

DELCATH SYSTEMS INC  
Form 424B5  
May 25, 2012  
Table of Contents

Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-178819

**PROSPECTUS SUPPLEMENT**

(To Prospectus dated February 13, 2012)

**13,333,340 Units consisting of Common Stock  
and Warrants**

We are offering 13,333,340 units at a price of \$1.50 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.3 of a share of common stock. The warrants can be exercised during the period commencing on the date of original issuance and ending on May 25, 2015 and may be exercised at a price of \$1.65 per share (as adjusted from time to time). Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately. The shares of common stock, warrants and shares of common stock underlying the warrants are sometimes collectively referred to herein as the securities. See Description of Securities We Are Offering for a more complete description of the securities, beginning on page S-19.

Our common stock is listed on The NASDAQ Capital Market under the symbol DCTH. The last reported sale price of our common stock on May 23, 2012 was \$2.19 per share. There is no established public trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the 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 S-12 of this prospectus supplement and the section entitled Risk Factors beginning on page 2 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2011, which is incorporated by reference into this prospectus supplement and the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<b>Per Unit</b>	<b>Total</b>
Public offering price <sup>(1)</sup>	\$ 1.50	\$ 20,000,010
Underwriting discount <sup>(2)</sup>	\$ 0.09	\$ 1,200,000
Proceeds, before expenses, to us	\$ 1.41	\$ 18,800,010

(1) The public offering price is \$1.49 per share of common stock and \$0.01 per warrant to purchase shares of common stock.

(2) Excludes underwriters' out-of-pocket expenses we have agreed to reimburse. See the section entitled "Underwriting" in this Prospectus Supplement for additional information.

The underwriters may also purchase up to an additional 2,000,000 shares of common stock and/or additional warrants to purchase up to 600,000 shares of common stock from us at the public offering price for each security, less the underwriting discount, within 30 days after the date of this prospectus supplement to cover over-allotments, if any. Exercise of this over-allotment option in full will result in an additional \$3,000,000 of gross proceeds to us, before expenses and before an additional underwriting discount of \$180,000.

Delivery of the securities is expected to be made on or about May 31, 2012.

*Joint Book-Runners*

**Cowen and Company**

**Wedbush PacGrow Life Sciences**

*Co-Manager*

**Roth Capital Partners**

May 25, 2012.

**Table of Contents**

**TABLE OF CONTENTS**

**Prospectus Supplement**

	<b>Page</b>
<u>Disclosure Regarding Forward-Looking Statements</u>	S-1
<u>Where You Can Find Additional Information</u>	S-2
<u>Summary</u>	S-3
<u>Risk Factors</u>	S-12
<u>Use of Proceeds</u>	S-13
<u>Dividend Policy</u>	S-13
<u>Dilution</u>	S-14
<u>Capitalization</u>	S-15
<u>Price Range of Common Stock</u>	S-16
<u>Description of the Securities We Are Offering</u>	S-17
<u>Underwriting</u>	S-18
<u>Legal Matters</u>	S-22
<u>Experts</u>	S-22

**Prospectus**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	2
<u>Disclosure Regarding Forward-Looking Statements</u>	2
<u>Where You Can Find Additional Information</u>	3
<u>Use of Proceeds</u>	4
<u>Selling Stockholders</u>	4
<u>Description of Debt Securities</u>	5
<u>Description of Capital Stock</u>	7
<u>Description of Stock Purchase Contracts</u>	9
<u>Description of Warrants</u>	10
<u>Plan of Distribution</u>	12
<u>Legal Matters</u>	16
<u>Experts</u>	16

**Table of Contents**

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a shelf registration process. Under the shelf registration process, we may offer from time to time common stock, preferred stock, warrants, debt securities and stock purchase contracts. In the accompanying prospectus, we provide you with a general description of the securities we may offer from time to time under our shelf registration statement. In this prospectus supplement, we provide you with specific information about the securities that we are selling in this offering. Both this prospectus supplement and the accompanying prospectus include important information about us, our securities and other information you should know before investing. This prospectus supplement also adds, updates and changes information contained in the accompanying prospectus. You should read both this prospectus supplement and the accompanying prospectus as well as additional information described under [Where You Can Find Additional Information](#) in this prospectus supplement and the accompanying prospectus before investing in our securities.

