

DELCATH SYSTEMS, INC.

Form S-1/A

July 15, 2015

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As filed with the Securities and Exchange Commission on July 14, 2015

No. 333-204979

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

Amendment No 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Delcath Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)
1301 Avenue of the Americas

06-1245881
(I.R.S. Employer
Identification No.)

43rd Floor

New York, New York 10019

(212) 489-2100

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

Jennifer K. Simpson

President and

Chief Executive Officer

Delcath Systems, Inc.

1301 Avenue of the Americas

43rd Floor

New York, New York 10019

(212) 489-2100

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

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

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A Professional Corporation

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Newark, New Jersey 07102

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

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

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

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

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

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

Large accelerated filer "

Accelerated filer "

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company "

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price⁽¹⁾	Amount of Registration Fee
Units, each consisting of one share of common stock, \$0.01 par value per share, 0.75 of one Series A Warrant to purchase one share of common stock, and one Series B Warrant to purchase one additional share of common stock and 0.75 of one additional Series A Warrant to purchase one additional share of common stock ⁽²⁾		
Shares of Common Stock included as part of the Units		
Shares of Common Stock issuable upon exercise of Series A and Series B Warrants ⁽²⁾		
Series A Warrants included as part of the Units		
Series A Warrants issuable upon exercise of Series B Warrants		
Series B Warrants included as part of the Units		
Total	\$30,000,000	\$3,486⁽³⁾

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

(2) The securities being registered also include such indeterminate number of securities as may be issued to prevent dilution resulting from stock splits, stock dividends, recapitalization or other similar transactions or anti-dilution adjustments.

(3) Registrant previously paid \$1,162.

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

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

Subject to Completion, Dated July 14, 2015

9,000,000 Units

Consisting of 9,000,000 Shares of Common Stock

and

6,750,000 Series A Warrants to Purchase 6,750,000 Shares

of Common Stock

and

9,000,000 Series B Warrants to Purchase 9,000,000 Shares of

Common Stock and 6,750,000 Series A Warrants

We are offering 9,000,000 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 \$ 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 \$ per share, which equals % of the last reported sales price of our common stock on The NASDAQ Capital Market. The Series A Warrants will expire on the fifth anniversary of the date of issuance.

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

Our common stock is listed on The NASDAQ Capital Market under the symbol DCTH. The last reported sale price of our common stock on July 13, 2015 was \$0.84 per share. There is no established public trading market for either series of warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of either series of warrants on any national securities exchange or other nationally recognized trading system.

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

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

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

(1) See Underwriting for more information about total underwriter compensation.

(2) Excludes potential proceeds from the exercise of the warrants through this prospectus.

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

Roth Capital Partners
The date of this prospectus is , 2015

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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.

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PROSPECTUS SUMMARY

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

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

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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.

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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 develop liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care 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.

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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.

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The Offering

Securities we are offering	<p>9,000,000 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 \$. The Series A Warrants (including the Series A Warrants issuable upon exercise of the Series B Warrants) will be exercisable immediately and expire on the fifth anniversary of the initial date of issuance at an initial exercise price per share equal to \$. See Description of Securities Series A Warrants.</p> <p>The Series B Warrants are exercisable immediately at an initial exercise price of \$. The Series B Warrants will expire at the close of business on the 90th trading day following the date of issuance. See Description of Securities Series B Warrants.</p>
Warrants we are offering	<p>6,750,000 Series A Warrants to purchase 6,750,000 shares of common stock (13,500,000 Series A Warrants to purchase 13,500,000 shares of common stock if all of the Series B Warrants offered hereby are exercised)</p> <p>9,000,000 Series B Warrants to purchase 9,000,000 shares of common stock and 6,750,000 Series A Warrants to purchase 6,750,000 shares of common stock</p>
Common stock we are offering	9,000,000 shares, excluding the shares underlying the Series A Warrants and Series B Warrants.
Common stock to be outstanding after this offering	21,385,016 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

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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

22,500,000 shares of common stock issuable upon the exercise of warrants offered hereby, including

6,750,000 shares of common stock issuable upon the exercise of the Series A Warrants included as part of the units,

9,000,000 shares of common stock issuable upon the exercise of the Series B Warrants included as part of the units, and

6,750,000 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.

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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

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	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

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RISK FACTORS

This offering and an investment in our securities involve a high degree of risk. You should carefully consider the risks described below, together with the financial and other information contained in this prospectus, before you decide to purchase our securities. If any of the following risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that event, the trading price of our common stock and the market value of the securities offered hereby could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Financial Condition

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We received a complete response letter from the FDA regarding our 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

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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

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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;

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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.

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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.

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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.

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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.

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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

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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 payors 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.

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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.

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**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 metastases. We may pursue agreements with additional contract manufacturers to produce melphalan and other

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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.

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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

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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;

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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

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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

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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

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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

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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.

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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/

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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.

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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

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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: