Filed Pursuant to Rule 424(b)(4)
Registration No. 333-204979

9,350,000 Units
Consisting of 9,350,000 Shares of Common Stock
and
7,012,500 Series A Warrants to Purchase 7,012,500 Shares of Common Stock
and
9,350,000 Series B Warrants to Purchase 9,350,000 Shares of Common Stock and 7,012,500 Series A Warrants

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We are offering 9,350,000 units, each of which consist of (i) one share of our common stock, (ii) 0.75 of 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 0.75 of one additional Series A Warrant to purchase one additional share of common stock. The units are being offered at a price of $0.75 per unit.

Purchasers will receive only shares of common stock, Series A Warrants and Series B Warrants. We will not issue fractional 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 $0.87 per share, which equals 105% 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 $0.75, which equals 90% 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 15, 2015 was $0.83 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	$ 0.75	$7,012,500
Underwriting discount(1)	$0.0525	$ 490,875
Proceeds, before expenses, to us(2)	$0.6975	$6,521,625

(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 July 21, 2015.

Roth Capital Partners

The date of this prospectus is July 16, 2015

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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	9,350,000 units, each consisting of one share of our common stock, 0.75 of 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 0.75 of one additional Series A Warrant to purchase one additional share of common stock at a price per unit equal to $0.75. 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 $0.87. See “Description of Securities—Series A Warrants.” The Series B Warrants are exercisable immediately at an initial exercise price of $0.75. 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.”
Warrants we are offering	7,012,500 Series A Warrants to purchase 7,012,500 shares of common stock (14,025,000 Series A Warrants to purchase 14,025,000 shares of common stock if all of the Series B Warrants offered hereby are exercised) 9,350,000 Series B Warrants to purchase 9,350,000 shares of common stock and 7,012,500 Series A Warrants to purchase 7,012,500 shares of common stock
Common stock we are offering	9,350,000 shares, excluding the shares underlying the Series A Warrants and Series B Warrants.
Common stock to be outstanding after this offering	21,735,016 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
- 23,375,000 shares of common stock issuable upon the exercise of warrants offered hereby, including
    - 7,012,500 shares of common stock issuable upon the exercise of the Series A Warrants included as part of the units,
    - 9,350,000 shares of common stock issuable upon the exercise of the Series B Warrants included as part of the units, and
    - 7,012,500 shares of common stock issuable upon the exercise of the Series A Warrants issuable upon the exercise of the Series B Warrants included as part of the units.

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.

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 $6.2 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.

We believe the fastest route to commercialization of the product is via the initiation, enrollment and completion of a global ocular melanoma phase 3 pivotal study. This is an overall survival study, where, upon completion of subject enrollment, data collection and monitoring, data will be statistically analyzed and interpreted and included in a New Drug Application (NDA) written and submitted to FDA for review and approval. We are currently discussing the overall trial design with FDA, as well as the sufficiency of overall survival data from one trial to demonstrate safety and effectiveness for NDA approval. The NDA will also contain requisite clinical pharmacology and drug and device engineering quality attributes for FDA’s review and approval. Additional funds will be required to complete enrollment into the registration trial and submission of the NDA, as well as market preparations for product launch. These market preparations will include market access preparation, hiring of a sales force/training, and appropriate marketing of the product approval.

The phase 2 clinical program, which includes the indications of HCC and ICC, will continue development upon positive interim results from the current phase 2 trials. If positive interim results are achieved, additional funds will be required should we deem it prudent to continue investment into such indications, including completion of the full single-arm phase 2 study after the positive go/no-go decision has been reached, as well as establishing and implementing a pivotal study program (randomized phase 3 trials), for each indication, in

accordance with FDA requirements for marketing authorizations. Additional funds will be required to complete enrollment into the registration trial and submission of the NDA, as well as market preparations for product launch. These market preparations will include market access preparation, hiring of a sales force/training, and appropriate marketing of the product approval.

Given the unpredictability of clinical trials, the FDA review process and product launch, we cannot meaningfully quantify the amount of additional funds we would require to commercialize our product for the indications described above.

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.

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 the net proceeds of 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	$ 24,684
Warrant liability	836	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, 21,550,397 shares issued and 21,519,706 shares outstanding, as adjusted	122	216
Additional paid-in capital	266,349	272,478
Accumulated deficit	(250,002)	(250,002)
Treasury stock, at cost; 1,757 shares	(51)	(51)
Accumulated other comprehensive income	6	6
Total stockholders' equity	16,424	22,647
Total capitalization	$ 17,260	$ 23,483

(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
- 23,375,000 shares of common stock issuable upon the exercise of warrants offered hereby, including
  - 7,012,500 shares of common stock issuable upon the exercise of the Series A Warrants included as part of the units,
  - 9,350,000 shares of common stock issuable upon the exercise of the Series B Warrants included as part of the units, and
  - 7,012,500 shares of common stock issuable upon the exercise of the Series A Warrants issuable upon the exercise of the Series B Warrants included as part of the units.

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 15, 2015)	0.92	0.83

The last reported trading price of our common stock on July 15, 2015 was $0.83. 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, which is expected to be covered by its insurance and is not expected to result in any additional expense in the Company’s financial statements.

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 July 2, 2015, the parties filed a Stipulation of Settlement that, if approved by the Court, will fully and finally resolve the claims brought by the Plaintiffs. The Company has made and/or has agreed to make certain changes to its corporate governance practices, policies and procedures for a period of no less than three years in connection with the proposed settlement, including, but not limited to, the appointment of additional independent directors as announced by the Company on December 15, 2014, complying with enhanced director independence standards, such as a five-year look back on employment of directors and remuneration of directors, directors' immediate family members or entities affiliated with directors, and the adoption of formal policies memorializing certain corporate governance standards, such as the separation of the roles of the Chairman of the Board and Chief Executive Officer, rotating the position of Audit Committee chairman, and continuing to facilitate annual stockholder "Say on Pay" votes. The Company has also agreed to pay plaintiffs' costs and attorneys' fees of $495,000, which is expected to be covered by its insurance and is not expected to result in any additional expense in the Company's financial statements.

The proposed settlement is subject to the preliminary approval of the Court as well as the Court's final approval after notice of the terms of the settlement has been provided to all current shareholders as of July 2, 2015. Timing of the approval process is dependent on the Court's calendar. Current shareholders will have the right to object to the settlement in writing to the Court once the Court has set a hearing for final approval. A preliminary approval hearing regarding the proposed settlement has been scheduled for August 12, 2015.

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.

The proposed settlement of the Weinstein matter is included in the Stipulation of Settlement filed on July 2, 2015, described above for the Consolidated Derivative Case.

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, 0.75 of 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 0.75 of one Series A Warrant.

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 7,012,500 shares of our common stock at an initial exercise price of $0.87 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 7,012,500 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. 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 9.99% 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 9,350,000 additional shares of common stock and an aggregate of 7,012,500 Series A Warrants, at an initial exercise price per share of $0.75 per share, 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.

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.

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 21,735,016 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	9,350,000

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	$ 0.0525
Total	490,875

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, June 11, 2015 and July 7, 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.

9,350,000 Units
Consisting of 9,350,000 Shares of Common Stock
and
7,012,500 Series A Warrants to Purchase 7,012,500 Shares of Common Stock
and
9,350,000 Series B Warrants to Purchase 9,350,000 Shares of Common Stock and 7,012,500 Series A Warrants

Delcath Systems, Inc.

PROSPECTUS

Roth Capital Partners

July 16, 2015