the Company in accordance with the terms of the Warrant.

(4) Pursuant to this Exercise Notice, the Company shall deliver to the Holder the number of Warrant Shares determined in accordance with the terms of the Warrant.

(5) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934) permitted to be owned under Section 11 of this Warrant to which this notice relates.

(6) The DWAC information for the transfer of the shares of Common Stock is set out below.

HOLDER:

_____
(Print Name)

By: _____
Name:
Title:

DWAC Information

Name of Holder's broker: _____

Broker's DTC No.: _____

Name on Holder's brokerage account: _____

Holder's brokerage account number: _____

WARRANT ORIGINALLY ISSUED , 20
WARRANT NO.

FORM OF ASSIGNMENT

To be completed and signed only upon transfer of Warrant

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto the right represented by the within Warrant to purchase shares of Common Stock to which the within Warrant relates and appoints attorney to transfer said right on the books of the Company with full power of substitution in the premises.

Dated:

TRANSFEROR:

_____
(Print Name)

By: _____
Name:
Title:

TRANSFEREE:

_____
(Print Name)

_____

_____
(Address of Transferee)

In the presence of:

_____

Exhibit 1.3

DELCATH SYSTEMS, INC.

SERIES B WARRANT (the "Warrant")

Warrant No. [●] Original Issue Date: [●], 2015

DELCATH SYSTEMS, INC., a Delaware corporation (the "**Company**"), hereby certifies that, for value received, [●] or its permitted registered assigns (the "**Holder**"), is entitled to purchase from the Company up to a total of [●] Units (subject to adjustment as provided herein), with each Unit consisting of (i) one share of common stock, $0.01 par value (the "**Common Stock**"), of the Company (an "**Option Share**") and (ii) one Series A Warrant in the form attached hereto as Exhibit A to purchase one share of Common Stock (an "**Option Series A Warrant Share**") of the Company at an exercise price equal to $[●] per Unit (as adjusted from time to time as provided herein, the "**Exercise Price**"), at any time and from time to time on or after the Closing Date (the "**Trigger Date**") and through and including 5:00 P.M., New York City time, on [●], 2015 (the "**Expiration Date**"), and subject to the following terms and conditions:

The original issuance of the Warrants and the Units by the Company has been registered pursuant to a Registration Statement on Form S-1 (File No. 333-204979) (together with any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act, the "**Registration Statement**").

1. Definitions.

"**Affiliate**" of a person means a person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the person specified.

"**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

"**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

"**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

"**Trading Day**" means any day on which trading of the Common Stock occurs on the applicable Trading Market.

"**Trading Market**" means the NASDAQ Capital Market or, if the Company's Common Stock is not then listed on the NASDAQ Capital Market, then such exchange or quotation system on which the Common Stock then primarily trades.

"**VWAP**" means, for any security as of any date, the dollar volume-weighted average price for such security on the applicable Trading Market during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg through its "Volume at Price" function or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30:01 a.m., New York City time,

and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg, or, if no dollar volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in the "pink sheets" by Pink Sheets LLC (formerly the National Quotation Bureau, Inc.). If the VWAP cannot be calculated for such security on such date on any of the foregoing bases, the VWAP of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved pursuant to Section 15(b) hereof. All such determinations shall be appropriately adjusted for any share dividend, share split or other similar transaction during such period.

2. List of Warrant Holders. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder from time to time). The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. List of Transfers.

(a) This Warrant, the Units, the Option Shares and the Option Series A Warrant Shares are transferable.

(b) The Company shall register any such transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, with the Form of Assignment attached hereto duly completed and signed, to the Company at its address specified herein. Upon any such registration or transfer, a new Warrant to purchase Common Stock, in substantially the form of this Warrant (any such new Warrant, a "**New Warrant**"), evidencing the portion of this Warrant so transferred shall be issued to the transferee and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Holder is responsible for any transfer taxes, fees or expenses payable upon such transfer.

