DELCATH SYSTEMS INC
Form 424B5
November 13, 2009
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-159913

PROSPECTUS SUPPLEMENT

(To Prospectus dated June 23, 2009)

8,500,000 Shares

Delcath Systems, Inc.

Common Stock

We are offering to sell 8,500,000 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 November 12, 2009 was $4.06 per share.

Investing in our common stock involves risks, including those described in the Risk Factors section beginning on page S-6 of this prospectus supplement and the section entitled Risk Factors beginning on page 11 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2008, which is incorporated by reference into 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.

	Per Share	*Total*
Public offering price	**$ 3.600**	**$ 30,600,000**
Underwriting discount	**$ 0.225**	**$ 1,912,500**
Proceeds, before expenses, to us	**$ 3.375**	**$ 28,687,500**

The underwriters may also purchase up to an additional 1,275,000 shares of common stock from us at the public offering price, less the underwriting discount, within 30 days following the date of this prospectus supplement to cover overallotments, if any. If the underwriters exercise the option in full, the total discount and commission will be $2,199,375 and the total net proceeds, before expenses, to us will be $32,990,625.

The underwriters expect to deliver the shares against payment on or about November 18, 2009.

Cowen and Company

Canaccord Adams

Wedbush PacGrow Life Sciences

Craig-Hallum Capital Group

The date of this prospectus supplement is November 12, 2009.

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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 3 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 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.

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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 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. Delcath is our registered U.S. trademark.

Overview

We are developing the Delcath Percutaneous Hepatic Perfusion, or PHP, System, an innovative drug delivery device designed to treat cancers of the liver. The System provides regional therapy by isolating the circulatory system of the liver in order to directly deliver high doses of therapeutic agents, while controlling the systemic exposure of those agents. The Delcath PHP System is minimally invasive and repeatable. We believe that the Delcath PHP System is a platform technology that may have broader applicability to other organs and body regions. The most advanced application being tested with our System is for the treatment of primary and secondary cancers of the liver. In our initial application, the Delcath PHP System isolates the liver from the patient s general circulatory system in order to deliver high doses of melphalan hydrochloride, an approved chemotherapeutic drug, directly to the liver. We are currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancers.

Our most advanced trial is a randomized Phase III multi-center study led by the National Cancer Institute, or NCI, for patients with metastatic ocular and cutaneous melanoma in the liver. The FDA has granted the Delcath PHP System with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. We have also been granted four orphan drug designations, including for the drug melphalan for the treatment of patients with ocular and cutaneous melanoma. We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process. The enrollment for the clinical trial was completed on October 20, 2009. By mid-2010, we expect to submit the Delcath PHP System for this treatment to the FDA for approval.

Advantages of the Delcath PHP 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 PHP 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 I clinical trial demonstrated that the Delcath PHP System is capable of delivering ten times more of the chemotherapy agent to the treated region, and the effective concentration at the tumor site is nearly 100 times greater, than traditional delivery methods.

Controls Toxicities Our Phase I clinical trial demonstrated that the Delcath PHP System is capable of extracting approximately 85% 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 PHP System allows for multiple courses of treatment with chemotherapeutic drugs and has a recovery period that is shorter than surgical resection.

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Strategy

We are seeking to establish the Delcath PHP System as the standard regional therapy technique for treating liver cancers and to further develop the Delcath technology for use in the treatment of other liver diseases as well as in other organs or regions of the body. Our strategy includes the following elements:

Complete our Phase III clinical trial and obtain FDA approval for use of the Delcath PHP System in combination with melphalan to treat metastatic melanoma in the liver.

Establish strategic alliances to introduce the Delcath PHP System into non-U.S. markets.

Obtain approval to market the Delcath PHP System in the U.S. for the treatment of cancers in addition to metastatic melanoma in the liver.

Develop U.S. sales force and marketing team.

Test the Delcath PHP System with drugs other than melphalan for the treatment of cancers of the liver.

Investigate treatment of hepatitis using anti-viral drugs with the Delcath PHP System.

Explore other regional therapy applications for the Delcath PHP System.

Clinical Trials

We are currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System in patients with liver cancer, summarized in the chart below. We have also received FDA approval to conduct a Phase III clinical trial of the Delcath PHP System with doxorubicin for patients suffering from primary liver cancer. This trial will be randomized between the Delcath PHP System and sorafenib. We plan to seek one or more corporate partners to fund our efforts prior to commencing this trial.

* This Phase III trial has not commenced.
** Patients who previously received surgical isolated hepatic perfusion are ineligible for the Phase III melanoma trial.

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Risks Affecting Our Business and Business Strategy

Our business is subject to numerous risks that could prevent us from successfully implementing our business strategy. These risks are highlighted in the section entitled Risk Factors.

We are entirely dependent on the success of the Delcath PHP System, our only product, the development and commercialization of which has been our sole focus.

We have incurred significant losses; since our inception on August 5, 1988 through September 30, 2009, we have incurred cumulative net losses of approximately $62.2 million.

We may not be able to develop, or obtain regulatory approval to market, our product.

We may not be able to successfully commercialize the Delcath PHP System despite obtaining regulatory approval.

Our Corporate Information

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 600 Fifth Avenue, 23rd Floor, New York, New York 10020. 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	8,500,000 shares
Common stock to be outstanding after this offering	34,816,485 shares[1][2]
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, including obtaining regulatory approvals, commercialization of our products, 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-6 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 11 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2008, 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 underwriters of their overallotment option.

(1) The number of shares of common stock to be outstanding after this offering is based on 26,316,485 shares of common stock outstanding on September 30, 2009.

(2) The number of shares of common stock to be outstanding after this offering excludes, as of September 30, 2009:

2,620,000 shares issuable upon the exercise of stock options at a weighted average exercise price of $3.42 per share; and

3,849,694 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.62 per share.

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Summary Historical Consolidated Financial Data

You should read the summary historical consolidated 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, 2008 and our quarterly report on Form 10-Q for the nine months ended September 30, 2009, each of which is incorporated by reference in the accompanying prospectus. We derived the following summary historical financial statement of operations data and the summary historical balance sheet data for each of the three years in the period ended December 31, 2008 from our audited consolidated financial statements. We derived the summary historical financial data for the nine months ended September 30, 2009 and 2008 from our unaudited condensed consolidated financial statements. In our opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as our audited consolidated 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.

	Nine months ended September 30, 2009	Nine months ended September 30, 2008	Year ended December 31, 2008	2007	2006
Statement of operations data:					
Cost and expenses:					
General and administrative expenses	$ 2,513,366	$ 1,730,040	$ 2,687,688	$ 2,671,782	$ 8,980,424
Research and development costs	5,983,392	3,712,823	5,378,335	4,241,517	2,718,084
Total costs and expenses	$ 8,496,758	$ 5,442,863	$ 8,066,023	$ 6,913,299	$ 11,698,508
Operating loss	(8,496,758)	(5,442,863)	(8,066,023)	(6,913,299)	(11,698,508)
Derivative instrument income	(8,296,958)	807,347	1,103,682	2,717,000	
Interest income	71,982	279,639	299,956	532,793	620,403
Other (expense)/income	1,689		(202,500)		126,500
Interest expense					
Net loss	$ (16,359,010)	$ (4,355,877)	$ (6,864,885)	$ (3,663,506)	$ (10,951,605)
Common share data:					
Basic and diluted loss per share	$ (0.64)	$ (0.17)	$ (0.27)	$ (0.16)	$ (0.55)
Weighted average number of basic and diluted common shares outstanding	25,753,795	25,285,366	25,300,703	22,321,488	19,906,932

	Nine months ended September 30, 2009	Nine months ended September 30, 2008	Year ended December 31, 2008	2007
Balance sheet data:				
Cash and cash equivalents	$ 6,038,590	$ 12,930,867	$ 6,939,233	$ 7,886,937
Total assets	6,766,103	13,450,701	11,358,682	18,106,126
Total liabilities	11,708,366	1,012,086	1,151,807	1,677,278
Accumulated deficit	(63,674,173)	(44,806,155)	(47,315,163)	(40,450,278)
Stockholders equity	(4,942,263)	12,438,615	10,206,875	16,428,848

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RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the information contained in this prospectus supplement and the accompanying prospectus before deciding whether to purchase our common stock. In addition, you should carefully consider, among other things, the matters discussed under Risk Factors beginning on page 11 of our Annual Report on Form 10-K for the year ended December 31, 2008, and in other documents that we subsequently file with the Securities and Exchange Commission, all of which are incorporated by reference in the accompanying prospectus. The risks and uncertainties described below and incorporated by reference in the accompanying prospectus are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. 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 could decline, and you may lose all or part of your investment in our common stock. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See Forward-Looking Statements.

Risks Related to Our Business and Financial Condition

If we are not successful in developing and obtaining FDA approval of both the device and drug components of the Delcath PHP System, or if we are unable to market and sell the product, we will not generate operating revenue or become profitable.

The Delcath PHP System, a platform technology for the isolation of various organs or regions of the body to permit the regional delivery of high doses of drugs for the treatment of a variety of diseases, is our only product, and our entire focus has been on developing, commercializing, and obtaining regulatory approvals of this product. If the Delcath PHP System fails as a commercial product, we have no other products to sell.

Continuing losses may exhaust our capital resources. We have had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow.

We expect to incur significant and increasing losses while generating minimal revenues over the next few years. From our inception on August 5, 1988 through September 30, 2009, we have incurred cumulative net losses of approximately $62.2 million. For the years ended December 31, 2008 and 2007, we incurred net losses of approximately $6.9 million and $3.7 million, respectively. To date, we have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000, 2003, 2007 and June 2009. 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 and commercialization of the Delcath PHP System.

If we cannot raise the additional capital that will be required to commercialize the Delcath PHP System, our potential to generate future revenues will be significantly limited even if we receive FDA approval, and if we cannot raise additional capital generally, our business operations will be harmed.

The Delcath PHP System is regulated by the FDA as a combination product, namely a drug administered by a device. Before we can obtain approval to sell our product commercially in the U.S., we will need approval from the FDA of the medical device component of the Delcath PHP System through a premarket approval application, or PMA, and FDA approval of the drug component of the Delcath PHP System through a Section 505(b)(2) new drug application, or NDA, or an abbreviated NDA. We will also need approval to market our products in foreign markets. While we believe that we have sufficient capital to conduct our operations through January 2010, our current resources are not sufficient to complete the Phase III clinical trial using melphalan or the other clinical trials that we are pursuing, or in the future may pursue and will be insufficient to fund the costs of commercializing the Delcath PHP System, which will be significant. Many of the costs of conducting clinical trials are uncertain and not within our control, including (i) the possibility that the FDA, or foreign regulators, may require additional trials; (ii) the charges payable to each current or prospective clinical test site which is based on the number of participants in the trial; (iii) the amount of the fee per patient, which is individually negotiated with each test site; (iv) the number of patients that may be required to be enrolled in any particular

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trial; (v) the location of the test site which can affect other costs, including the costs of retaining a clinical research organization, monitoring and other out of pocket costs such as travel; (vi) the actual number of treatments performed per patient in each clinical trial; and (vii) the possible increase or reduction in trial costs billed to us where a patient s insurer refuses or agrees to cover certain treatment expenses. We do not know if additional financings will be available when needed, or if they are available, that they will be available on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to complete our trials, obtain regulatory approvals or sell the Delcath PHP System commercially.