**You should rely only on the information incorporated by reference or provided in this prospectus supplement and the accompanying prospectus or any free writing prospectus prepared by or on behalf of us. Neither we nor the underwriters have authorized anyone to provide you with additional or different information. If anyone provided you with additional or different information, you should not rely on it. Neither we nor the underwriters are making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates.**

S-ii

**Table of Contents**

**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement contain certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, could, would, will, may, can, continue, potential, should, and the negative of these terms or other terminology often identify forward-looking statements. Statements in this prospectus supplement, the accompanying prospectus and the other documents incorporated by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus supplement, the accompanying prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 in Item 1A under Risk Factors as well as in Item 7A Quantitative and Qualitative Disclosures About Market Risk, our Quarterly Report on Form 10-Q for the period ended March 31, 2012 in Part I, Item 3 Quantitative and Qualitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

the progress and results of our research and development programs;

our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;

the commencement of future clinical trials and the results and timing of those clinical trials;

submission and timing of applications for regulatory approval and approval thereof;

our ability to successfully source certain components of the system and enter into supplier contracts;

our ability to successfully manufacture and commercialize the Delcath chemosaturation system;

our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and

our estimates of potential market opportunities and our ability to successfully realize these opportunities.

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

**Table of Contents**

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

**You should rely only on the information contained in this prospectus supplement, the accompanying prospectus, and any documents incorporated by reference. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date on the front page of this prospectus supplement, regardless of the time of delivery of this prospectus supplement or any sale of securities.**

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

**Important Information Incorporated By Reference**

The SEC allows us to incorporate by reference information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus supplement contain important information that you should read about us.

The following documents are incorporated by reference into this document:

(File No. 001-16133)	Date of Filing(s)
Proxy Statement on Schedule 14A for our 2012 Meeting of Shareholders	April 27, 2012
Annual Report on Form 10-K for year ended December 31, 2011	March 6, 2012
Quarterly Report on Form 10-Q for quarter ended March 31, 2012	May 9, 2012
Current Reports on Form 8-K	January 13, 2012; January 31, 2012; February 2, 2012; March 26, 2012; April 18, 2012 and April 24, 2012

We also incorporate by reference into this prospectus supplement all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, or (ii) from the date of this prospectus supplement but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus supplement and the accompanying prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus supplement, other than exhibits which are specifically incorporated by reference into such documents. Requests should be directed to Controller at Delcath Systems, Inc., 810 Seventh Avenue, 35<sup>th</sup> Floor, New York, New York 10019 or by calling us at 212-489-2100.

## **Table of Contents**

### **SUMMARY**

*This summary highlights selected information more fully described elsewhere in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this prospectus supplement, the accompanying prospectus, any free writing prospectus and the documents incorporated by reference herein and therein carefully, especially the risks of investing in our securities discussed in Risk Factors below and the other risks described in the incorporated documents.*

*In this prospectus supplement, 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.*

### **Company Overview**

We are a development stage, specialty pharmaceutical and medical device company focused on oncology. Since our inception, we have directed our research efforts towards the development and clinical study of the Delcath chemosaturation system. The Delcath chemosaturation system is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. Our initial focus is on the treatment of primary and metastatic liver cancers.

The Delcath chemosaturation system allows the administration of concentrated regional chemotherapy by isolating the circulatory system of the targeted organ. Once the organ is isolated, the Delcath chemosaturation system delivers high doses of chemotherapeutic agents directly to the liver, while limiting systemic exposure and the related side effects by filtering the blood prior to returning it to the patient. The Delcath chemosaturation system involves a series of three catheter insertions, each of which is placed percutaneously through standard interventional radiology techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs and the potential for concomitant cancer therapies. We believe that the Delcath chemosaturation system is a platform technology that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body.

### **Europe**

On April 13, 2011, we obtained the right to affix the CE Mark to the first generation Delcath Hepatic CHEMOSAT® Delivery System (Generation 1 CHEMOSAT System) as a class III medical device. The right to affix the CE mark allows us to market and sell the CHEMOSAT System in the European Economic Area (EEA). The EEA consists of the 27 member countries of the European Union as well as Lichtenstein, Iceland, and Norway. In the EEA, the CHEMOSAT System is regulated as a medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return. On April 5, 2012, we obtained the right to affix the CE Mark to the CHEMOSAT System with our second generation hemofiltration cartridge (Generation 2 CHEMOSAT System). The Generation 2 CHEMOSAT System carries the same broad indication as the previous generation system permitting physicians to use the product for the percutaneous intra arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver to any patient who in their opinion may benefit. The Generation 2 CHEMOSAT System has demonstrated filter efficiency greater than 98% during drug infusion of melphalan in an in vivo study; the same study also showed that this system removes fewer blood platelets than the Generation 1 CHEMOSAT System.