4. Exercise and Duration of Warrants.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 hereof at any time and from time to time on or after the Trigger Date and through and including the Expiration Date. Subject to Section 11 hereof, at 5:00 p.m., New York City time, on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value and this Warrant shall be terminated and no longer outstanding. In addition, if cashless exercise would be permitted under Section 10(b) hereof, then all or part of this Warrant may be exercised by the registered Holder utilizing such cashless exercise provisions at any time, or from time to time, on or after the Trigger Date and through and including the Expiration Date.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached hereto (the "**Exercise Notice**"), completed and duly signed,

and (ii) if such Holder is not utilizing the cashless exercise provisions set forth in this Warrant, payment of the Exercise Price for the number of Units as to which this Warrant is being exercised. The date the Exercise Notice is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "**Exercise Date**;" provided that the Exercise Price is paid by Holder to Company within two Trading Days of such Exercise Date. For the avoidance of doubt, the Exercise Notice does not need to be notarized or contain a medallion guarantee or any other guarantee of any nature. The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Units. On or before the first (1st) business day following the date on which the Company has received the Exercise Notice, the Company shall transmit a confirmation of receipt of the Exercise Notice to the Holder and also will notify the Company's transfer agent.

5. Delivery of Units.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than three Trading Days after the Exercise Date) issue or cause to be issued and cause to be delivered to or upon the written order of the Holder and in such name or names as the Holder may designate (provided that, if the Registration Statement is not then effective and the Holder directs the Company to deliver certificates for the Option Shares and Option Series A Warrant Shares in a name other than that of the Holder or an Affiliate of the Holder, it shall deliver to the Company on the Exercise Date an opinion of counsel reasonably satisfactory to the Company to the effect that the issuance of such Option Shares and Series A Warrants in such other name may be made pursuant to an available exemption from the registration requirements of the Securities Act of 1933, as amended (the "**Securities Act**") and all applicable state securities or blue sky laws), a certificate for the Option Shares or Series A Warrants issuable upon such exercise, free of restrictive legends unless the Registration Statement is not then effective or the Option Shares or Series A Warrants are not freely transferable without volume restrictions pursuant to Rule 144 under the Securities Act. The Holder, or any Person permissibly so designated by the Holder to receive Option Shares and Series A Warrants, shall be deemed to have become the holder of record of such Option Shares and Series A Warrants as of the Exercise Date. If the Option Shares can be issued without restrictive legends, the Company shall, upon the written request of the Holder, use its best efforts to deliver, or cause to be delivered, Option Shares hereunder electronically through the Depository Trust and Clearing Corporation ("**DTC**") or another established clearing corporation performing similar functions, if available; provided, that, the Company may, but will not be required to, change its transfer agent if its current transfer agent cannot deliver Option Shares electronically through DTC.

(b) If by the close of the third Trading Day after delivery of an Exercise Notice, duly completed and executed by the Holder, the Company fails to deliver to the Holder certificates representing the required number of Option Shares in the manner required pursuant to Section 5(a) hereof, and if after such third Trading Day and prior to the receipt of such Option Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Option Shares which the Holder anticipated receiving upon such exercise (a "**Buy-In**"), then the Company shall, within three Trading Days after the Holder's request, and in the Holder's sole discretion, either (i) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "**Buy-In Price**"), at which point the Company's obligation to deliver such certificates (and to issue such Option

Shares) shall terminate or (ii) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Option Shares and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of Option Shares, times (B) the closing bid price on the date of the event giving rise to the Company's obligation to deliver such certificate.

(c) To the extent permitted by law, the Company's obligations to issue and deliver Option Shares and Series A Warrants in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Option Shares and Series A Warrants. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, withholding tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided, however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any certificates for Option Shares, Series A Warrants or Warrants in a name other than that of the Holder. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Option Shares and Series A Warrants upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction and customary and reasonable indemnity (which shall not include a surety bond), if requested. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Option Shares. The Company covenants that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Option Shares upon exercise of this Warrant as herein provided, the number of Option Shares that are then issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9 hereof). The Company covenants that all Option Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable.