Our liquidity and capital requirements will depend on numerous factors, including: our research and product development programs, including clinical studies; the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations; the timing of product commercialization activities, including marketing 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. We do not know if additional financing will be available when needed, or if it is available, if it will be available on acceptable terms. Insufficient funds may require us to curtail or stop our research and development activities.

There are risks associated with forward-looking statements made by us and actual results may differ.

Some of the information contained in this prospectus supplement contains forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as may, will, expect, anticipate, believe, estimate and co or similar words. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other forward-looking information.

We believe it is important to communicate our expectations. However, there may be events in the future that we are not able to accurately predict and/or over which we have no control. The risk factors listed in this section, other risk factors about which we may not be aware, as well as any cautionary language in this prospectus supplement, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. You should be aware that the occurrence of the events described in these risk factors could have an adverse effect on our business, results of operations and financial condition.

Risks Related to FDA and Foreign Regulatory Approval

Even if the FDA grants approval for use of both components of the Delcath PHP System for the treatment of melanoma that has metastasized to the liver with melphalan, our ability to market the Delcath PHP System would be limited to that use.

If the FDA grants approval for use of the Delcath PHP System in the treatment of melanoma that has metastasized to the liver with the drug melphalan, our ability to market the Delcath PHP System would be limited to its use with that drug in treating that disease. If we are unable to obtain FDA approval or successfully market the Delcath PHP System for treatment of other diseases, organs and regions and with other drugs, our ability to generate revenue and grow will be limited.

If we do not obtain required approvals, we may not be able to export the Delcath PHP System to foreign markets, which will limit our sales opportunities.

If we do not receive CE mark approval for the Delcath PHP System, we will not be able to export the Delcath PHP System from the U.S. for marketing in the European Economic Area, or EEA, unless approval has been obtained from each nation in the EEA. In addition, regulatory approval is required before we can market the Delcath PHP System in other parts of the world. If the FDA does not approve our applications or we are not able to obtain approval from one or more other countries where we would like to sell the Delcath PHP System, we

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will be unable to market the Delcath PHP System as we intend. If we are unable to market the Delcath PHP System internationally because we are unable to obtain required approvals, our international market opportunity will be materially limited.

Obtaining FDA approvals could be delayed.

We have experienced, and may continue to experience, delays in conducting and completing required clinical trials, caused by many factors. The pace of completing these clinical trials will be dependent on a number of factors, some of which are out of our control. We have received a letter from the FDA stating that the special protocol assessment, or SPA, we submitted to the FDA was acceptable. An SPA is generally binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun. Any requirement by the FDA that we amend our SPA by requiring us to conduct additional trials or otherwise would delay the FDA s review of our application. Any significant delay in completing clinical trials or in the FDA s response to our submission would delay the commercialization of the Delcath PHP System and our ability to generate revenues.

The FDA could temporarily or permanently halt the conduct of our clinical trials.

If the FDA decides for any reason that the Delcath PHP System is not sufficiently safe or efficacious, it may require us to halt the trials. We may not be able to resume our trials if the FDA were to halt them.

In October 2007, we suspended enrollment in the Phase III and Phase II trials of the Delcath PHP System at the recommendation of the FDA for a one month period in anticipation of a meeting with the agency to discuss gastrointestinal safety concerns. During the meeting at the FDA, we presented an analysis of the previously reported gastrointestinal toxicities and of the changes already incorporated into the trial protocols to prevent a recurrence of those toxicities. Following the meeting, in November 2007 we were notified by the FDA that the studies could proceed and we resumed patient enrollment in the trials. If similar events were to occur in the future, our clinical trials, and as a result, our business, operations and stock price could be materially impacted.

We may experience a number of events that could further delay or prevent development of the Delcath PHP System, including:

- the FDA may put the Phase III and/or Phase II trials on hold;
- the results of those trials could be negative;
- additional serious adverse events in the clinical trials could occur;
- we could experience manufacturing difficulties; and
- other regulators or institutional review boards may not authorize, or may delay, suspend or terminate the clinical trial program due to safety concerns.

Third-party reimbursement may not be available to purchasers of the Delcath PHP System or may be inadequate, resulting in lower sales even if FDA approval is granted.

Physicians, hospitals and other health care providers may be reluctant to purchase the Delcath PHP System if they do not receive substantial reimbursement for the cost of using our products from third-party payors, including Medicare, Medicaid and private health insurance plans.

The Delcath PHP System is currently characterized by the FDA as an investigational device, and melphalan is an investigational drug at the dosage we are using. As such, Medicare, Medicaid and private health insurance plans will not reimburse its use in the U.S. We will seek reimbursement by third-party payors of the cost of the Delcath PHP System after its use is approved by the FDA. There are no assurances that third-party payors in the U.S. or abroad will agree to cover the cost of procedures using the Delcath PHP System. Further, third-party payors may deny reimbursement if they determine that the Delcath PHP System is not used in accordance with established payor protocols regarding

cost effective treatment methods or is used for forms of cancer or with drugs not specifically approved by the FDA.

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Risks Related to Manufacturing, Commercialization and Market Acceptance of the Delcath PHP System

We purchase components for the device in the Delcath PHP System from sole-source suppliers. These manufacturers must comply with a number of FDA requirements and regulations. If we or one of our suppliers fails to meet such requirements or if we change suppliers, the successful completion of our clinical trials and/or commercialization of the Delcath PHP System could be jeopardized.

The components of the Delcath PHP System must be manufactured and assembled in accordance with manufacturing and performance specifications of the Delcath PHP System on file with the FDA and meet good manufacturing practice and quality systems requirements. Some states also have similar regulations. We intend to assemble, sterilize and package the Delcath PHP System at our Kingsbury, NY facility. Many of the components of the Delcath PHP System are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If we or any of our suppliers fail to meet those regulatory obligations, we may be forced to suspend or terminate our clinical trials, and once a product is approved for marketing, the manufacture, assembly or distribution thereof. Further, if we need to find a new source of supply, we may face long interruptions in obtaining necessary components for the Delcath PHP System, in obtaining FDA approval of these components and establishing the manufacturing process, which could jeopardize our ability to supply the Delcath PHP System to the market. Further, if the Kingsbury facility fails to obtain or maintain approvals under ISO 13485 and FDA cGMP facility inspection or audits, our ability to manufacture at the facility could be limited.

We do not have any contracts with suppliers for the manufacture of components for the Delcath PHP System. If we are unable to obtain an adequate supply of the necessary components, the commercialization of the Delcath PHP System could be delayed.

We do not have long term supply contracts with suppliers of components for the Delcath PHP System. Certain components are available from only a limited number of sources. Components of the Delcath PHP System are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA approval of that supplier, commercialization of the Delcath PHP System could be delayed.

We have limited experience in marketing products, and as a result, we may not be successful in marketing and selling the Delcath PHP System even if we receive FDA approval.

Delcath has not previously sold, marketed or distributed any products. In order to commercialize the Delcath PHP System or any other product successfully, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. We intend to develop our own sales force to market our products in the U.S., but we have limited experience in building a sales and marketing organization. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If we cannot successfully develop the infrastructure to market and commercialize the Delcath PHP System, our ability to generate revenues may be harmed, and we may be required to enter into strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms. Competition for sales and marketing personnel is intense, and we may not be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel or to reach an agreement with a third party could adversely affect our business, financial condition and results of operations. If we are not able to collaborate with an alliance partner to market our products outside of the U.S., our efforts to commercialize the Delcath PHP System or any other product may be less successful.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell our product candidates may not be successful.

We intend to enter into one or more strategic alliances to further address markets outside the United States and to fund the development of additional indications or for use with additional chemotherapy agents within the U.S. We may not be able to enter into any additional alliances on acceptable terms, if at all, and may face

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competition in our search for alliances. Our collaborative relationships may never result in the successful development or commercialization of the Delcath PHP System or any other product or the generation of revenue.

The success of any collaboration will be dependent upon the commitment of our collaborators and the timely performance of their obligations, both of which are beyond our control. The terms of any such collaborations may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We cannot assure you that we will be able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with our product candidates or the withdrawal of their support for our products. The failure of any such collaborations could have a material adverse effect on our business.

Market acceptance of the Delcath PHP System will depend on substantial efforts within the healthcare arena.

Market acceptance of the Delcath PHP System will depend upon a variety of factors including:

- Whether our clinical trials demonstrate significantly improved, cost effective patient outcomes;
- Our ability to educate physicians and drive acceptance of the use of the Delcath PHP System;
- Our ability to convince healthcare payors that use of the Delcath PHP System results in reduced treatment costs and improved outcomes for patients;
- Whether the Delcath PHP System replaces and/or complements treatment methods in which many hospitals have made a significant investment. Hospitals may be unwilling to replace their existing technology in light of their investment and experience with competing technologies; and
- Whether doctors and hospitals are reluctant to use a new medical technology until its value has been demonstrated. As a result, the Delcath PHP System may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. The Delcath PHP System competes with all forms of liver cancer treatments that are alternatives to the gold standard treatment of surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

The loss of key personnel could adversely affect our business.

Our Chief Executive Officer is responsible for the operation of our business, and we have entered into an employment agreement with him for his services. The loss of his services could delay our completion of the clinical trials, our obtaining FDA approval, our introducing the Delcath PHP System commercially and our generating revenues and profits. Competition for experienced personnel is intense. If we cannot retain our current personnel or attract additional experienced personnel, our ability to compete could be adversely affected.

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Risks Related to Patents, Trade Secrets and Proprietary Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and commercialize the Delcath PHP System prior to the expiration of our patent protection.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed. Companies in the medical device industry may use intellectual property infringement litigation to gain a competitive advantage. If this type of litigation is successful, a third party may be able to obtain an injunction prohibiting us from offering our product. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the Delcath PHP System or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Certain of our U.S. and foreign patents have already expired and other U.S. patents relating to the Delcath PHP System will expire beginning in 2012 through 2016. To the extent the Delcath PHP System is not commercialized significantly ahead of this date, and we have no other patent protection on our product, the Delcath PHP System may not be protected by patents beyond 2016. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Risks Related to Products Liability

We may not carry sufficient products liability insurance and we may not be able to acquire sufficient coverage in the future to cover large claims.

Clinical trials, manufacturing and product sales may expose us to liability claims from the use of the Delcath PHP System. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in the clinical trials and result in the loss of physician endorsement. A successful products liability claim or recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry some clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

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Risks Related to an Investment in Our Securities

Our stock price and trading volume may be volatile, which could result in losses for our stockholders.

The equity markets may experience periods of volatility, which could result in highly variable and unpredictable pricing of equity securities. The market price of our common stock could change in ways that may or may not be related to our business, our industry or our operating performance and financial condition. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include:

- results of our clinical trials;
- FDA delay or disapproval of our product;
- manufacturing difficulties;
- unexpected adverse events caused by the Delcath PHP System;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;
- a challenge to one of our patents, either in court or via administrative proceedings in the U.S. Patent and Trademark Office;
- conditions generally affecting the healthcare and cancer treatment industries; and
- the success of our operating strategy.

