DELCATH SYSTEMS INC
Form 424B5
July 14, 2011
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The information in this prospectus supplement is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED July 14, 2011

PROSPECTUS SUPPLEMENT
(To Prospectus dated April 13, 2010)

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-165677

5,000,000 Shares

Common Stock

We are selling 5,000,000 shares of our common stock through this prospectus supplement and the accompanying prospectus.

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, 2011 was $6.28 per share.

Investing in our common stock involves risks, including those described in the Risk Factors section beginning on page S-17 of this prospectus supplement and the section entitled Risk Factors beginning on page 10 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2010, 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.

The underwriter has agreed to purchase the common stock from us at a price of $ per share which will result in $ of proceeds to us (before expenses). We have granted the underwriter a 30-day option to purchase up to an additional 750,000 shares of our common stock at a price of $ per share to cover any over-allotments which, if exercised in full, will result in an additional $ of proceeds to us (before expenses).

The underwriter may offer our common stock in transactions on The NASDAQ Capital Market, in the over-the-counter market or through negotiated transactions at market prices or negotiated prices.

Delivery of the shares of common stock is expected to be made on or about , 2011.

Sole Book-Running Manager

Jefferies

Prospectus Supplement dated July , 2011.

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Prospectus Supplement

Prospectus

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 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 shares of our common stock that we are selling in this offering. Both this prospectus supplement and the accompanying prospectus include important information about us, our common stock 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 on page S-2 of this prospectus supplement and on page 4 of the accompanying prospectus before investing in our common stock.

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 underwriter 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 underwriter 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.

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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, 2010 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, 2011 in Part II, Item 1A under Risk Factors as well as 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; and
- our ability to successfully negotiate and enter into agreements with strategic and corporate partners.

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.

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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:

SEC Filing (File No. 001-16133)	Date of Filing
Quarterly Report on Form 10-Q for quarter ended March 31, 2011	May 5, 2011
Proxy Statement on Schedule 14A for our 2011 Meeting of Stockholders	April 27, 2011
Annual Report on Form 10-K for year ended December 31, 2010	March 8, 2011
	January 25, 2011
	February 23, 2011
	April 1, 2011
	April 14, 2011
	May 4, 2011
Current Reports on Form 8-K and 8-K/A	June 10, 2011

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, Suite 3505, New York, New York 10019 or by calling us at 212-489-2100.

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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 common stock. 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 common stock 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 subsidiary. Delcath is our registered United States trademark.

Company Overview

We are a development stage, specialty pharmaceutical and medical device company focused on oncology, initially cancers in the liver. Since our inception, we have directed our research efforts towards the development and clinical study of the Delcath chemosaturation system.

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 chemotherapy agents, currently melphalan hydrochloride, or melphalan, 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 procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs. 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.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the protocol s design, execution, and analysis under a Special Protocol Assessment, or SPA. A SPA is an evaluation by the U.S. Food and Drug Administration, or FDA, of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in a new drug application, or NDA, without the sponsor s agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. We conducted our Phase III trial under a SPA.

In February 2010, we concluded a Phase III clinical trial for the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver, which demonstrated a statistically significant improvement in hepatic progression-free survival, or hPFS, compared to the best alternative care. Our Phase III trial successfully met the study s primary endpoint of extended hPFS, demonstrating that the Delcath chemosaturation system with melphalan patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the best alternative care control arm. This reflects a 144-day prolongation of hPFS over that of the best alternative care control arm, with less than half the risk of progression and/or death in the Delcath chemosaturation system with melphalan group compared to the best alternative care control group. In addition, we recently completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer.

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Based on the Phase III results, we submitted our Section 505(b)(2) NDA, to the FDA in December 2010, 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, or RTF, 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 represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. 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. At this time, the FDA has not requested additional studies to be conducted. We have had subsequent communications with the FDA, including a meeting in early April 2011 to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. Based on management s current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011.