9. Certain Adjustments. The Exercise Price and number of Units issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, (ii) subdivides outstanding shares of Common Stock into a larger number of shares, or (iii) combines outstanding shares of Common Stock into a smaller number of shares, then in each such case the Exercise Price shall be adjusted by multiplying the Exercise Price by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph), (iii) rights or warrants to subscribe for or purchase any security, or (iv) any other asset (including cash) (in each case, "**Distributed Property**"), then the Holder shall receive with respect to all Units the Distributed Property that such Holder would have been entitled to receive in respect of such number of Units had the Holder been the record holder of such Units immediately prior to the record date for such Distributed Property.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, (ii) the Company effects any sale of all or substantially all of its assets in one or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of a majority of the outstanding shares of Common Stock tender or exchange their shares for other securities, cash or property, or (iv) the Company effects any reclassification of its outstanding Common Stock or any compulsory share exchange pursuant to which outstanding Common Stock is effectively converted into or exchanged for other securities, cash or property (each, a "**Fundamental Transaction**"), then the Holder shall have the right thereafter to receive, upon any subsequent exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Units then issuable upon exercise in full of this Warrant (the "**Alternate Consideration**"). The Company shall not effect any such Fundamental Transaction unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or the corporation purchasing or otherwise acquiring such assets or other appropriate corporation or entity shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to purchase, and the other obligations under this Warrant. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any successor entity shall pay in exchange for this Warrant at the Holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the Fundamental Transaction, an amount of cash equal to the value of this Warrant as determined in accordance with the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg L.P. using (i) a price per share of Common Stock equal to the VWAP of the Common Stock for the Trading Day immediately preceding the date of consummation of the applicable Fundamental Transaction,

(ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of this Warrant as of the date of consummation of the applicable Fundamental Transaction and (iii) an expected volatility equal to the greater of 100% and the 60 day volatility obtained from the "HVT" function on Bloomberg L.P. determined as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction. The provisions of this paragraph (c) shall similarly apply to subsequent Fundamental Transactions.

(d) Number of Units. Simultaneously with any adjustment to the Exercise Price pursuant to paragraph (a) of this Section 9, the number of Units that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Units shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Subsequent Equity Sales.

(i) If the Company shall at any time issue shares of Common Stock, Options or Convertible Securities entitling any Person to acquire shares of Common Stock, at a price per share less than the Exercise Price in effect immediately prior to the time of such issuance (if the holder of the Common Stock, Options or Convertible Securities so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights issued in connection with such issuance, be entitled to receive shares of Common Stock at a price less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price), then, the Exercise Price shall be reduced to equal such lower price, but the number of Units which the Holder may acquire under this Warrant will not be affected thereby. Such adjustment shall be made whenever such Common Stock, Options or Convertible Securities are issued. The Company shall notify the Holder in writing, no later than the Trading Day following the issuance of any Common Stock, Options or Convertible Securities subject to this Section, indicating therein the applicable issuance price, or the applicable reset price, exchange price, conversion price and other pricing terms.

(ii) For purposes of this subsection 9(e), the following subsections (e)(ii)(l) to (e)(ii)(7) shall also be applicable:

(1) Issuance of Rights or Options. In case at any time the Company shall in any manner grant (directly and not by assumption in a merger or otherwise) any Options or Convertible Securities, whether or not such Options or the right to convert or exchange any such Convertible Securities are immediately exercisable, and the price per share for which Common Stock is issuable upon the exercise of such Options or upon the conversion or exchange of such Convertible Securities (determined by dividing (i) the sum (which sum shall constitute the applicable consideration) of (x) the total amount, if any, received or receivable by the Company as consideration for the granting of such Options, plus (y) the aggregate amount of additional consideration payable to the Company upon the exercise of all such Options, plus (z), in the case of such Options that relate to Convertible Securities, the aggregate amount of additional consideration, if any, payable upon the issue or sale of such Convertible Securities and upon the conversion or exchange thereof, by (ii) the total maximum number of shares of Common Stock issuable upon the exercise of such Options or upon the conversion or exchange of all such

Convertible Securities issuable upon the exercise of such Options) shall be less than the Exercise Price in effect immediately prior to the time of the granting of such Options, then the total number of shares of Common Stock issuable upon the exercise of such Options or upon conversion or exchange of the total amount of such Convertible Securities issuable upon the exercise of such Options shall be deemed to have been issued for such price per share as of the date of granting of such Options or the issuance of such Convertible Securities and thereafter shall be deemed to be outstanding for purposes of adjusting the Exercise Price. Except as otherwise provided in subsections 9(e)(i) and 9(e)(ii)(3), no adjustment of the Exercise Price shall be made upon the actual issue of such Common Stock or of such Convertible Securities upon exercise of such Options or upon the actual issue of such Common Stock upon conversion or exchange of such Convertible Securities.