Many of these factors are beyond our control, and we cannot predict their potential impact on the price of our common stock. We cannot assure you that the market price of our common stock will not fluctuate or decline significantly in the future.

Future sales of our common stock may cause our stock price to decline.

The market price of our common stock has historically been volatile. During the three years ended December 31, 2008, the range of the high and low last reported sales prices of our common stock have ranged from a high of $5.85 (during the quarter ended June 30, 2006) to a low of $0.87 (during the quarter ended December 31, 2008). During the nine months ended September 30, 2009, the range of the high and low last reported sales prices of our common stock have ranged from a high of $5.05 (during the quarter ended September 30, 2009) to a low of $1.18 (during the quarter ended March 31, 2009).

Sales of substantial amounts of common stock, or the perception that such sales could occur, could have an adverse effect on prevailing market prices for our common stock.

Our insiders beneficially own a significant portion of our stock.

As of September 30, 2009, our executive officers, directors and affiliated persons beneficially owned approximately 16.3% of our common stock. As a result, our executive officers, directors and affiliated persons will have significant influence to:

elect or defeat the election of our directors;

amend or prevent amendment of our articles of incorporation or bylaws;

effect or prevent a merger, sale of assets or other corporate transaction; and

affect the outcome of any other matter submitted to the stockholders for vote.

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Sales of significant amounts of shares held by our directors and executive officers, or the prospect of these sales, could adversely affect the market price of our common stock.

Anti-takeover provisions in our Certificate of Incorporation and By-laws and under our stockholder rights agreement may reduce the likelihood of a potential change of control, or make it more difficult for our stockholders to replace management.

Certain provisions of our Certificate of Incorporation and By-laws and of our stockholders rights agreement could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of our stockholders might favor a change in management. These provisions include:

providing for a staggered board; and

authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. Our board s ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We also have a stockholder rights agreement that could have the effect of substantially increasing the cost of acquiring us unless our board of directors supports the transaction even if the holders of a majority of our common stock are in favor of the transaction.

Our common stock is listed on the NASDAQ Capital Market. If we fail to meet the requirements of the NASDAQ Capital Market for continued listing, our common stock could be delisted.

Our common stock is currently listed on the NASDAQ Capital Market. To keep such listing, we are required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders, and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders equity of at least $2.5 million. We are presently in compliance with these requirements.

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ s corporate governance requirements, and we fail to regain compliance within the applicable cure period, our common stock could be delisted from the NASDAQ Capital Market.

If our common stock is delisted from the NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on the NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market.

A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

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We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that we may authorize and issue.

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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 financial condition, results of operations and business. Words such as anticipates, expects, intends, plans, predicts, believes, estimates, could, would, will, may, can, continue, potential, should, and the negative of these terms or other comparable termino 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 Securities Exchange Act of 1934, as amended, 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, 2008 in Item 1A under Risk Factors as well as in Item 7A Qualitative and Quantitative Disclosures About Market Risk, our Quarterly Report on Form 10-Q for the period ended September 30, 2009 in Part II, Item 1A under Risk Factors as well as in Part I, Item 3 Qualitative and Quantitative 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 results and timing of our clinical trials and the commencement of future clinical trials; and
- submission and timing of applications for regulatory approval.

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.

USE OF PROCEEDS

We estimate that the net proceeds from this offering, after deducting underwriters discounts and estimated offering expenses, will be approximately $28.1 million (or approximately $32.4 million if the underwriters exercise their overallotment option in full). We intend to use the net proceeds from this offering for general corporate purposes, including obtaining regulatory approvals, commercialization of our products, 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.

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DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the adjusted net tangible book value per share of our common stock after this offering.

The net tangible book value of our common stock as of September 30, 2009, was approximately $(4.9) million, or approximately $(0.19) per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities divided by the total number of shares of our common stock outstanding.

Dilution per share to new investors represents the difference between the amount per share paid by purchasers for our common stock in this offering and the net tangible book value per share of our common stock immediately following the completion of this offering.

After giving effect to the sale of shares of common stock offered by this prospectus supplement and after deducting the estimated underwriting discounts and our estimated offering expenses, our pro forma net tangible book value as of September 30, 2009 would have been approximately $23.7 million or approximately $0.68 per share. This represents an immediate increase in net tangible book value of approximately $0.87 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $2.92 per share to purchasers of our common stock in this offering, as illustrated by the following table:

Offering price per share	$ 3.60
Net tangible book value per share as of September 30, 2009	$ (0.19)
Increase per share attributable to new investors	$ 0.87
Pro forma net tangible book value per share as of September 30, 2009 after giving effect to this offering	$ 0.68
Dilution per share to new investors	$ 2.92

The discussion of dilution, and the table quantifying it, assume no exercise of any outstanding options or warrants or other potentially dilutive securities. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

The table above excludes the following potentially dilutive securities as of September 30, 2009:

- 2,620,000 shares issuable upon the exercise of stock options at a weighted average exercise price of $3.42 per share; and
- 3,849,694 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.62 per share.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2009 on a historical basis and as adjusted to give effect to this offering and the application of the estimated net proceeds of this offering as described under Use of Proceeds. This table should be read in conjunction with Management s Discussion and Analysis of Results of Operations and Financial Condition and the consolidated financial statements and notes thereto included in our quarterly report on Form 10-Q for the nine months ended September 30, 2009, which is incorporated by reference in the accompanying prospectus.

	As of September 30, 2009	
	Historical	As Adjusted
	(unaudited)	
Cash and cash equivalents	$ 6,038,590	$ 34,726,090
Derivative instrument liability	$ 10,936,255	$ 10,936,255
Stockholders equity:		
Preferred stock, $0.01 par value: 10,000,000 shares authorized; no shares issued and outstanding	$	$
Common stock, $0.01 par value: 70,000,000 shares authorized; 26,344,585 shares issued and 26,316,485 shares outstanding at September 30, 2009; 34,844,585 shares issued and 34,816,485 shares outstanding as adjusted	263,446	348,446
Additional paid-in capital	58,537,767	87,140,267
Deficit accumulated during development stage	(63,674,173)	(63,674,173)
Treasury stock at cost, 28,100 shares at September 30, 2009	(51,103)	(51,103)
Accumulated other comprehensive loss	(18,200)	(18,200)
Total stockholders equity	$ (4,942,263)	$ 23,745,237
Total capitalization	$ 6,766,103	$ 35,453,603

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SELECTED FINANCIAL DATA

You should read the selected historical consolidated 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, 2008 and our quarterly report on Form 10-Q for the nine months ended September 30, 2009, each of which is incorporated by reference in the accompanying prospectus. We derived the following summary historical financial statement of operations data and the summary historical balance sheet data for each of the five years in the period ended December 31, 2008 from our audited consolidated financial statements. We derived the summary historical financial data for the nine months ended September 30, 2009 and 2008 from our unaudited condensed consolidated financial statements. In our opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as our audited consolidated 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.

	Nine Months Ended September 30,		Year Ended December 31,				
	2009	2008	2008	2007	2006	2005	2004
	(Dollars in thousands)						
Statement of Operations Data							
Costs and expenses	$ 8,497	$ 5,443	$ 8,066	$ 6,913	$ 11,699	$ 3,112	$ 3,367
Operating loss	(8,497)	(5,443)	(8,066)	(6,913)	(11,699)	(3,112)	(3,367)
Net loss	(16,359)	(4,356)	(6,865)	(3,664)	(10,952)	(2,865)	(3,266)
Loss per share	(0.64)	(0.17)	(0.27)	(0.16)	(0.55)	(0.18)	(0.28)

	Nine Months Ended September 30,		Year Ended December 31,				
	2009	2008	2008	2007	2006	2005	2004
	(Dollars in thousands)						
Balance Sheet Data							
Current assets	$ 6,733	$ 13,432	$ 11,341	$ 18,091	$ 8,760	$ 12,920	$ 7,338
Total assets	6,766	13,451	11,359	18,106	8,764	12,928	7,352
Current liabilities	11,708	1,012	1,152	1,677	670	330	565
Stockholder s equity	(4,942)	12,439	10,207	16,429	8,093	12,598	6,787

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BUSINESS

Overview

We are developing the Delcath PHP System, an innovative drug delivery device designed to treat cancers of the liver. The System provides regional therapy by isolating the circulatory system of the liver in order to directly deliver high doses of therapeutic agents, while controlling the systemic exposure of those agents. The Delcath PHP System is minimally invasive and repeatable. We believe that the Delcath PHP System is a platform technology that may have broader applicability to other organs and body regions. The most advanced application being tested with our system is for the treatment of primary and secondary cancers of the liver. In our initial application, the Delcath PHP System isolates the liver from the patient s general circulatory system in order to deliver high doses of melphalan hydrochloride, an approved chemotherapeutic drug, directly to the liver. We are currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancers.

Our most advanced trial is a randomized Phase III NCI led multi-center study for patients with metastatic ocular and cutaneous melanoma in the liver. The FDA has granted the Delcath PHP System with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. We have also been granted four orphan drug designations, including for the drug melphalan for the treatment of patients with ocular and cutaneous melanoma.

We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process for the Delcath PHP System. As of October 20, 2009, we have enrolled all of the 92-patients called for under the SPA. By mid-2010, we expect to submit the Delcath PHP System for this treatment to the FDA for approval. The FDA regulates the Delcath PHP System as a combination product: the combination of a medical device and a drug. Before we can market the Delcath PHP System, we must obtain FDA approval of the device under a premarket approval application and FDA approval of a revision of the current melphalan label under a Section 505(b)(2) NDA, or an abbreviated NDA.

We are also conducting a separate Phase II clinical trial of the Delcath PHP System with melphalan in patients with primary and metastatic hepatic malignancies (liver cancer), stratified into four arms: neuroendocrine tumors (carcinoid and islet cell tumors), hepatocellular carcinoma (primary liver cancer), ocular or cutaneous melanoma (eye or skin cancer who have been previously treated with regional therapy using melphalan), and metastatic adenocarcinoma (glandular cancer). In the future, we plan to conduct preclinical and clinical trials to treat liver cancer using the Delcath PHP System with chemotherapy agents other than melphalan.

Since our inception, we have raised approximately $55.3 million in aggregate funds (net of expenses), and we have invested approximately $35.4 million of those funds in research and development costs associated with development and testing of the Delcath PHP System. In 2006, we accelerated our investment in clinical trials and expanded the scope of our clinical trails. In 2009, we re-focused our management team and appointed a new Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. For the years ended December 31, 2008, 2007 and 2006 and the nine month periods ended September 30, 2009 and 2008 we invested $5.4 million, $4.2 million, $2.7 million, $6.0 million and $3.7 million respectively on research and development activities.

Advantages of the Delcath PHP System

The results of our initial Phase I, Phase II and Phase III trials demonstrated that the Delcath PHP System:

Allows Higher Dosing By isolating the liver, the Delcath PHP System delivers chemotherapeutic drugs directly to the tumor site allowing more chemotherapy agent at a higher concentration to be delivered to the liver than traditional treatment methods. Our Phase I clinical trial demonstrated that the Delcath PHP System is capable of delivering ten times more of the chemotherapy agent to the treated region, and the effective concentration at the tumor site is nearly 100 times greater, than traditional delivery methods.