On April 13, 2011, we obtained the right to affix the CE Mark to the Delcath chemosaturation system. The right to affix the CE mark allows us to market and sell the Delcath chemosaturation system in the European Economic Area, or EEA. In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. 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 our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion.

We believe the Delcath chemosaturation system may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in the EEA. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We intend to establish a European headquarters within the EEA and utilize third-party contract sales organizations, or CSOs, and a direct sales force in the United Kingdom, Germany and the Netherlands and distributors in France, Italy and Spain. We also intend to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in these countries in order to develop key opinion thought leadership and foster initial market acceptance.

Advantages of the Delcath Chemosaturation System

Limited effective treatment options are currently available for liver cancer and they are generally associated with significant side effects and even death. 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 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 up to ten times more of the chemotherapy agent to the treated region than traditional delivery methods. In our clinical studies on patients with metastatic melanoma it was shown that higher dosing led to significantly improved disease control in the liver.

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Controls Toxicities Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of extracting on average 72% of the chemotherapy agent administered to the liver, which reduces the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents.

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.

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 new treatment option for cancers in the liver. We are seeking to establish the Delcath chemosaturation system as the standard regional therapy technique for the treatment of melanoma liver metastases and other liver cancer histologies.

We also intend to develop the system for use with other chemotherapeutic agents, as well as other drug compounds. 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, for use with the Delcath chemosaturation system. As part of our development efforts, we intend to pursue U.S. pharmaceutical partners to co-develop and fund additional indications for the Delcath chemosaturation system.

Our strategy includes the following elements:

Commercialize the Delcath Chemosaturation System in the European Economic Area. We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly market the Delcath chemosaturation system in certain markets and enter into agreements with third-party distributors in others.

Leverage the CE Mark to Commercialize the Delcath Chemosaturation 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 United States, including but not limited to Argentina, Australia, Brazil, China, Colombia, Dubai, Hong Kong, Japan, Jordan, Malaysia, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, Thailand and Turkey. It is our intention to leverage the CE Mark in some or all of these countries to commercialize the Delcath chemosaturation system, where appropriate.

Obtain FDA Approval for Use of the Delcath Chemosaturation System in Combination with Melphalan to Treat Metastatic Melanoma in the Liver. Based on management s current understanding of the issues raised in the RTF, we have begun to take action to address the FDA s concerns, and currently plan to resubmit our NDA to the FDA by December 31, 2011.

Commercialize the Delcath Chemosaturation System in the United States. If we obtain FDA approval of our NDA, we intend to market the Delcath 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.

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Establish Strategic Alliances. We intend to pursue strategic partners to develop certain Asian markets including China, Korea and Japan. In the United States, we intend to pursue pharmaceutical partners to co-develop and fund other indications for the Delcath chemosaturation system.

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 recently concluded a multi-arm Phase II trial to evaluate the Delcath chemosaturation system for the treatment of other cancers in the liver, such as tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver, primary liver cancer and melanomas in the liver that received certain prior regional treatment with melphalan. 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 intend to evaluate melphalan and other drug candidates for use with the Delcath chemosaturation system to treat other liver cancers, as well as other organs and body regions.

Sales and Marketing

Having obtained the right to affix the CE Mark in Europe, we plan to market and sell the Delcath chemosaturation system in the EEA. The EEA consists of the 27 member countries of the European Union as well as Lichtenstein, Iceland, and Norway. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly and indirectly market the Delcath chemosaturation system. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and 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.

Under the regulatory scheme in the EEA, the Delcath chemosaturation system has received authorization to affix the CE Mark as a device only. Melphalan is currently approved in 14 member states of the EEA, including the six countries we are initially targeting. Physicians must separately obtain melphalan for use with the Delcath chemosaturation system.

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, or NCI, designated cancer centers in the United States, beginning with the hospitals which participated in the 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.

We intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals.