## **Table of Contents**

We believe the CHEMOSAT System may ultimately fulfill an annual unmet clinical need for as many as 55,000 liver cancer patients in the EEA. We intend to focus our initial efforts on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. We believe these countries represent a majority of the total potential liver cancer market in EEA countries. We plan to use a combination of direct and indirect sales channels to market and distribute the CHEMOSAT System in the EEA. Our European commercialization strategy involves the establishment of clinical training and centers of excellence to educate and train physicians in these countries in order to develop key opinion thought leadership and foster initial market acceptance. To support our commercialization efforts in the EEA, we have established our European Headquarters in Galway, Ireland.

On November 21, 2011 we announced that we had entered into our first initial training and marketing agreement with the European Institute of Oncology (IEO) in Milan, Italy. Since then, we have entered into eight additional initial launch and training agreements with leading European cancer centers, and have established a presence in five of our seven target markets. We plan to add additional cancer centers in these target markets in the near future.

In February 2012, our first European patient treatments with the Generation 1 CHEMOSAT System took place at IEO in Italy and Frankfurt University Hospital in Germany. The initial patients involved were treated for inoperable liver-dominant metastases from ocular melanoma, cutaneous melanoma, breast cancer and gastric cancer.

In March 2012, we received our first commercial order for the CHEMOSAT System from the IEO. This order was fulfilled with Generation 2 CHEMOSAT Systems in April 2012 following the receipt of the CE Mark approval. The first patient was treated using the Generation 2 CHEMOSAT System in April 2012.

### ***United States***

In the United States, the Delcath chemosaturating system for the administration of melphalan hydrochloride is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration (FDA). In December 2010, we submitted our Section 505(b)(2) New Drug Application (NDA), to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, we received a Refusal to File (RTF) letter from the FDA for the NDA. The FDA will issue an RTF if it determines, upon an initial review, that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. On January 12, 2012, we held a pre-NDA meeting with the FDA to discuss our NDA submission and provide an update on the items identified in the RTF. Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission.

The very substantive work of clinical and safety data gathering from all of the clinical sites and the migration to FDA compliant clinical and safety databases is now complete and we are in the final stages of preparing our NDA submission. The last remaining task before the database is locked is resolution of a relatively small number of outstanding database queries at each site. Queries are routine questions about individual patient data records in an effort to complete a final reconciliation of the data. This task will be concluded on May 25th, at which point the database will be locked. Immediately after this, a final statistical analysis will be conducted and the final NDA submission package will be completed. We expect these final steps to take approximately 10



## **Table of Contents**

weeks to complete following the May 25<sup>th</sup> database lock, putting submission of the NDA in mid-August. The database lock is also important with respect to publications. Once the database is locked, the principle investigators will have the complete information needed to incorporate the data for the Phase 3 trial and multi-arm Phase 2 trials into their manuscripts and then submit them for publication.

In addition to the ongoing work on the NDA submission, we believe it is in the best interest of patients to explore ways of accelerating the availability of our second generation product to patients in the United States and therefore we have submitted to the FDA an amendment to our Investigational New Drug application to include the second generation Delcath chemosaturation system in the FDA's expanded access program, as well as all future clinical trials and compassionate use cases. Additionally, we have initiated dialogue with the FDA to discuss the optimal approval path for the second generation Delcath chemosaturation system in the United States. From these discussions, we hope to gain insight to ensure that our NDA submission is prepared in the best possible manner to support a future second generation Delcath chemosaturation system NDA supplement, which would be filed after the first generation Delcath chemosaturation system NDA is approved.

### ***International***

Having obtained the CE Mark for the CHEMOSAT System, we believe the right to affix the CE Mark can result in an accelerated regulatory approval in a number of countries outside the EEA and the United States. We recently received regulatory approval for the CHEMOSAT System in Australia and completed the product notification process in New Zealand, where we expect to launch the CHEMOSAT System in the second half of 2012 through authorized distributors. We have submitted applications for regulatory approval as a device for the CHEMOSAT System in Hong Kong, South Korea, Singapore and Brazil and intend to submit regulatory applications in Israel, Canada, Mexico, Argentina, Russia, India, Japan, China, and Taiwan. We are in the process of determining the regulatory pathway in some of these countries subject to negotiations with the applicable health authority. It is our intention to leverage the CE Mark in some or all of these countries to commercialize the Delcath CHEMOSAT System, where appropriate. Our facility in Galway, Ireland has obtained certificates of free sale from the Irish Medicines Board as many markets require country of origin manufacturing, such as Mexico, Argentina, Brazil, Japan, China, and Taiwan, as a prerequisite to obtain regulatory approval.