(2) Issuance of Convertible Securities. In case the Company shall in any manner issue (directly and not by assumption in a merger or otherwise) or sell any Convertible Securities, whether or not the rights to exchange or convert any such Convertible Securities are immediately exercisable, and the price per share for which Common Stock is issuable upon such conversion or exchange (determined by dividing (i) the sum (which sum shall constitute the applicable consideration) of (x) the total amount received or receivable by the Company as consideration for the issue or sale of such Convertible Securities, plus (y) the aggregate amount of additional consideration, if any, payable to the Company upon the conversion or exchange thereof, by (ii) the total number of shares of Common Stock issuable upon the conversion or exchange of all such Convertible Securities) shall be less than the Exercise Price in effect immediately prior to the time of such issue or sale, then the total maximum number of shares of Common Stock issuable upon conversion or exchange of all such Convertible Securities shall be deemed to have been issued for such price per share as of the date of the issue or sale of such Convertible Securities and thereafter shall be deemed to be outstanding for purposes of adjusting the Exercise Price, provided that (a) except as otherwise provided in subsection 9(e)(ii)(3), no adjustment of the Exercise Price shall be made upon the actual issuance of such Common Stock upon conversion or exchange of such Convertible Securities and (b) no further adjustment of the Exercise Price shall be made by reason of the issue or sale of Convertible Securities upon exercise of any Options to purchase any such Convertible Securities for which adjustments of the Exercise Price have been made pursuant to the other provisions of subsection 9(e). No adjustment pursuant to this Section 9 shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(3) Change in Option Price or Conversion Rate. Upon the happening of any of the following events, namely, if the purchase price provided for in any Option referred to in subsection 9(e)(ii)(l) hereof, the additional consideration, if any, payable upon the conversion or exchange of any Convertible Securities referred to in subsections 9(e)(ii)(l) or 9(e)(ii)(2), or the rate at which Convertible Securities referred to in subsections

9(e)(ii)(l) or 9(e)(ii)(2) are convertible into or exchangeable for Common Stock shall change at any time (including, but not limited to, changes under or by reason of provisions designed to protect against dilution), the Exercise Price in effect at the time of such event shall forthwith be readjusted to the Exercise Price that would have been in effect at such time had such Options or Convertible Securities still outstanding provided for such changed purchase price, additional consideration or conversion rate, as the case may be, at the time initially granted, issued or sold.

(4) Stock Dividends. Subject to the provisions of this Section 9(e), in case the Company shall declare a dividend or make any other distribution upon any stock of the Company (other than the Common Stock) payable in Common Stock, Options or Convertible Securities, then any Common Stock, Options or Convertible Securities, as the case may be, issuable in payment of such dividend or distribution shall be deemed to have been issued or sold without consideration.

(5) Calculation of Consideration Received. In case any Option is issued in connection with the issue or sale of other securities of the Company, together comprising one integrated transaction in which no specific consideration is allocated to such Options by the parties thereto, the Options will be deemed to have been issued for a consideration of $0.01. If any shares of Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount received by the Company therefor. If any shares of Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of securities, in which case the amount of consideration received by the Company will be the VWAP of such security on the date of receipt. If any shares of Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities, as the case may be. The fair value of any consideration other than cash or securities will be determined by the Company.

(6) Record Date. In case the Company shall take a record of the holders of its Common Stock for the purpose of entitling them (i) to receive a dividend or other distribution payable in Common Stock, Options or Convertible Securities or (ii) to subscribe for or purchase Common Stock, Options or Convertible Securities, then such record date shall be deemed to be the date of the issue or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase, as the case may be.

(7) Treasury Shares. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company or any of its wholly-owned subsidiaries, and the disposition of any such shares (other than the cancellation or retirement thereof) shall be considered an issue or sale of Common Stock for the purpose of this subsection (e).

(iii) Notwithstanding the foregoing, no adjustment will be made under this paragraph (e) in respect of: (i) the issuance of securities upon the exercise or conversion of any Common Stock or Convertible Securities issued by the Company prior to the date hereof; provided that neither the conversion price, exercise price nor number of shares issuable under such Convertible Securities (excluding any Convertible Securities covered by clause (ii) below) is amended, modified or changed after the date hereof, (ii) the grant of options, warrants, Common Stock or other Convertible Securities (but not including any amendments to such instruments) under any duly authorized Company stock option, restricted stock plan or stock purchase plan whether now existing or hereafter approved by the Company and its stockholders in the future, and the issuance of Common Stock in respect thereof, (iii) the issuance of securities in connection with a Strategic Transaction, or (iv) the issuance of securities in a transaction described in Section 9(a) or 9(b) (collectively, "**Excluded Issuances**"). For purposes of this paragraph, a "**Strategic Transaction**" means a transaction or relationship in which (1) the Company issues shares of Common Stock to a Person that the Board of Directors determined in good faith is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company (or a shareholder thereof) and (2) the Company expects to receive benefits in addition to the investment of funds.

