DELCATH SYSTEMS, INC.
Form S-1/A
July 02, 2015
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As filed with the Securities and Exchange Commission on July 2, 2015

No. 333-204979

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No 1

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Delcath Systems, Inc.

(Exact name of registrant as specified in its charter)

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

1301 Avenue of the Americas

43rd Floor

New York, New York 10019

(212) 489-2100

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

Jennifer K. Simpson

President and

Chief Executive Officer

Delcath Systems, Inc.

1301 Avenue of the Americas

43rd Floor

New York, New York 10019

(212) 489-2100

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

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

Steven A. Navarro

Finnbarr D. Murphy

Morgan, Lewis & Bockius LLP

101 Park Avenue

James T. Seery

LeClairRyan,

A Professional Corporation

One Riverfront Plaza

New York, NY 10178

(212) 309-6000

1037 Raymond Boulevard, Sixteenth Floor

Newark, New Jersey 07102

(973) 491-3600

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

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

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

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

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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 2, 2015

Units

Each Unit Consisting of One Share of Common Stock

and

One Series A Warrant to Purchase One Share of Common Stock

and

One Series B Warrant to Purchase One Share of Common Stock and One Series A Warrant

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

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

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

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

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

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

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

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

(1) See Underwriting for more information about total underwriter compensation.
(2) Excludes potential proceeds from the exercise of the warrants through this prospectus.
The underwriter expects to deliver the securities to the purchasers on or about , 2015.

Roth Capital Partners
The date of this prospectus is , 2015

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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 development liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care for patients with ocular melanoma liver metastases. As a result, we estimate that up to 4,300 patients with ocular melanoma liver metastases in the U.S. and Europe may be eligible for treatment with our Melphalan/HDS.

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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	units, each consisting of one share of our common stock, one Series A Warrant to purchase one share of our common stock and one Series B Warrant to purchase one additional share of common stock and one additional Series A Warrant to purchase one additional share of common stock at a price per unit equal to $. The Series A Warrants (including the Series A Warrants issuable upon exercise of the Series B Warrants) will be exercisable immediately and expire on the fifth anniversary of the initial date of issuance at an initial exercise price per share equal to $. See Description of Securities Series A Warrants. The Series B Warrants are exercisable immediately at an initial exercise price of $. The Series B Warrants will expire at the close of business on the 90th trading day following the date of issuance. See Description of Securities Series B Warrants.
Common stock we are offering	Shares, excluding the shares underlying the Series A Warrants and Series B Warrants.
Common stock to be outstanding after this offering	shares, excluding the shares underlying the Series A Warrants and Series B Warrants.
Use of proceeds	We expect to use the net proceeds from this offering (including any resulting from the exercise of the warrants, if any) to fund the clinical and regulatory development of clinical studies, commercialization of our products, obtaining regulatory approvals, as well as for working capital and other general corporate purposes, including funding the costs of operating as a public company. See Use of Proceeds.
Dividend policy	We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain any earnings for use in connection with the expansion of our business and for general corporate purposes.
NASDAQ Capital Market symbol for common stock	DCTH

Risk factors	See Risk Factors and other information included or incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities
Transfer agent and registrar	American Stock Transfer and Trust Company, LLC

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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

the shares of common stock issuable upon the exercise of warrants offered hereby.

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Summary of Historical Financial Data

You should read the summary of historical financial data set forth below in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operation and the consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 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 mo