### ***Clinical Trials***

In 2010, we announced that our randomized Phase III clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. We also completed a multi-arm Phase II trial to treat other liver cancers. We intend to evaluate our CHEMOSAT System with melphalan for use in the treatment of metastatic colorectal cancer (mCRC) and hepatocellular carcinoma (HCC or primary liver cancer) in future clinical trials. In addition, we are currently developing a CHEMOSAT System with the chemotherapeutic agent doxorubicin and intend to evaluate the CHEMOSAT System with doxorubicin for use in the treatment of HCC in new clinical trials in Asia. We intend to initiate certain new clinical trials in these cancers in 2013. We also intend to evaluate a variety of chemotherapeutic agents for use with the Delcath chemosaturation system to treat other liver cancers, as well as other organs and body regions. We will need to conduct additional clinical trials in order to maximize the commercial opportunities of the chemosaturation system and, in certain markets including the United States, will need to seek additional approvals for each new indication for our system.

### **Advantages of the Delcath Chemosaturation System**

Currently there are few effective treatment options for cancers in the liver and they are generally associated with significant side effects. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgically isolated perfusion and liver transplant. We believe the Delcath chemosaturation

## **Table of Contents**

system may address the critical shortcomings of traditional liver cancer treatments based on the results of our Phase I, Phase II and Phase III trials:

*Allows Higher Dosing* Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of delivering over 100 times more of the chemotherapeutic agent to the treated organ than traditional systemic chemotherapy. In our clinical studies on patients with metastatic melanoma it was shown that higher dosing led to significantly improved disease control in the liver.

*Controls Toxicities* In pre-clinical studies, the Generation 2 CHEMOSAT System demonstrated filter efficiency greater than 98% during drug infusion, which reduces the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents. The Generation 2 CHEMOSAT System builds on the success of our Generation 1 CHEMOSAT System, which in our Phase III clinical trial, demonstrated filter efficiency of on average 72%.

*Minimally Invasive and Repeatable* The Delcath chemosaturation system allows for multiple courses of treatment with chemotherapeutic drugs and has a recovery period that is shorter than surgical resection or isolated hepatic perfusion.

*Treats the Entire Liver* By introducing the chemotherapeutic agent into the arterial blood supply feeding the liver, the Delcath chemosaturation system perfuses the entire liver with chemotherapy, treating both tumors that are visible as well as micro metastases that cannot be detected by imaging.

## **Strategy**

We believe the Delcath chemosaturation system represents a potentially important advancement in regional therapy for cancers in the liver that include both primary liver cancer and metastatic liver cancer with tumor cells originating from other organs. We are seeking to establish the Delcath chemosaturation system as the standard of care for disease control in the liver by concentrating the power of chemotherapy.

We also intend to develop the system for use with other chemotherapeutic agents, as well as for other organs in addition to the liver. We are continuing our research and development efforts with respect to other chemotherapeutic agents and the treatment of other types of cancer and will need to conduct additional clinical trials and seek approval for escalating doses of anti-cancer agents, including melphalan and doxorubicin for use with the Delcath chemosaturation system.

Our strategy includes the following elements:

*Commercialize the Delcath CHEMOSAT System in the European Economic Area.* We have established our EEA headquarters in Galway, Ireland and have begun hiring initial staff to support our commercialization strategy. As of February 2012, we have entered into initial training and marketing agreements with nine leading European cancer centers, and two of these centers have utilized the CHEMOSAT System to treat initial European patients. We are pursuing a two-pronged commercialization strategy in the EEA under which we will directly market the CHEMOSAT System in certain markets and enter into agreements with third-party distributors in others.

*Leverage the CE Mark to Commercialize the Delcath CHEMOSAT System in Other Countries.* We believe the right to affix the CE Mark can result in an accelerated regulatory approval in a number of countries outside the EEA and the United States. We recently received regulatory approval for the CHEMOSAT System in Australia and completed the product notification process in New Zealand. We have submitted applications for regulatory approval in Hong Kong, South Korea, Singapore and Brazil and intend to submit in Israel, Canada, Mexico, Argentina, Russia, India, Japan, China, and Taiwan. It is our intention to leverage the CE Mark in some or all of these countries to commercialize the CHEMOSAT System, where appropriate.