(f) Calculations. All calculations under this Section 9 shall be made to the nearest cent or the nearest 1/100th of a share, as applicable. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company, and the disposition of any such shares shall be considered an issue or sale of Common Stock.

(g) De Minimis Adjustments. No adjustment in the Exercise Price shall be required unless such adjustment would require an increase or decrease of at least $0.01 in such price; provided, however, that any adjustment which by reason of this Section 9(g) is not required to be made shall be carried forward and taken into account in any subsequent adjustments under this Section 9. All calculations under this Section 9 shall be made by the Company in good faith and shall be made to the nearest cent or to the nearest one hundredth of a share, as applicable. No adjustment need be made for a change in the par value or no par value of the Company's Common Stock.

(h) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, notify the Holder in writing of the occurrence of such adjustment and, at the written request of the Holder, promptly compute such adjustment in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Units or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the American Stock Transfer & Trust Company, the transfer agent of the Company.

(i) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including without limitation any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any Subsidiary, (ii) authorizes or approves, enters into any definitive agreement for or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice describing the material terms and conditions of such transaction at least 10 Trading Days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction, and the Company will take all reasonable steps to give Holder the practical opportunity to exercise this Warrant prior to such time; *provided*, *however*, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

10. Payment of Exercise Price. The Holder may pay the Exercise Price in one of the following manners:

(a) Cash Exercise. The Holder may deliver immediately available funds; or

(b) Cashless Exercise. If an Exercise Notice is delivered at a time when the Registration Statement is not then effective, then the Holder may notify the Company in an Exercise Notice of its election to utilize cashless exercise, in which event the Company shall issue to the Holder the number of Units determined as follows:

X = Y [(A-B)/A]

Where

X = the number of Units to be issued to the Holder

Y = the number of Units with respect to which this Warrant is being exercised

A = the VWAP for the five Trading Days immediately prior to (but not including) the Exercise Date

B = the Exercise Price

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Units issued in a cashless exercise transaction shall be deemed to have been acquired by the Holder, and the holding period for the Units shall be deemed to have commenced, on the date this Warrant was originally issued.

After the Trigger Date, the Company shall use commercially reasonable efforts to maintain an effective Registration Statement registering the Units.

(c) Company-Elected Conversion. (i) The Company shall provide to the Holder prompt written notice of any time that the Company is unable to issue the Units via DTC transfer (or otherwise without restrictive legend), because (A) the Securities and Exchange Commission (the "**Commission**") has issued a stop order with respect to the Registration Statement, (B) the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, (C) the Company has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, or (D) otherwise (each a "**Restrictive Legend Event**"). To the extent that a Restrictive Legend Event occurs after the Holder has exercised this Warrant in accordance with Section 4(b) but prior to the delivery of the Units, the Company shall (i) if the VWAP (as calculated above) of the Units is greater than

the Exercise Price, provide written notice to the Holder that the Company will deliver that number of Units to the Holder as should be delivered in a cashless exercise transaction in accordance with Section 10(b), and return to the Holder all consideration paid to the Company in connection with the Holder's attempted exercise of this Warrant pursuant to Section 4(b) (a "**Company-Elected Conversion**"), or (ii) at the election of the Holder to be given within five (5) days of receipt of notice of a Company-Elected Conversion, the Holder shall be entitled to rescind the previously submitted Exercise Notice and the Company shall return all consideration paid by Holder for such shares upon such rescission. The Company shall provide to the Holder prompt written notice of the termination of the Restrictive Legend Event. If a Restrictive Legend Event is occurring as of the Expiration Date, the term of this Warrant shall be extended until the fifth (5th) business day after the termination of such Restrictive Legend Event.

11. Limitations on Exercise. Notwithstanding anything to the contrary contained herein, the number of Units that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), does not exceed 9.99% of the total number of issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise). For such purposes, beneficial ownership shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. Each delivery of an Exercise Notice by the Holder will constitute a representation by the Holder that it has evaluated the limitation set forth in this Section and determined that issuance of the full number of Units requested in such Exercise Notice is permitted under this Section. The Company's obligation to issue shares of Common Stock in excess of the limitation referred to in this Section shall be suspended (and, except as provided below, shall not terminate or expire notwithstanding any contrary provisions hereof) until such time, if any, as such shares of Common Stock may be issued in compliance with such limitation; provided, that, if, as of 5:30 p.m., New York City time, on the Expiration Date, the Company has not received written notice that the shares of Common Stock may be issued in compliance with such limitation, the Company's obligation to issue such shares shall terminate. This provision shall not restrict the number of shares of Common Stock which a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant. By written notice to the Company, which will not be effective until the 61st day after such notice is delivered to the Company, the Holder may waive the provisions of this Section to change the beneficial ownership limitation to 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant, and the provisions of this Section 11 shall continue to apply. Upon such a change by a Holder of the beneficial ownership limitation from such 9.99% limitation to such 4.99% limitation, the beneficial ownership limitation may not be further waived by such Holder.

12. No Fractional Shares. No fractional Option Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the closing price of one Option Share as reported by the applicable Trading Market on the Exercise Date.

13. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address, respectively, specified in this Section 13 at or prior to 5:00 p.m. (New York City time) on a Trading Day, (ii) the next Trading Day after the date of

transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section 13 on a day that is not a Trading Day or later than 5:00 p.m. (New York City time) on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. The addresses for such notices or communications shall be: (a) if to the Company, to Delcath Systems, Inc., 1301 Avenue of the Americas, 43rd Floor, New York, New York 10019, Attention: Senior Vice President, Finance, Facsimile No.: (212) 489-2102, email: warrants@delcath.com (or such other address as the Company shall indicate in writing in accordance with this Section 13) or (b) if to the Holder, to the address or facsimile number appearing on the Warrant Register (or such other address as the Company shall indicate in writing in accordance with this Section 13). The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

14. Warrant Agent. The Company shall serve as warrant agent under this Warrant. Upon 30 days' notice to the Holder, the Company may appoint a new warrant agent provided any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. Miscellaneous.

(a) This Warrant shall be binding on and inure to the benefit of the parties hereto and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(b) All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of this Warrant and the transactions herein contemplated ("**Proceedings**") (whether brought against a party hereto or its respective Affiliates, employees or agents) shall be commenced exclusively in the courts of the State of New York located in the City and County of New York or in the United States District Court for the Southern District of New York (the "**New York Courts**"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any Proceeding, any claim that it is not personally subject to the jurisdiction of any New York Court, or that such Proceeding has been commenced in an improper or inconvenient forum. Each party hereto hereby irrevocably waives personal service of process and consents to process being served in any such Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Warrant or the transactions contemplated hereby. If either party shall commence a Proceeding to enforce any provisions of this Warrant, then the prevailing party in such Proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Proceeding.

(c) The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(d) In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefore, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

(e) Prior to exercise of this Warrant, the Holder hereof shall not, by reason of by being a Holder, be entitled to any rights of a stockholder with respect to the Units, Option Shares or Series A Warrants.

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

DELCATH SYSTEMS, INC.

By: _____
Name: Barbra C. Keck
Title: Senior Vice President, Finance

EXERCISE NOTICE

DELCATH SYSTEMS, INC.

WARRANT NO. DATED , 20

Ladies and Gentlemen:

(1) The undersigned hereby elects to exercise the above-referenced Warrant with respect to shares of Common Stock. Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The Holder intends that payment of the Exercise Price shall be made as (check one):

☐ Cash Exercise under Section 10(a)

☐ Cashless Exercise under Section 10(b)

(3) If the Holder has elected a Cash Exercise, the holder shall pay the sum of $ to the Company in accordance with the terms of the Warrant.

(4) Pursuant to this Exercise Notice, the Company shall deliver to the Holder the number of Units determined in accordance with the terms of the Warrant.

(5) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934) permitted to be owned under Section 11 of this Warrant to which this notice relates.

(6) The DWAC information for the transfer of the shares of Common Stock is set out below.

HOLDER:

_____
(Print Name)

By: _____
Name:
Title:

DWAC Information

Name of Holder's broker: _____

Broker's DTC No.: _____

Name on Holder's brokerage account: _____

Holder's brokerage account number: _____

WARRANT ORIGINALLY ISSUED , 20
WARRANT NO.

FORM OF ASSIGNMENT

To be completed and signed only upon transfer of Warrant

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto the right represented by the within Warrant to purchase shares of Common Stock to which the within Warrant relates and appoints attorney to transfer said right on the books of the Company with full power of substitution in the premises.