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Strategic Alliances

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 Delcath chemosaturation system, accounting for approximately 80% of the world s liver cancer patients. We also intend to leverage our CE Mark in order to expedite approval in select countries in Latin America and South America. 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 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.

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, 2010 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, Suite 3505, 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.

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The Offering

Common stock offered by us	5,000,000 shares
Common stock to be outstanding after this offering	48,056,339 shares[1][2]
Use of proceeds	We intend to use the net proceeds from the sale of the shares for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital.
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 all 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 beginning on page S-17 of this prospectus supplement 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 10 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2010, for a discussion of the factors you should carefully consider before deciding to invest in our common stock.
Transfer Agent and Registrar	American Stock Transfer and Trust Company, LLC

Unless otherwise indicated, this prospectus supplement reflects and assumes no exercise by the underwriter of its overallotment option.

(1) The number of shares of common stock to be outstanding after this offering is based on 43,056,339 shares of common stock outstanding on July 13, 2011.

(2) The number of shares of common stock to be outstanding after this offering excludes, as of March 31, 2011:

4,140,629 shares issuable upon the exercise of stock options at a weighted average exercise price of $5.07 per share; and

2,512,934 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.51 per share.

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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, 2010 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2011, 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, 2010 and the summary historical balance sheet data as of December 31, 2010 and 2009 from our audited financial statements. We derived the summary historical financial data as of and for the three months ended March 31, 2011 and 2010 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.

Statement of operations data:	**Three months ended March 31, 2011**	**Three months ended March 31, 2010**	**Year ended December 31, 2010**	**2009**	**2008**
Cost and expenses:					
General and administrative expenses	$ 4,166,014	$ 2,546,172	$ 13,187,278	$ 3,898,705	$ 2,687,688
Research and development costs	3,648,224	2,941,110	17,555,698	9,637,050	5,378,335
Total costs and expenses	$ 7,814,238	$ 5,487,282	$ 30,742,976	$ 13,535,755	$ 8,066,023
Operating loss	(7,814,238)	(5,487,282)	(30,742,976)	(13,535,755)	(8,066,023)
Derivative instrument (expense) income	5,965,657	(8,687,717)	(15,951,367)	(8,567,917)	1,103,682
Interest income	559	1,264	10,698	73,833	299,956
Other (expense)/income				(26,753)	(202,500)
Interest expense					
Net loss	$ (1,856,022)	$ (14,165,735)	$ (46,683,645)	$ (22,056,592)	$ (6,864,885)
Common share data:					
Basic and diluted loss per share	$ (0.04)	$ (0.39)	$ (1.20)	$ (0.82)	$ (0.27)
Weighted average number of basic and diluted common shares outstanding	42,953,553	36,261,688	38,991,481	27,072,556	25,300,703

Balance sheet data:	**As of March 31, 2011**	**As of March 31, 2010**	**As of December 31, 2010**	**2009**
Cash and cash equivalents	$ 39,284,758	$ 26,933,593	$ 45,621,453	$ 35,486,319
Total assets	43,283,653	32,234,339	50,577,709	36,807,041
Total liabilities	14,623,240	21,460,950	21,497,324	13,048,694
Accumulated deficit	(117,903,422)	(83,545,490)	(116,055,400)	(69,371,755)
Stockholders equity	28,660,414	10,773,389	29,080,385	23,758,347

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REGULATORY ENVIRONMENT

The Delcath chemosaturation system is subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

International Regulation

In order for our products to be marketed and sold in Asia, Europe, or other foreign jurisdictions, we must obtain the required regulatory approvals or clearances and comply with the extensive regulations regarding safety, manufacturing processes and quality requirements of the respective countries. These regulations, including the requirements for approvals to market, and the various regulatory frameworks may differ. In addition, there may be foreign regulatory barriers other than approval or clearance.

In the EEA, the Delcath chemosaturation system is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the European Union and Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the Delcath chemosaturation system are governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the Delcath chemosaturation system on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments. For Class III medical devices, such as the Delcath chemosaturation system, before iss