## **Table of Contents**

*Obtain FDA Approval for Use of the Delcath Chemosaturation System in Combination with Melphalan to Treat Metastatic Melanoma in the Liver.* Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission. We will lock the database on May 25, 2012. Accordingly, we will continue with the preparation of our NDA submission and expect to make the submission in mid-August of 2012. In addition, we have initiated a dialogue with the FDA to discuss the optimal approval path for our second generation chemosaturation system in United States.

*Commercialize the Delcath Chemosaturation System in the United States.* If we obtain FDA approval of our NDA, we intend to market our chemosaturation system with melphalan in the United States through our own sales force and focus our initial marketing efforts on major cancer centers beginning with those hospitals that participated in our Phase III clinical trial.

*Establish Strategic Alliances and Distribution Partners.* In addition to our existing partnership with Chi-Fu Trading Co., Ltd in Taiwan, we are pursuing strategic partners to develop certain Asian markets including China, Korea and Japan. We are also pursuing distribution partners to commercialize the product in other foreign markets including Australia, New Zealand, Brazil and Argentina.

*Obtain Approval to Market the Delcath Chemosaturation System in the United States for the Treatment of Other Cancers in addition to Metastatic Melanoma in the Liver.* We concluded a multi-arm Phase II trial to evaluate the first generation chemosaturation system for the treatment of other cancers in the liver, such as tumors of neuroendocrine and colorectal adenocarcinoma and cholangiocarcinoma origin that have spread to the liver as well as primary liver cancer. Furthermore, we also intend to pursue pharmaceutical partners to co-develop and fund additional cancer indications for the chemosaturation system. Upon successful conclusion of the related clinical trials, we intend to apply for regulatory approval of additional indications.

*Expand the Application of the Delcath Chemosaturation System.* We are currently developing a chemosaturation system for use with doxorubicin. We intend to evaluate a variety of chemotherapeutic agents for use with the Delcath chemosaturation system to treat liver cancers, as well as other organs and body regions.

## **Sales and Marketing**

### ***European Economic Area***

Having obtained the right to affix the CE Mark in Europe, we plan to market and sell the Generation 2 CHEMOSAT System in the EEA. In March 2012, we received our first commercial order for our system from the IEO. This order was fulfilled with Generation 2 CHEMOSAT Systems in April 2012 following the receipt of the CE Mark approval. We intend to focus our initial efforts on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. We believe these countries represent a majority of the total potential liver cancer market in the EEA countries. We intend to pursue a two-pronged commercialization strategy under which we will both directly and indirectly market the Generation 2 CHEMOSAT System. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors. We have engaged a third party to provide a dedicated team to educate the medical oncologists in the seven target markets.

Under the regulatory scheme in the EEA, we have received authorization to affix the CE Mark to the Generation 2 CHEMOSAT System as a device only, and physicians must separately obtain melphalan for use with the system. Our ability to market and promote the Generation 2 CHEMOSAT System is limited to the

## **Table of Contents**

approved indication. Melphalan is currently approved in 14 member states of the EEA, including the seven markets we are initially targeting. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use the Generation 2 CHEMOSAT System must obtain and use melphalan independently at their discretion.

### ***United States***

In the United States, if granted FDA approval, our intention is to market the system ourselves focusing our initial marketing efforts on the over fifty National Cancer Institute (NCI) designated cancer centers in the United States, beginning with the hospitals which participated in our Phase III clinical trial. We plan to focus our efforts on three distinct groups of medical specialists:

surgical oncologists who administer the Delcath chemosaturation system;

medical oncologists who have initial responsibility for cancer patients; and

interventional radiologists who are physicians specialized in working with catheter-based systems and who will also administer the Delcath chemosaturation system.

We intend to utilize MSLs to provide clinical-based education to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals.

### **Strategic Alliances and Distribution Partners**

We plan to seek one or more corporate partners in other markets outside the United States, including Asia where we intend to pursue strategic partners to develop markets in China, Korea and Japan. Asia represents a potentially large market for the Generation 2 CHEMOSAT System, with its primary liver cancer, or HCC, incidence accounting for an overwhelmingly large majority of the world's primary liver cancer patients. We also intend to leverage our CE Mark in order to expedite approval in select countries, as we have already done successfully in Australia, having received regulatory approval to commercialize the Generation 1 CHEMOSAT System in February 2012, and we have filed for approval of the Generation 2 CHEMOSAT System. We believe distribution or corporate partnering arrangements in select markets internationally will be cost effective, can be implemented more quickly than a direct sales force and will enable us to capitalize on local marketing expertise in the countries we target. We are actively pursuing distribution partners to commercialize the product in other foreign markets including Australia, New Zealand, Hong Kong, Mexico, Brazil, Argentina and Colombia.