Dated:

TRANSFEROR:

_____
(Print Name)

By: _____
Name:
Title:

TRANSFEREE:

_____
(Print Name)

_____

_____
(Address of Transferee)

In the presence of:

_____

Exhibit 5.1

July 2, 2015

Delcath Systems, Inc.
1301 Avenue of the Americas
43rd Floor
New York, New York 10019

Re: Registration Statement on Form S-1 (Registration No. 333-204979) (the "Registration Statement")

Ladies and Gentlemen:

We have acted as counsel to Delcath Systems, Inc., a Delaware corporation (the "Company"), in connection with the offering by the Company of up to $10,000,000 of units, each of which consists of (i) one share ("Initial Share") of common stock, par value $0.01 per share ("Common Stock"), (ii) one Series A Warrant ("Initial Series A Warrant") to purchase one share of Common Stock ("Initial Series A Warrant Share") and (iii) one Series B Warrant ("Series B Warrant" and, together with the Initial Series A Warrant, the "Initial Warrants") to purchase one additional share of Common Stock ("Additional Series B Warrant Share") and one additional Series A Warrant ("Additional Series A Warrant" and, together with the Initial Warrants, the "Warrants") to purchase one additional share of Common Stock ("Additional Series A Warrant Share" and, together with the Initial Series A Warrant Share and the Additional Series B Warrant Share, the "Warrant Shares"), pursuant to the Registration Statement and the prospectus included in the Registration Statement (the "Prospectus"), filed under the Securities Act of 1933, as amended (the "Act"), with the Securities and Exchange Commission (the "SEC"). The Warrants and the Warrant Shares are collectively referred to as the "Securities." We understand that the Securities are being offered and sold pursuant to and in accordance with the Registration Statement and the Prospectus.

In connection with this opinion letter, we have examined the Registration Statement, the Prospectus and originals, or copies certified or otherwise identified to our satisfaction, of the Amended and Restated Certificate of Incorporation of the Company, as amended, the Amended and Restated Bylaws of the Company, and the minutes of meetings of the Board of Directors of the Company as provided to us by the Company and such other documents, records and other instruments as we have deemed appropriate for purposes of the opinion set forth herein.

We have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of the documents submitted to us as originals, the conformity with the originals of all documents submitted to us as certified, facsimile or photostatic copies and the authenticity of the originals of all documents submitted to us as copies.

Based upon the foregoing, we are of the opinion that (i) the Initial Shares have been duly authorized by the Company and, when issued and sold by the Company and delivered by the Company against receipt of the purchase price therefor, in the manner contemplated by the Registration Statement and the Prospectus, will be validly issued, fully paid and non-assessable,

(ii) the Initial Warrants have been duly authorized by the Company and, provided that the Initial Warrants have been duly executed and delivered by the Company and duly delivered to the purchasers thereof against payment therefor, then the Initial Warrants, when issued and sold in the manner contemplated by the Registration Statement and the Prospectus, will be valid and legally binding obligations of the Company, enforceable against the Company in accordance with their terms, (iii) assuming that there is a sufficient number of authorized and unissued Common Stock at the time of the Warrant exercise, the Warrant Shares, when issued and delivered by the Company against payment therefor, upon the exercise of the Warrants in accordance with the terms therein, will be duly authorized, validly issued, fully paid and non-assessable, and (iv) the Additional Series A Warrants have been duly authorized by the Company and, provided that the Additional Series A Warrants have been duly issued and delivered against payment therefor upon the exercise of the Series B Warrants in accordance with the terms therein, then the Additional Series A Warrants, when so issued and delivered, will be valid and legally binding obligations of the Company, enforceable against the Company in accordance with their terms.

The opinions expressed herein are subject to bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditors' rights generally and by general equitable principles (regardless of whether such enforceability is considered in a proceeding at law or in equity) and implied covenants of good faith and fair dealing.

The opinions expressed herein are limited to the Delaware General Corporation Law and we express no opinion with respect to the laws of any state or jurisdiction.

We hereby consent to the use of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to us under the caption "Legal Matters" in the Registration Statement and the Prospectus. In giving such consent, we do not hereby admit that we are acting within the category of persons whose consent is required under Section 7 of the Act or the rules or regulations of the SEC thereunder.