Controls Toxicities The Delcath PHP System is a regional therapy and controls systemic toxicities by isolating the circulation of the organ or region from the patient s circulatory system. This allows a higher

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dose of a chemotherapeutic agent to be used than would be safe to deliver intravenously. Our Phase I clinical trial demonstrated that the Delcath PHP System is capable of extracting approximately 85% 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 PHP System involves a series of three catheter insertions, each of which is made through standard interventional techniques. The Delcath PHP System allows for multiple courses of treatment with chemotherapeutic drugs and has a recovery period that is shorter and easier than surgical resection.

Strategy

We are seeking to establish the Delcath PHP System as the standard technique for delivering high dose chemotherapy agents directly to the liver and to further develop the Delcath technology for use in the treatment of other liver diseases as well as in other organs or regions of the body. Our strategy includes the following elements:

Complete our Phase III clinical trial and obtain FDA approval for use of the Delcath PHP System in combination with melphalan to treat metastatic melanoma in the liver. Our highest priority is completing our Phase III clinical trial and related data preparation, statistical analysis and filing of necessary regulatory documents associated with obtaining FDA approval of the commercial sale of the Delcath PHP System in the U.S. for the treatment of melanoma that has spread to the liver. Clinical trials of the Delcath PHP System for this indication are currently being conducted at a number of hospitals in the U.S., led by the NCI.

Establish strategic alliances to introduce the Delcath PHP System into non-U.S. markets. Our strategy includes non-U.S. markets that have both a high incidence of liver disease and the public or private means to provide and pay for treatment with our technology, including Asia and Europe. We have begun the process of seeking the CE mark approval to market the Delcath PHP System in the European Economic Area, or EEA, and hope to receive approval by mid-2010. We also are establishing strategic relationships with domestic and foreign firms that have an established presence or experience in certain foreign markets.

Obtain approval to market the Delcath PHP System in the U.S. for the treatment of cancers in addition to metastatic melanoma in the liver. We are currently conducting a multi-arm Phase II trial to evaluate the Delcath PHP System for the treatment of other cancers of the liver, such as primary liver cancer, tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver, as well as melanomas in the liver that received certain prior regional treatment with melphalan.

Develop U.S. sales force and marketing team. We intend to market the Delcath PHP System in the U.S. directly by focusing our initial marketing efforts on the over fifty NCI-designated cancer centers in the U.S., beginning with the hospitals participating in our Phase III clinical trial. We plan to focus our efforts on (i) surgeons who administer the Delcath PHP System; (ii) oncologists who have primary responsibility for the cancer patient; and (iii) interventional radiologists who are physicians specialized in working with catheter-based systems.

Test the Delcath PHP System with drugs other than melphalan for the treatment of cancers of the liver. In addition to testing melphalan, we have tested the drugs doxorubicin and 5-FU with the Delcath PHP System in humans and we intend to evaluate other drug candidates for use with the Delcath PHP System to treat other tumors in the liver. We are currently developing filters with affinity to agents used in treatments for these areas.

Investigate treatment of hepatitis using anti-viral drugs with the Delcath PHP System. We believe that our technology may be compatible with other compounds, including anti-virals, to treat other diseases of the liver such as hepatitis. The World Health Organization estimates that about 350 million people are infected with hepatitis B chronically and that up to 3% of the world s population may harbor hepatitis C infection.

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Explore other regional therapy applications for the Delcath PHP System. We are evaluating the treatment of other organs and regions of the body that may be well suited for the use of our technology. Other organs or body regions that may be evaluated for compatibility with our technology include kidneys, pancreas and lungs.

Industry Background

According to the American Cancer Society, cancer remains the second leading cause of death in the U.S., exceeded only by heart disease, with an estimated 562,000 deaths and 1.5 million new cases diagnosed in 2009. Cancer is also the second leading cause of death worldwide, accounting for approximately 7.6 million deaths and 12.0 million new cases diagnosed in 2007. The financial burden of cancer is great for patients, their families and society. Cancer Facts & Figures 2009 estimates the overall costs of cancer to be $228.1 billion during 2008 including $93.2 billion for direct medical costs, $18.8 billion for indirect morbidity costs attributable to lost productivity due to illness and $116.1 billion for indirect mortality costs attributable to lost productivity due to premature death.

The Liver Cancer Market

There are two forms of liver cancer: primary and metastatic. Primary liver cancer, or hepatocellular carcinoma, originates in the liver and is particularly prevalent in populations where the primary risk factors for the disease are present. These risk factors include: hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants. Liver cancer is one of the most prevalent and lethal forms of cancer. According to Global Cancer Facts & Figures 2007 liver cancer is the third leading cause of cancer death in men and the sixth leading cause among women. In 2007, there were estimated to be 711,000 new liver cancer cases worldwide and 680,000 people worldwide were projected to die from liver cancer. According to Cancer Facts & Figures 2009, the five-year survival rate for liver cancer patients is approximately 12%, compared to 66% for all forms of cancer combined.

Metastatic, 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. This growth often continues even after removal of the primary cancer in another part of the body has occurred. Given the primary biological function of the liver, including filtering toxins from the blood, it is not uncommon for metastases to settle in the liver and in many cases, patients die not as a result of their primary cancer, but from the tumors that metastasize in their liver. We believe that in the United States, metastatic liver cancer may be more prevalent than primary liver cancer. Our most advanced trial is a study for patients with metastatic ocular and cutaneous melanoma in the liver. The incidence of cutaneous melanoma is approximately 55,100 cases per year, with 15% to 20% of cases metastasizing in the liver. The incidence of ocular melanoma is approximately 4,000 cases per year, with up to 40% of cases metastasizing in the liver. The preferred method to treat liver cancer, once detected, is surgical removal of the diseased portion of the liver. Frequently, symptoms of liver cancer do not appear until the liver tumors have spread broadly within the liver, making surgical resection impractical. As a consequence, less than 10% of primary and metastatic liver tumors can be surgically removed. A significant number of patients who are surgically resected for primary or metastatic liver cancer will also experience a recurrence of their disease.

Existing Liver Cancer Treatments

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.

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Resection

Surgical resection is considered the gold standard treatment option for liver tumors. However, approximately 90% of liver tumors are unresectable, which means they do not qualify for surgical removal. For the patients who qualify for surgery, the procedure is highly invasive and can result in significant complications. Additionally, recurrence of tumors is common, and in that event, surgery typically cannot be repeated because the patient cannot survive removal of additional liver tissue or the new tumor sites are too widespread. Resection is a limited solution for patients with liver cancer because it is not an option for many patients and it is not a repeatable procedure.

Chemoembolization

Chemoembolization is a commonly used focal therapy that involves the injection of a chemotherapeutic drug in combination with an embolic material to block normal blood flow into tumors in the liver. Blocking blood flow deprives the tumor of essential oxygen and nutrients and ultimately can kill the tumor. Although chemoembolization allows for focal delivery of chemotherapeutic drugs, the drugs cannot be delivered at an escalated dosage level comparable to the levels at which they are delivered with the Delcath PHP System. Furthermore, the treatment is for specific tumors, not the entire region of the liver.

Chemotherapy

Systemic chemotherapy uses anti-cancer drugs that are injected into a vein or given by mouth to destroy cancer cells. The effectiveness of this treatment option often depends upon the dose of chemotherapeutic drug administered. Generally, the higher the dosage of chemotherapy administered, the greater its ability to kill cancer cells. Due to the toxic side effects of chemotherapy agents, the higher the dosage administered, the greater the damage caused to healthy tissues. The high doses of chemotherapy often required to kill cancer cells are highly toxic and may even be lethal to patients.

Radiation Therapy

Radiation therapy uses high dose x-rays or the delivery of localized radiation to kill cancer cells. A number of localized radiation delivery mechanisms are currently being used and tested, and may demonstrate some effectiveness against certain types of liver cancers. For example, in selective internal radiation therapy, also known as SIRT, tiny beads or microspheres that contain a radioactive isotope are administered through a catheter in the liver where they lodge in small vessels in order to deliver radiation to the tumor. Radiation therapy using x-rays is rarely used for treating liver cancer due to toxicities that impact healthy tissue.

Thermal Therapies

Radio frequency ablation uses electric current to destroy cancerous cells. The procedure utilizes an ultrasound or CT scan to guide several needles into the abdomen through small incisions. The needles are heated with an electric current that burns the tumor and destroys the cancerous cells. Microwave ablation is an experimental therapy similar to radio frequency ablation that uses microwaves instead of electrical current to destroy cancerous cells. These procedures are focal treatments and only treat the tumor, not the tumorous region; therefore, they are generally available only to patients with a limited number of smaller unresectable tumors.

Treatment of Liver Cancer with the Delcath PHP System

The Delcath PHP System is designed to address the critical shortcomings of traditional liver cancer treatments. The Delcath PHP System employs a minimally invasive, repeatable procedure that allows for a higher dose of chemotherapeutic drugs by reducing the systemic exposure of such drugs.

The most advanced application for which the Delcath PHP System is being evaluated is treatment of metastatic melanoma in the liver. The Delcath PHP System isolates the liver from the patient s general circulatory system, allowing for the administration of high and concentrated doses of chemotherapeutic drugs

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directly to the isolated liver. The Delcath PHP System then captures and diverts the flow of blood exiting the liver, which contains high doses of chemotherapeutic agents. The blood passes through filters located outside of the body that remove the majority of these high doses of chemotherapy from the blood before it is reintroduced to the patient s general circulatory system. The chemotherapeutic agent remaining in the bloodstream after filtration is a fraction of the infused drug, resulting in manageable toxicities.

Based on our human clinical trial data, we believe that the Delcath PHP System allows for higher doses of the chemotherapy agent to be delivered to the liver than what would otherwise be possible through conventional intravenous chemotherapy or chemoembolization. As a result, we believe the treatment kills a greater number of cancer cells and may lead to better clinical outcomes. For example, by reducing the size and number of tumors by an amount sufficient to make resection feasible, we believe that, in some cases, delivery of drugs with the Delcath PHP System may allow for a surgical option for tumors that are currently inoperable. Chemotherapy can also be administered through the Delcath PHP System after resection with the objective of destroying micro metastases in the liver that may remain undetected, thus preventing or delaying any recurrence of tumor growth. The side effects caused by the drug we use in our current clinical trials, melphalan, are similar to the side effects associated with delivery of the drug by traditional methods. However, because the Delcath PHP System filters out the high doses of the drug, it reduces the exposure of healthy tissue and organs against the effects of chemotherapeutic agents.

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The Delcath PHP System kit includes the following disposable components manufactured for Delcath by third parties:

Infusion catheter an arterial infusion catheter used to deliver chemotherapy to the liver.

Double balloon catheter a multi-passageway catheter containing two low-pressure occlusion balloons which are positioned to isolate and capture the blood flow from the liver. The space between the balloons contains holes that collect the drug-laden blood exiting the liver and divert it outside of the body through the catheter to the filtration circuit.

Filtration circuit outside the body a blood tubing circuit containing disposable components used with a non-disposable blood pump which push the isolated blood through the Delcath PHP System s filters and deliver the filtered blood back to the patient.

Filters two hemoperfusion filters used to remove most of the chemotherapy agent from the isolated blood coming out of the liver before the blood is returned to the patient s general circulatory system.