In February 2010, we entered into a research and distribution agreement with Chi-Fu Trading Co., Ltd., a Taiwanese company. Under the agreement Chi-Fu will conduct clinical studies of the Delcath chemosaturation system and, upon obtaining the approval from the Taiwan Food and Drug Administration (TFDA), will market, sell and distribute the Delcath chemosaturation system in Taiwan and possibly Singapore for TFDA indications of use.

We believe that the Delcath chemosaturation system may have broader applicability, including using other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. As such, we also intend to pursue U.S. pharmaceutical partners to co-develop and fund possible additional indications for the Delcath chemosaturation system.

**Table of Contents**

**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 supplement and the accompanying prospectus and those described in our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC and incorporated by reference in this prospectus supplement and the accompanying prospectus as well as other information we include or incorporate by reference in this prospectus supplement and the accompanying prospectus.

**Corporate Information**

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 810 Seventh Avenue, 35<sup>th</sup> 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 supplement or the accompanying prospectus.

**Table of Contents**

**THE OFFERING**

Common stock offered by us	13,333,340 shares, plus 4,000,002 shares of common stock underlying the warrants offered hereby
Warrants offered by us	Warrants to purchase up to 4,000,002 shares of common stock. The warrants can be exercised during the period commencing on the date of original issuance and ending on May 25, 2015 at an exercise price of \$1.65 per share of common stock (as adjusted from time to time).
Common stock to be outstanding after this offering	63,492,832 shares <sup>(1)(2)</sup>
Use of proceeds	We intend to use the net proceeds from this offering (including any resulting from the exercise of the warrants) for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, research, capital expenditures and working capital. 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	DCTH
Risk Factors	See Risk Factors and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, including the section entitled Risk Factors beginning on page 15 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2011, for a discussion of the factors you should carefully consider before deciding to invest in our securities.
Transfer Agent and Registrar	American Stock Transfer and Trust Company, LLC
Unless otherwise indicated, this prospectus supplement reflects and assumes no exercise by the underwriters of their over-allotment option and that none of the warrants issued hereunder will be exercised.	

(1) The number of shares of common stock to be outstanding after this offering is based on 50,159,492 shares of common stock outstanding on May 22, 2012.

(2) The number of shares of common stock to be outstanding after this offering excludes, as of March 31, 2012:

5,048,311 shares issuable upon the exercise of stock options at a weighted average exercise price of \$4.96 per share;

2,711,776 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of \$3.03 per share; and

4,000,002 shares issuable upon the exercise of the warrants issued hereunder.

S-10



**Table of Contents****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, 2011 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2012, 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, 2011 and the summary historical balance sheet data as of December 31, 2011 and 2010 from our audited financial statements. We derived the summary historical financial data as of and for the three months ended March 31, 2012 and 2011 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.

(in thousands, except share and per share data)

	Three Months Ended March 31,		Year Ended December 31,		
	2012	2011	2011	2010	2009
<b>STATEMENT OF OPERATIONS DATA:</b>					
Cost and expenses:					
General and administrative expenses	\$ 7,423	\$ 4,166	\$ 21,283	\$ 13,187	\$ 3,899
Research and development costs	7,131	3,648	25,173	17,556	9,637
Total costs and expenses	\$ 14,554	\$ 7,814	\$ 46,456	\$ 30,743	\$ 13,536
Operating loss	(14,554)	(7,814)	(45,456)	(30,743)	(13,536)
Change in fair value of warrant liability, net	(338)	5,966	15,566	(15,951)	(8,568)
Interest income	3		5	10	74
Other expense and interest expense					(27)
Net loss	\$ (14,889)	\$ (1,848)	\$ (30,885)	\$ (46,684)	\$ (22,057)
Common share data:					
Basic and diluted loss per share	\$ (0.31)	\$ (0.04)	\$ (0.68)	\$ (1.20)	\$ (0.82)
Weighted average number of basic and diluted common shares outstanding	48,341,670	42,953,553	45,236,921		