Very truly yours,

/s/ Morgan, Lewis & Bockius LLP

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in Amendment No. 1 to the Registration Statement (Form S-1 333-204979) and related Prospectus of Delcath Systems, Inc. for the registration of units each unit consisting of one share of common stock, one Series A warrant to purchase one share of common stock, and Series B warrants, each to purchase one unit with an aggregate initial offering price not to exceed $10,000,000, and to the incorporation by reference therein of our report dated March 11, 2015, with respect to the consolidated financial statements of Delcath Systems, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2014, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

MetroPark, New Jersey
July 2, 2015

Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178

July 2, 2015

United States Securities and Exchange
Commission Division of Corporation Finance
Washington, D.C. 20549
Attention: Amanda Ravitz
Assistant Director

Re: Delcath Systems, Inc.
Registration Statement on Form S-1
Filed on June 15, 2015
File No. 333-204979

Dear Ms. Ravitz:

On behalf of our client, Delcath Systems, Inc. (the "Company"), set forth below is the Company's response to the comments contained in the letter dated June 29, 2015 (the "Comment Letter") from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission"), which relates to the Company's Registration Statement on Form S-1 filed on June 15, 2015 (the "Registration Statement"). The Company is filing Amendment No. 1 to the Registration Statement (the "First Amendment") simultaneously with this letter. All references to page numbers in the responses below are to page numbers in the First Amendment. In order to facilitate your review, we have repeated each comment (each, a "Comment") in its entirety in the original numbered sequence.

Capitalized terms used in this letter but not defined herein have the meanings given to them in the First Amendment. Information provided in this letter on behalf of the Company has been provided to us by the Company.

Prospectus

1. Please provide the information required by Item 505 of Regulation S-K in an appropriate location in your prospectus. See Item 5 of Form S-1.

Response: In response to the Staff's comment, the Company has added the disclosure on page 69 of the First Amendment.

Use of Proceeds, page 35

2. Your disclosure currently indicates that you will use the net proceeds of your offering for the clinical and regulatory development of clinical studies and identifies the various studies for which the proceeds will be used. Please expand your disclosure to specify what steps in the clinical and regulatory development will be achieved with the proceeds from your offering, what steps will remain until commercialization, what amount of additional financing will be required to accomplish any remaining steps, and what the anticipated sources of the financing are. To the extent proceeds will be used to complete a portion of a clinical trial, please disclose what the application of the offering proceeds will allow you to accomplish in the trial. Please also disclose which of your products the offering proceeds will allow you to commercialize and which regulatory approvals your offering proceeds will allow you to seek.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 35 of the First Amendment. In addition, the Company acknowledges the Staff's comment about quantifying the amount of additional financing required by the Company to accomplish any remaining steps to commercialization and advises

the Staff that given the early stage of development of the Company's product candidates and the unpredictability of clinical trials, the Company is not able to meaningfully quantify the amount of additional financing required to reach commercialization. Furthermore, the Company believes that an estimate of additional financing required would be misleading to stockholders based on the inherent uncertainty in such an estimate.

3. Please also disclose the solicitation fee disclosed on page 69 that you will pay to the underwriters upon the exercise of any warrants sold in your offering and having an expiration equal to or less than 18 months, and ensure that your net proceeds disclosure also reflects the payment of those solicitation fees.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 35 of the First Amendment.

Description of Securities We Are Offering, page 59

4. Please reconcile your disclosure in this section that each unit consists of one share of common stock and one Series A Warrant and that you are also offering Series B Warrants, each to purchase one unit, with your disclosure on your prospectus cover page and fee table that each unit consists of one share of common stock, one Series A Warrant and one Series B Warrant.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 59 of the First Amendment.

Underwriting, page 69

5. We note your disclosure on page 59 that the underwriters will receive Series B Warrants for each unit sold in your offering. Please ensure that you disclose all forms of underwriter's compensation in accordance with Item 508(f) of Regulation S-K in the appropriate locations in your prospectus. If you will be issuing Series B Warrants to the underwriters please tell us, with a view toward clarified disclosure in your fee table, if you are registering those securities, and any underlying securities, as part of your offering.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 59 and 69 of the First Amendment. The Company is not issuing Series B Warrants to the underwriter.

* * * * *

Please contact the undersigned at (212) 309-6147 if you have any questions regarding the foregoing.

Very truly yours,

Steven A. Navarro

cc: Delcath Systems, Inc.