Return catheter a thin-walled blood sheath used to deliver the filtered blood from the filtration circuit outside the body back into the patient s general circulatory system.

Series of introducers and related accessories to properly place the catheters.

The Delcath PHP System involves a series of three catheter insertions, each of which is made through standard interventional techniques. In most cases to date, general anesthesia has been used. An infusion catheter is positioned in the artery that supplies blood to the liver. A second catheter the Delcath double balloon catheter is positioned in the inferior vena cava, a major vessel leading back to the heart. A third catheter is placed in the patient s jugular vein to return the filtered blood to the patient.

The balloons on the double balloon catheter are then inflated. This procedure prevents the normal flow of blood from the liver to the heart through the inferior vena cava because the inferior vena cava has been blocked. After isolation of the liver is confirmed, a chemotherapy agent is infused into the liver through the infusion catheter. The drug-laden blood is prevented from flowing to the heart and instead is collected as it exits the liver through the double balloon catheter. Blood flows through the double balloon catheter out of the body where it is pumped through two filters to remove most of the chemotherapy agent. The filtered blood is returned via the return catheter to the patient s general circulatory system through the jugular vein. In our clinical trials, chemotherapy infusion takes place over a period of thirty minutes. Filtration occurs during infusion and for an additional thirty minutes after the infusion is completed. After the sixty-minute filtration period is complete, the catheters are removed and manual pressure is maintained on the catheter puncture sites. The entire procedure takes approximately two to three hours to administer.

During our clinical trials, patients typically remain in the hospital overnight for observation after undergoing treatment with the Delcath PHP System. An advantage of the Delcath PHP System is that the procedure is repeatable and in the current clinical trials, a patient may undergo six treatments at approximately four to six week intervals. A new disposable Delcath PHP System kit is used for each treatment.

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Our Clinical Trials

We are currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancer, summarized in the chart below. The Phase III and Phase II clinical trials are subject to the terms and conditions of the Cooperative Research and Development Agreement, the CRADA, between us and the NCI. The Phase III trial is also enrolling patients at centers throughout the U.S., with separately negotiated and agreed to grant agreements with each center. We have also received FDA approval to conduct a Phase III clinical trial of the Delcath PHP System with doxorubicin for patients suffering from primary liver cancer. This trial will be randomized between the Delcath PHP System and sorafenib. We plan to seek one or more corporate partners to fund our efforts prior to commencing this trial.

* This Phase III trial has not commenced.

** Patients who previously received surgical isolated hepatic perfusion are ineligible for the Phase III melanoma trial.

Phase III Melanoma Metastases Trial

Our most advanced trial is a randomized Phase III multi-center study enrolling 92 patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. The primary endpoint of the study is to determine hepatic progression free survival, which is the length of time a patient is both alive and free from any significant increase in the size of the tumor within their liver.

In the trial, patients are randomly assigned to receive treatments with melphalan using the Delcath PHP System, or to a control group providing best available care. Patients assigned to the Delcath PHP System may receive up to six cycles of treatment at approximately four to six week intervals. Patients randomized to the non- Delcath PHP System arm are permitted to cross-over into the Delcath arm at documentation of hepatic disease progression. To date, a majority of the control patients have been crossed over to the treatment arm.

Secondary objectives of the study are to determine the response rate, safety and tolerability of treatments using the Delcath PHP System in patients with cutaneous and ocular melanoma metastatic to the liver and the patterns of recurrence of patients treated with the Delcath PHP System for metastatic melanoma, and to determine the overall survival in patients with hepatic metastases following treatment with standard treatments and after treatment with the Delcath PHP System.

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The FDA has granted the Delcath PHP System with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. We have submitted our protocol for the Delcath PHP System with melphalan to the FDA pursuant to a Special Protocol Assessment, or SPA. An SPA is an evaluation by the FDA of our 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. We have received a letter from the FDA stating that the SPA we submitted to the FDA was acceptable. We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process for the Delcath PHP System. As of October 20, 2009, we have enrolled all of the 92-patients called for under the SPA. By mid-2010, we expect to submit the Delcath PHP System for this treatment to the FDA for approval of both a premarket application for the device and a Section 505(b)(2) NDA or accelerated NDA to change the drug label.

Phase II Trial

We are also conducting a separate Phase II clinical trial of the Delcath PHP System with melphalan in patients with primary and metastatic hepatic malignancies (liver cancer), stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell), hepatocellular carcinoma (primary liver cancer), ocular or cutaneous melanoma (eye or skin cancer), and metastatic adenocarcinoma (glandular cancer). The primary objective of this trial is to determine the response rate and duration of response to the administration of melphalan with the Delcath PHP System. Secondary objectives of this trial are to determine patterns of reoccurrence and the disease free and survival rates following treatment using the Delcath PHP System, evaluate the safety and tolerability of treatment using the Delcath PHP System and assess filter characteristics. Based on promising initial clinical results, we plan to focus our efforts on enrolling patients for the treatment of metastatic neuroendocrine cancer.

Phase I Trials

Melphalan Proof-of-Concept Studies. In 2004, we completed a multi-arm Phase I feasibility and dose-escalation trial evaluating the safety and tolerability of melphalan delivered to the liver using the Delcath PHP System in patients with primary and metastatic hepatic tumors. The primary objective of this study was to determine the maximum tolerated dose and potential dose-limiting toxicities of melphalan infusion to the liver using the PHP System. In this trial, we determined that the delivery of melphalan using the Delcath PHP System was feasible, with limited and manageable toxicity. Specifically we observed a maximum tolerated dose and dose-limiting toxicity of 3.0 mg/kg and 3.5 mg/kg, respectively. This dosing compares favorably to a 0.25 mg/kg standard label dose of melphalan delivered intravenously to the liver.

Delcath PHP System Safety Studies. Our early studies also included Phase I studies designed to demonstrate the safety of the Delcath PHP System and its ability to administer to and extract from the liver three different approved and marketed chemotherapy agents, including melphalan.

Results

Our Phase I clinical trials demonstrated that the Delcath PHP System is capable of delivering ten times more of the chemotherapy agent to the treated region, and the effective concentration at the tumor site is nearly 100 times greater, than traditional delivery methods. An equivalent dose of melphalan administered intravenously would destroy a patient s bone marrow which would be fatal without a bone marrow transplant.

The Delcath PHP System also controls systemic toxicities by isolating the circulation of the organ or region from the patient s circulatory system. This allows a higher dose of a chemotherapeutic agent to be used than would be safe to deliver intravenously. Our Phase I clinical trials demonstrated that the Delcath PHP System is capable of extracting approximately 85% of the chemotherapy agent administered to the liver, which reduces the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents.

Strategic Alliances

We continue to actively pursue strategic partners to develop markets in China, Korea, Japan and Europe and from time to time are engaged in negotiations with potential partners. We are also pursuing U.S. pharmaceutical partners to co-develop and fund additional indications for the Delcath PHP System.

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Sales and Marketing

We plan to seek one or more corporate partners to market products outside the U.S. We believe distribution or corporate partnering arrangements 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 intend to market the Delcath PHP System in the U.S. ourselves focusing our initial marketing efforts on the over fifty NCI-designated cancer centers in the U.S., beginning with the hospitals participating in the Phase III clinical trial. We plan to focus our efforts on three distinct groups of medical specialists in these comprehensive cancer centers:

surgeons who administer the Delcath PHP System;

oncologists who have primary responsibility for the cancer patient; and

interventional radiologists who are physicians specialized in working with catheter-based systems.

Third-Party Reimbursement

Because the Delcath PHP System is characterized by the FDA as an experimental device, it is not currently reimbursable in the U.S. After it is approved by the FDA, we will seek to have third-party payers, such as Medicare, Medicaid and private health insurance plans, reimburse the cost of the Delcath PHP System and the associated procedures.

In the U.S., third-party payors consist of government programs, such as Medicare, private health insurance plans, managed care organizations and other similar programs. Three factors are key to the reimbursement of any product:

Coding, which ensures uniform descriptions of the procedures, diagnoses and medical products involved;

Coverage, which is the payor s policy describing the clinical circumstances under which it will pay for a given treatment; and

Payment processes and amounts.

Outside of the U.S., government managed health care systems and private insurance control reimbursement for devices and procedures.

Attractive reimbursement levels for hospitals and physicians can speed the rate at which our technology is adopted as a standard of care for treating tumors in the liver. Currently there is no unique code for the Delcath PHP System. However, many of the component parts of the procedure, such as arterial catheterization and vascular imaging, are currently reimbursable.

We have retained an expert in medical coding and reimbursement to assist us in developing a strategy to maximize reimbursement for the Delcath PHP System. We are compiling data comparing the Delcath PHP System with alternative cancer treatments to prepare an analysis of the relative procedure costs and the expected therapeutic advantages of the Delcath PHP System to support our efforts to secure coding, coverage and reimbursement.

Manufacturing

We plan to assemble, sterilize and package the Delcath PHP System kit at our facility in Kingsbury, New York. We currently utilize contract manufacturers to manufacture the components of the Delcath PHP System. The Delcath PHP System kit components must be manufactured and sterilized in accordance with manufacturing and performance specifications that will be established under the device premarket application.

The catheters and catheter accessories contained within the Delcath PHP System kit are being manufactured domestically by the OEM division of B. Braun Medical, Inc. Medtronic USA, Inc. manufactures the components of the blood filtration circuit, including the medical tubing through which a patient s blood flows and various

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connectors, as well as the blood filtration pump accessories. Bipore Medical Devices, Inc. manufactures the filters used with the Delcath PHP System. Delcath is working with Bipore and other filter manufacturers to develop other specialized filters for use within the Delcath PHP System. Our suppliers manufacturing facilities are ISO 13485 approved. We have not entered into a written agreement with any of our suppliers to manufacture the Delcath PHP System either for the clinical trials or for commercial sale.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors.

The Delcath PHP System competes with all forms of liver cancer treatments. Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. In addition, some of our competitors have considerable experience in conducting clinical trials and in regulatory approval procedures. Our competitors may develop more effective or more affordable products or treatment methods, or achieve earlier product development, in which case the likelihood of our achieving meaningful revenues or profitability will be substantially reduced.

Government Regulation

General. The Delcath PHP System is regulated by the FDA as a combination product consisting of a device and a drug. The manufacture and sale of medical devices and drugs are subject to extensive governmental regulation in the U.S. and in other countries. The Delcath PHP System is regulated in the U.S. by the FDA under the Federal Food, Drug and Cosmetic Act. As such, it requires FDA approval of a premarket approval application for the device component and Section 505(b)(2) NDA or accelerated NDA for the drug prior to the commercial distribution of the Delcath PHP System.

Melphalan, the drug that we are initially seeking to have approved for use with the Delcath PHP System, is a widely used chemotherapy agent that has already been approved by the FDA for use at a lower dose than we propose. The approved labeling for melphalan includes indications for use, method of action, dosing, side effects and contraindications. Because the Delcath PHP System delivers the drug through a different mode of administration and at a dose strength that is substantially higher than that currently approved, we will be seeking a revised label of melphalan for use with the Delcath PHP System through a Section 505(b)(2) NDA or accelerated NDA. The clinical trials are designed to provide the necessary clinical data to support this required labeling change.

Our contract manufacturers are also subject to numerous federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, and disposal of hazardous or potentially hazardous substances.

Medical Devices. The Delcath PHP System is a Class III medical device. Class III medical devices are subject to the most stringent regulatory controls to assure reasonable safety and effectiveness. FDA premarket approval is required for most Class III medical devices. An application for premarket approval must be supported by data about the device and its components, including the manufacturing and labeling of the device, the results of animal and laboratory testing and data from human clinical trials. The conduct of Phase III clinical trials is subject to extensive regulation and to ongoing oversight by the FDA as well as the institutional review boards at hospitals and research centers that conduct the trials. Before commencing clinical trials, we obtained an FDA-approved investigational device exemption allowing for the initiation of clinical trials. The investigational device exemption included approval of our investigational plan, including the proposed protocols and informed consent statement that patients sign before undergoing treatment with the Delcath PHP System, by the FDA and the institutional review boards at the sites where the trials are being conducted.

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We believe that the FDA will review our premarket application expeditiously. However, approval of the Delcath PHP System may take longer than anticipated if the FDA requests additional information or clarification, or if any major amendments to our application are requested. In addition, the FDA may refer this application to an advisory committee of experts. This process is referred to as a panel review, and could delay the review of the Delcath PHP System.

If the FDA s evaluations of the application, clinical study sites and manufacturing facilities are favorable, the FDA will issue either an approval letter or an approvable letter. An approvable letter contains a list of information that must be submitted or conditions that must be met to obtain full approval of an application. If and when the information is submitted or those conditions are met to the satisfaction of the FDA, the agency will issue an order of approval for the application, authorizing commercial marketing of the device for the specific indications approved. If the FDA s evaluation of the application, the clinical study sites or the manufacturing facilities is not favorable, the FDA may deny approval of the application or issue a not approvable letter. The FDA may also determine that additional preclinical testing or human clinical trials should be performed before approval, or that post-approval studies must be conducted.

Approved medical devices remain subject to extensive ongoing regulation. Advertising and promotional activities are subject to regulation by the FDA and by the Federal Trade Commission. Other ongoing FDA medical device reporting regulations require that we provide information to the FDA on any deaths or serious adverse events that may have been caused or contributed to by the use of marketed device and product malfunctions that would likely cause or contribute to a death or serious injury if the malfunction were to recur.

Drugs. Delcath must obtain a change to the current approved label for the drug melphalan before the Delcath PHP System may be marketed in the U.S. The current FDA-approved labeling for melphalan provides for administration of the drug at lower doses than we are currently using and does not provide for its delivery with the Delcath PHP System. We have no assurance that the FDA will approve the application for a change to the current label.

The Phase III clinical trial protocol using melphalan is designed to obtain approval of both new drug labeling and a premarket approval application providing for the use of melphalan with the Delcath PHP System. The trial protocol was accepted by both the FDA division that approves new drugs and the division that reviews applications to market new devices. All of the data generated in the trial will be submitted to both of these FDA divisions.

Under the Federal Food, Drug and Cosmetic Act, the Delcath PHP System cannot be marketed until a new drug application and the device premarket approval application are approved, and then only in conformity with any conditions of use set forth in the approved labeling.

Orphan Drug Regulation. The Orphan Drug Act provides for a seven-year period of exclusive marketing to the sponsor who obtains marketing approval for that designated orphan drug or biological product. Exclusivity begins on the date that the marketing application is approved by FDA for the designated orphan drug, and the exclusivity only applies to the indication for which the drug has been approved. An orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting. The FDA has granted Delcath four orphan drug designations. In November 2008, the FDA granted Delcath two orphan-drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan-drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan-drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer.

Foreign Regulation. In order for our products to be marketed and sold in Asia, Europe, Latin America 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, may differ from the FDA regulatory framework. In addition, there may be foreign regulatory barriers other than approval or clearance.

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The European Economic Area (EEA) has an agreement between member states of the European Free Trade Association (EFTA), the European Community (EC), and all member states of the European Union (EU) regarding certain certifications for medical devices. The CE marking (also known as CE mark) is a mandatory conformity mark on many products placed on the single market in the EEA. The CE marking does not certify that a product has met EU consumer safety, health or environmental requirements, but can permit the marketing of a medical device once obtained. We have begun the process of seeking the CE Mark for the Delcath PHP System and hope to receive approval by mid-2010.

We have also begun the process of applying for an import license for the Delcath PHP System into China. Marketing our device in other parts of the world, including China, requires the obtaining of country specific regulatory approvals and compliance with extensive local regulations.

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with bringing new products through the development and regulatory approval process, the health care industry places considerable emphasis on obtaining patent and trade secret protection for new technologies, products and processes. We hold seven U.S. patents, as well as nine corresponding foreign patents and five corresponding pending foreign patent applications in Canada, Europe and Asia that we believe are or may be material to our business.

We plan to enforce our intellectual property rights vigorously. In addition, we conduct searches and other activities relating to the protection of existing patents and the filing of new applications. We seek to patent improvements that we identify through manufacturing and clinical use of the Delcath PHP System which allow us to expand the use of the Delcath PHP System beyond the treatment of cancers in the liver.

In certain circumstances, U.S. Patent law allows for the extension of a patent s duration for a period of up to five years after FDA approval. We intend to seek extension for one of our patents after FDA approval.

We also rely on trade secrets and proprietary technological experience. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. These agreements may not provide meaningful protection of our proprietary technologies or other intellectual property if unauthorized use or disclosure occurs or if they do not adequately protect against disclosure of material proprietary information.

In addition to our proprietary protections, the FDA has granted Delcath four orphan drug designations which provides us a seven-year period of exclusive marketing beginning on the date that our marketing application is approved by FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, we believe that this protection will provide us with added protection while we commercialize the Delcath PHP System.

Employees and Facilities

As of September 30, 2009, we had ten full-time employees. In 2009, we hired a Controller, a Director of Plant Operations, and a Chief Financial Officer, transitioned a new Chief Executive Officer and a new Chief Medical Officer, and intend to recruit additional personnel in connection with the research, development, manufacturing and marketing of our products. None of our employees is represented by a union and we believe relationships with our employees are good.

On September 3, 2009, we announced that we signed a three-year lease with an option to buy on a 10,000 square foot facility in Kingsbury, New York, where we plan to locate assembling, sterilization and packaging of the Delcath PHP System. We anticipate hiring approximately 20 people at this facility by the end of 2009 to establish manufacturing, distribution, research and development capabilities. Since major medical device

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companies have located their catheter operations in this area for decades, the local labor force is well acquainted with the manufacturing requirements that Delcath will face as it progresses toward full-scale production of the Delcath PHP System.

Internet Access to Periodic Reports

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the Commission). Our Commission filings (File No. 1-16133) are available to the public free of charge over the Internet at the Commission s web site at http://www.sec.gov, and on our web site at http://www.delcath.com. Other information contained on our web site is not part of this prospectus supplement or the accompanying prospectus.

You may also read and copy any document we file at the Commission s public reference room located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may request copies of these documents by writing to the Commission and paying a fee for the copying cost.

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MANAGEMENT

Executive Officers and Directors

Our executive officers and directors, their current positions and their ages as of September 30, 2009 are set forth below:

Name	Age	Position(s)
Eamonn P. Hobbs	51	President and Chief Executive Officer, Director
David A. McDonald	49	Chief Financial Officer
Jonathan A. Foltz, MBA, CFA	48	Executive Vice President Special Projects
Krishna Kandarpa, M.D. Ph.D.	58	Executive Vice President Research and Development, Chief Medical Officer
John J. Talarico, MBA	54	Senior Vice President Regulatory Affairs and Quality Systems
Jason Rifkin, J.D., M.B.	31	Senior Vice President Clinical Affairs, Secretary
Harold S. Koplewicz, M.D.	55	Director, Chairman of the Board
Robert B. Ladd, MBA, CFA	50	Director
Richard L. Taney, J.D.	52	Director
Laura A. Philips, Ph.D., MBA	51	Director
Roger G. Stoll, Ph.D.	66	Director
Pamela R. Contag, Ph.D.	51	Director

Eamonn P. Hobbs was appointed President and Chief Executive Officer of Delcath in July 2009 and has been a director of the Company since October 2008. He has over 25 years of experience in the interventional radiology, interventional cardiology and gastroenterology medical device industries. From 1988 until earlier this year, Mr. Hobbs was President and CEO of AngioDynamics, Inc. In 2004, AngioDynamics was spun off from E-Z-EM, Inc., a healthcare company focused on diagnostic technologies, where Mr. Hobbs served as Senior Vice-President since 1988. Before his involvement with these companies, Mr. Hobbs was the Director of Marketing and Product Development at NAMIC, Founder, President and CEO of Hobbs Medical, Inc., and a Product Development Engineer at Cook Incorporated. He received a Bachelor of Science in Plastics Engineering with a Biomaterials emphasis at the University of Massachusetts, Lowell in 1980. In addition, since 2001, Mr. Hobbs has served as the only industry member of the strategic planning committee of the Society of Interventional Radiology, was elected to and served from 2002 to 2008 on the Board of Directors of the Society of Interventional Radiology Foundation (SIRF) and is currently Vice Chairman of the Medical Device Manufacturers Association (MDMA).

David A. McDonald joined Delcath in September 2009. He was formerly the Senior Vice President of Business Development at AngioDynamics, Inc., where he led the company s business development activities. Mr. McDonald founded Minneapolis-based Cornerstone Healthcare Advisors LLC in April 2005, which he led until joining AngioDynamics in July 2008. At Cornerstone he provided advisory and consulting services to emerging medical technology companies and their financial sponsors. Prior to 2005, Mr. McDonald was a Managing Director and leader of Medical Technology Investment Banking at RBC Capital Markets. Before his involvement with these companies, Mr. McDonald was a Senior Vice President and Equity Portfolio Manager at

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Investment Advisers, Inc as well as a research analyst covering the healthcare industry for more than a dozen years. He received a Bachelor of Arts Degree in Economics from St. Olaf College in Northfield, Minnesota in 1982.

Jonathan A. Foltz, MBA, CFA has been an Executive Vice President since June 2007. He had been working with Delcath in an advisory role for periods between 2001 and 2007. Mr. Foltz is a founder and Director of Os Technology, a women s health medical device company. From 1992 to 2001, he was Director of Operations at Delcath and served as Acting Chief Operating Officer from 1999 to 2001 and Acting Chief Financial Officer from 1998 to 2000. Prior to 1992, Mr. Foltz held supervisory and analytical positions at Venkol Ventures, a healthcare-focused venture capital fund, Nicholas Lawrence & Co., a regional stock brokerage, Value Line, Inc. and Walter Heller & Co. A Chartered Financial Analyst, Mr. Foltz received a B.S. in Finance and Computer Science from Lehigh University and an MBA from the University of Connecticut.

Krishna Kandarpa, M.D., Ph.D. joined Delcath as Executive Vice President, Research and Development and Chief Medical Officer in October 2009. Prior to joining Delcath, from 2002 to 2009, he was a tenured Professor and former Chair of the Department of Radiology at the University of Massachusetts Medical School (UMMS) and Radiologist-in-Chief at the University of Massachusetts Memorial Medical Center. Before joining the University of Massachusetts Memorial Medical Center in 2002, he was at the Weill Medical College of Cornell University, where he was a Professor of Radiology and Chief of Service and Director of the Division of Cardiovascular & Interventional Radiology at The New York Presbyterian Hospital (Cornell). He was also a faculty member at the Harvard-Massachusetts Institute of Technology, Division of Health Sciences and Technology from 1987 to 1998. Before deciding to attend medical school at the University of Miami, Dr. Kandarpa was a Research and Development Engineer at Duracell International Laboratory for Physical Science. He earned a PhD in Engineering Science & Mechanics from Penn State University and a B.S. in Aerospace & Mechanical Engineering from Washington University (St. Louis).
Dr. Kandarpa is past-President (1997-2001) and past-Chair (2001-2002) of the Cardiovascular & Interventional Radiology Research and Education Foundation (CIRREF) of the Society of Interventional Radiology (SIR). He completed his final term on the Board of Directors of the Academy of Radiology Research in 2007. Dr. Kandarpa has authored over 50 original peer-reviewed scientific publications, including book chapters and solicited review articles, and is the author/editor of several specialized books, including *The Handbook of Interventional Radiologic Procedures*, and a new textbook entitled *Peripheral Vascular Interventions* (2008), which will be available in Chinese this year.

John J. Talarico, MBA has been the Senior Vice President since July 2008. From 2005 to 2008, Mr. Talarico held a similar title at Excelsior Medical and ProRhythm, Inc., manufacturers of Class II and III combination products involving a drug and device. From 1981 to 2004, he held senior engineering, quality and regulatory roles at a series of medical device companies. Mr. Talarico holds a B.E. from Stevens Institute of Technology and a Masters in Business Administration from Florida Institute of Technology.

Jason Rifkin, J.D., M.B. joined Delcath in June 2007 and is Senior Vice President Clinical Affairs and Secretary. Prior to joining Delcath, from 2006 to 2007, Mr. Rifkin practiced law at Fox Rothschild LLP, where he was an Associate in the Corporate Department Pharmaceuticals and Biotechnology Group. From 2004 to 2006, Mr. Rifkin practiced at a boutique litigation firm in New York City, Goldstein & Weinstein. Prior to that, Mr. Rifkin worked for the Legal Aid Society. Mr. Rifkin holds a B.A. from the University of Pennsylvania, a J.D. from Northeastern University School of Law and a Masters in Biotechnology from the University of Pennsylvania, School of Engineering and Applied Sciences.

Harold S. Koplewicz, M.D. was first appointed a director in September 2006. He was appointed Chairman of the Board in February 2007. In May 2006, Dr. Koplewicz was appointed by then-New York Governor George Pataki to the position of Executive Director of the Nathan S. Kline Institute for Psychiatric Research, where he is the third person to hold this position since 1952. Dr. Koplewicz is also the Arnold and Debbie Simon Professor and Chairman of the Department of Child and Adolescent Psychiatry and Professor of Pediatrics and founder of the NYU Child Study Center at the New York University School of Medicine. He has served as a member of the National Board of Medical Examiners and as a commissioner of the New York State Commission on Youth, Crime and Violence and Reform of the Juvenile Justice System.

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Robert B. Ladd, MBA, CFA was first appointed a director in October 2006. Since January 2003, Mr. Ladd has served as the founder and managing member of Laddcap Value Associates LLC, the general partner of Laddcap Value Partners LP, an investment management company. From 1988 to November 2002, Mr. Ladd served as a Managing Director of Neuberger Berman, an investment management company. Mr. Ladd graduated from the University of Pennsylvania s Wharton School with a B.S. in Economics in 1980. He received his MBA from Northwestern University s Kellogg School of Management in 1983. Mr. Ladd has also earned a CFA designation.

Richard Taney, J.D. was first appointed a director in November 2006. Mr. Taney served as our Chief Executive Officer from December 2006 until July 2009 and our President from April 2007 until July 2009 and is currently an independent consultant. Mr. Taney was a founding partner of Sandpiper Capital Partners, an investment partnership that focuses on private equity investments and advisory work for privately held companies involved in a variety of emerging technologies, and managing partner from March 2003 until December 2006. In 1999, he founded T2 Capital Management, LLC, an investment management company and was the managing member until December 2004. Prior to establishing his money management ventures, he spent 20 years advising and managing assets for high net worth and institutional clients, at Salomon Brothers, Goldman Sachs and most recently as Managing Director of Banc of America Securities. He earned his B.A. from Tufts University and his J.D. from Temple University School of Law.

Laura A. Philips, Ph.D., MBA was appointed a director in May 2007. Dr. Philips has been an independent consultant since 2006. From 2003 to 2006, she was Chief Operating Officer and Acting Chief Financial Officer of NexGenix Pharmaceuticals. Prior to that, she was Vice President, Program Management for the AMDeC Foundation. Dr. Philips worked at Corning Incorporated from 1997 to 2002, where she held several positions including Program Director of the Fuel Cells Division. From 1994 to 1996 Dr. Philips held various government positions in Washington, D.C., most recently in a Presidential appointment as Senior Policy Advisor to Secretary of Commerce Ronald Brown. Dr. Philips was on the faculty of Cornell University in the Department of Chemistry from 1987 to 1994 and was an NIH Post-Doctoral Fellow at the University of Chicago. She received a B.A. in Chemistry from Williams College, a Ph.D. in Physical Chemistry from the University of California Berkeley and an MBA with Distinction from Cornell University s Johnson School of Management.

Roger G. Stoll, Ph.D. was appointed a director in December 2008. From 2002 to 2008 he served as Chief Executive Officer and President of Cortex Pharmaceuticals, Inc., where he was appointed Executive Chairman in August 2008. From 2001 to 2002, he was a consultant to several east coast venture capital firms and startup ventures. From 1998 to 2001, he was Executive Vice President of Fresenius Medical Care-North America, in charge of the dialysis products division and the diagnostic systems business units, which included hemodialysis machines and dialysis filters equipment. From 1991 to 1998 he was Chief Executive of Ohmeda. From 1986 to 1991, Dr. Stoll held several executive management positions at Bayer, AG, including Executive Vice-President and General Manager for the worldwide Diagnostic Business Group. Prior to that, Dr. Stoll worked for American Hospital Supply Corp, where he rose from Director of Clinical Pharmacology to President of its American Critical Care Division. He began his pharmaceutical career at the Upjohn Company in 1972. Dr. Stoll obtained his BS in Pharmacy from Ferris State University, obtained a Ph.D. in Biopharmaceutics and Drug Metabolism at the University of Connecticut, and was a post-doctoral fellow for two years at the University of Michigan. Dr. Stoll also serves on the board of directors of Chelsea Therapeutics and School of Pharmacy Advisory Board of the University of Connecticut.

Pamela R. Contag, Ph.D. was appointed a director in December 2008. Dr. Contag founded in 2006, and currently is Chief Technology Officer of, Cobalt Technologies, Inc., which engages in the development of biofuel production technologies. Prior to starting Cobalt, she founded Xenogen Corporation, which specializes in technology and services for preclinical drug development and testing, where she served as President and Director from 1995 to 2006. Xenogen, which went public in 2004, was acquired in 2006 by Caliper Life Sciences.

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Dr. Contag received her Ph.D. in Microbiology from the University of Minnesota Medical School and completed her postdoctoral training at Stanford University School of Medicine. Dr. Contag is a consulting Professor at the Stanford School of Medicine and is widely published in the field of non-invasive molecular and cellular imaging.

Recent Management Additions

Agustin Gago joined us in early November 2009 as Executive Vice President, Global Sales and Marketing and John Purpura will join us in mid-November 2009 as Executive Vice President, Regulatory Affairs and Quality Assurance. Prior to joining Delcath, Mr. Gago was Vice President, International Oncology Surgery Sales at Angiodynamics, Inc. since 2008. Mr. Purpura was most recently the Head of Regulatory Affairs, North and Latin America at E-Z-EM, which was acquired in 2008 from Bracco Diagnostics, since 2007.

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UNDERWRITING

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock set forth opposite its name below. Cowen and Company, LLC is the representative of the underwriters.

Underwriter	Number of Shares
Cowen and Company, LLC	4,250,000
Canaccord Adams Inc.	1,912,500
Wedbush Morgan Securities, Inc.	1,487,500
Craig-Hallum Capital Group LLC	850,000
Total	8,500,000

The underwriting agreement provides that the obligations of the underwriters are conditional and may be terminated at their discretion based on their assessment of the state of the financial markets. The obligations of the underwriters may also be terminated upon the occurrence of the events specified in the underwriting agreement. The underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the overallotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Overallotment Option to Purchase Additional Shares. We have granted to the underwriters an option to purchase up to 1,275,000 additional shares of common stock at the public offering price, less the underwriting discount. This option is exercisable for a period of 30 days. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with the sale of common stock offered hereby. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

Discounts and Commissions. The following table shows the public offering price, underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares.

	Per Share	Total Without Over-Allotment	With Over-Allotment
Public offering price	$ 3.600	$ 30,600,000	$ 35,190,000
Underwriting discount	$ 0.225	$ 1,912,500	$ 2,199,375
Proceeds, before expenses, to Delcath Systems, Inc.	$ 3.375	$ 28,687,500	$ 32,990,625

We estimate that the total expenses of the offering, excluding the underwriting discount, will be approximately $600,000 and are payable by us.

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus supplement. The underwriters may offer the shares of common stock to

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securities dealers at the public offering price less a concession not in excess of $0.110 per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

Discretionary Accounts. The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.

Overallotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriters may close out any short position by exercising their overallotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the overallotment option. If the underwriters sell more shares than could be covered by exercise of the overallotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making. In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker s bid, that bid must then be lowered when specified purchase limits are exceeded.

Lock-Up Agreements. Pursuant to certain lock-up agreements, we and our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar

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agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act of 1933, as amended, relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, for a period of 90 days after the date of the pricing of the offering. The 90-day restricted period will be automatically extended if (i) during the last 17 days of the 90-day restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the 90-day restricted period, we announce that we will release earnings results or become aware that material news or a material event will occur during the 16-day period beginning on the last day of the 90-day restricted period, in either of which case the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit us, among other things and subject to restrictions, to: (a) issue common stock or options pursuant to employee benefit plans, (b) issue common stock upon exercise of outstanding options or warrants, (c) issue securities in connection with acquisitions or similar transactions, (d) file registration statements on Form S-8, or (e) file resale registration statements on Form S-3. The exceptions permit parties to the lock-up agreements, among other things and subject to restrictions, to: (a) make certain gifts, (b) if the party is a corporation, partnership, limited liability company or other business entity, make transfers to any shareholders, partners, members of, or owners of similar equity interests in, the party, or to an affiliate of the party, if such transfer is not for value, and (c) if the party is a corporation, partnership, limited liability company or other business entity, make transfers in connection with the sale or transfer of all of the party s capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the party s assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by the lock-up agreement. In addition, the lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

Electronic Offer, Sale and Distribution of Shares. A prospectus supplement in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectus supplements electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus supplement in electronic format, the information on these websites is not part of this prospectus supplement or the registration statement of which this prospectus supplement forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they received, and may in the future receive, customary fees.

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LEGAL MATTERS

The validity of our common stock offered in this offering and certain other legal matters will be passed upon for us by Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Goodwin Procter LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of Delcath Systems, Inc. appearing in our Annual Report on Form 10-K for the year ended December 31, 2008 (including schedule appearing therein) and the effectiveness of our internal control over financial reporting as of December 31, 2008 have been audited by CCR LLP, independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

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PROSPECTUS

$60,000,000

Common Stock

Preferred Stock

Warrants

Debt Securities

Stock Purchase Contracts

Delcath Systems, Inc. (the Company) may offer to sell from time to time debt securities, common stock, preferred stock, stock purchase contracts and warrants. The preferred stock of the Company may be convertible into common stock or preferred stock of another series.

The Company may offer securities at an aggregate offering price of up to $60,000,000. The debt securities, common stock, preferred stock, stock purchase contracts and warrants of the Company and the debt securities of the Company may be offered separately or together, in multiple series, in amounts, at prices and on terms that will be set forth in one or more prospectus supplements to this prospectus. Because the maximum aggregate offering price of all securities is $60,000,000, the Company s issuance of any securities will reduce the amount of other securities that it can issue.

This prospectus describes some of the general terms that may apply to these securities and the general manner in which they may be offered. Each time the Company sells securities, a prospectus supplement will be provided that will contain specific information about the terms of any securities offered and the specific manner in which the securities will be offered. The prospectus supplement will also contain information, where appropriate, about material United States federal income tax consequences relating to, and any listing on a securities exchange of, the securities covered by the prospectus supplement. The prospectus supplement may add to, update or change the information in this prospectus. You should read this prospectus and any prospectus supplement carefully before you invest in our securities. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement.

The Company may offer the securities directly to investors, through agents designated from time to time by the Company, or to or through underwriters or dealers. If any agents, underwriters, or dealers are involved in the sale of any of the securities, their names, and any applicable purchase price, fee, commission or discount arrangement with, between or among them will be set forth, or will be calculable from the information set forth, in an accompanying prospectus supplement. For more detailed information, see Plan of Distribution on page 22.

Our common stock is traded on the NASDAQ Global Market under the symbol DCTH. On June 10, 2009, the last reported sale price of our common stock on the NASDAQ Global Market was $3.65.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties referenced under the heading Risk Factors beginning on page 2 of this prospectus.

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

The date of this prospectus is June 23, 2009.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus and the accompanying prospectus supplement or incorporated by reference in these documents. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. If anyone provides you with different, inconsistent or unauthorized information or representations, you must not rely on them. This prospectus and the accompanying prospectus supplement are an offer to sell only the securities offered by these documents, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or any prospectus supplement is current only as of the date on the front of those documents.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus, before making an investment decision.

DELCATH SYSTEMS, INC.

We are a development stage company that has developed an innovative device designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body. We were incorporated in the State of Delaware in 1988 and since inception have focused our efforts on the development of a single product, The Delcath PHP System , which isolates the circulatory system of a specific organ or body region in order to deliver high dose chemotherapy or other therapeutic agents directly to that diseased organ or body region. The first application being tested with our system is for the treatment of cancers of the liver. The Delcath PHP System isolates the liver from the patient s general circulatory system and delivers high doses of the chemotherapeutic drug, melphalan hydrochloride, directly to tumors in the liver while avoiding most of the toxicities that normally result from such high doses of the drug. In 2006, we began a Phase III clinical trial to support the United States Food and Drug Administration (the FDA) approval process for the Delcath PHP System . The Delcath PHP System is not currently approved by the FDA, and it cannot be marketed in the United States without FDA pre-market approval.

We also are conducting Phase II clinical trials, testing the Delcath PHP System with the drug melphalan against hepatocellular tumors (primary liver cancer) and neuroendocrine and adenocarcinoma tumors that have spread to the liver, as well as melanomas metastatic to the liver that have received certain prior regional treatment.

Our principal executive office is located at 600 Fifth Avenue, 23rd Floor, New York, NY 10020. Our telephone number is (212) 489-2100. Our website address is www.delcath.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

Unless the context indicates otherwise, as used in this prospectus, the terms Delcath Systems, we, us and our refer to Delcath Systems, Inc., a Delaware corporation. We use The Delcath PHP System and the Delcath Systems logo as trademarks in the United States and other countries. All other trademarks or trade names, if any, referred to in this prospectus are the property of their respective owners.

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risk factors set forth in the documents and reports filed by us with the Securities and Exchange Commission, which we refer to as the SEC, that are incorporated by reference into this prospectus, as well as any risks described in any applicable prospectus supplement, before deciding whether to buy our securities. Additional risks not known to us or that we believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our financial condition, results of operations and business. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, could, would, will, m potential, should, and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this 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 Securities Exchange Act of 1934, as amended, 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, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 in Item 1A under Risk Factors as well as in Item 7A Qualitative and Quantitative Disclosures About Market Risk, our Quarterly Report on Form 10-Q for the period ended March 31, 2009 in Part II, Item 1A under Risk Factors as well as in Part I, Item 3 Qualitative and Quantitative 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 results and timing of our clinical trials and the commencement of future clinical trials; and
- submission and timing of applications for regulatory approval.

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

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WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information contained in this prospectus or 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 state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus 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, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The SEC file number for the documents incorporated by reference in this prospectus is 001-16133. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this document:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and filed with the SEC on March 3, 2009;
- The information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 from our definitive proxy statement on Schedule 14A filed with the SEC on April 30, 2009;
- Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 and filed with the SEC on April 24, 2009;
- Our Current Report on Form 8-K, filed on April 10, 2009; and
- The description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A12B, filed with the SEC on September 22, 2000, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference into this prospectus 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 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.

Any documents filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) after the date of this prospectus and on or before the completion of the resale of the shares by the selling stockholders shall also be deemed incorporated herein by reference. These documents include our periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

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USE OF PROCEEDS

Unless we provide otherwise in a supplement to this prospectus, we intend to use the net proceeds from the sale of our securities covered by this prospectus for general corporate purposes. These purposes may include funding our clinical trials, capital expenditures, working capital, repayment of debt and investments.

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DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we may include in any applicable prospectus supplements and in any related free writing prospectuses, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms summarized below will apply generally to any debt securities that we may offer, we will describe the particular terms of any debt securities in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below.

We may issue debt securities from time to time in one or more distinct series. The debt securities may be senior debt securities or subordinated debt securities. Senior debt securities may be issued under a senior indenture and subordinated debt securities may be issued under a subordinated indenture. If we issue debt securities pursuant to an indenture, in the applicable prospectus supplement we will specify the trustee under such indenture. We will include in a supplement to this prospectus the specific terms of debt securities being offered, including the terms, if any, on which debt securities may be convertible into or exchangeable for common stock, preferred stock or other debt securities. The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of debt securities and any indentures are summaries of these provisions, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the debt securities and the indentures (including any amendments or supplements we may enter into from time to time which are permitted under the debt securities or any indenture).

Unless otherwise specified in a prospectus supplement, the debt securities will be direct unsecured obligations of the Company. Any debt securities designated as senior will rank equally with any of our other senior and unsubordinated debt. Any debt securities designated as subordinated will be subordinate and junior in right of payment to any senior indebtedness. There may be subordinated debt securities that are senior or junior to other series of subordinated debt securities.

The applicable prospectus supplement will set forth the terms of the debt securities or any series thereof, including, if applicable:

- the title of the debt securities and whether the debt securities will be senior debt securities or subordinated debt securities;
- any limit upon the aggregate principal amount of the debt securities;
- whether the debt securities will be issued as registered securities, bearer securities or both, and any restrictions on the exchange of one form of debt securities for another and on the offer, sale and delivery of the debt securities in either form;
- the date or dates on which the principal amount of the debt securities will mature;
- if the debt securities bear interest, the rate or rates at which the debt securities bear interest and the date or dates from which interest will accrue;
- if the debt securities bear interest, the dates on which interest will be payable and the regular record dates for interest payments;
- the place or places where the payment of principal, any premium and interest will be made, if other than or in addition to the Borough of Manhattan, The City of New York, where the debt securities may be surrendered for transfer or exchange and where notices or demands to or upon us may be served;
- any optional redemption provisions, which would allow us to redeem the debt securities in whole or in part;

any sinking fund or other provisions that would obligate us to redeem, repay or purchase the debt securities;

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if the currency in which the debt securities will be issuable is United States dollars, the denominations in which any registered securities will be issuable, if other than denominations of $1,000 and any integral multiple thereof, and the denominations in which any bearer securities will be issuable, if other than the denomination of $5,000;

if other than the entire principal amount, the portion of the principal amount of debt securities which will be payable upon a declaration of acceleration of the maturity of the debt securities;

the events of default and covenants relevant to the debt securities, including, the inapplicability of any event of default or covenant set forth in the indenture relating to the debt securities, or the applicability of any other events of defaults or covenants in addition to the events of default or covenants set forth in the indenture relating to the debt securities;

the name and location of the corporate trust office of the applicable trustee under the indenture for such series of notes;

if other than United States dollars, the currency in which the debt securities will be paid or denominated;

if the debt securities are to be payable, at our election or the election of a holder of the debt securities, in a currency other than that in which the debt securities are denominated or stated to be payable, the terms and conditions upon which that election may be made, and the time and manner of determining the exchange rate between the currency in which the debt securities are denominated or stated to be payable and the currency in which the debt securities are to be so payable;

the designation of the original currency determination agent, if any;

if the debt securities are issuable as indexed securities, the manner in which the amount of payments of principal, any premium and interest will be determined;

if the debt securities do not bear interest, the dates on which we will furnish to the applicable trustee the names and addresses of the holders of the debt securities;

if other than as set forth in an indenture, provisions for the satisfaction and discharge or defeasance or covenant defeasance of that indenture with respect to the debt securities issued under that indenture;

the date as of which any bearer securities and any global security will be dated if other than the date of original issuance of the first debt security of a particular series to be issued;

whether and under what circumstances we will pay additional amounts to non-United States holders in respect of any tax assessment or government charge;

whether the debt securities will be issued in whole or in part in the form of a global security or securities and, in that case, any depositary and global exchange agent for the global security or securities, whether the global form shall be permanent or temporary and, if applicable, the exchange date;

if debt securities are to be issuable initially in the form of a temporary global security, the circumstances under which the temporary global security can be exchanged for definitive debt securities and whether the definitive debt securities will be registered securities, bearer securities or will be in global form and provisions relating to the payment of interest in respect of any portion of a global security payable in respect of an interest payment date prior to the exchange date;

the extent and manner to which payment on or in respect of debt securities will be subordinated to the prior payment of our other liabilities and obligations;

whether payment of any amount due under the debt securities will be guaranteed by one or more guarantors, including one or more of our subsidiaries;

whether the debt securities will be convertible and the terms of any conversion provisions;

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the forms of the debt securities; and

any other terms of the debt securities, which terms shall not be inconsistent with the requirements of the Trust Indenture Act of 1939, as amended.

This prospectus is part of a registration statement that does not limit the aggregate principal amount of debt securities that we may issue and provides that we may issue debt securities from time to time in one or more series under one or more indentures, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities under the applicable indenture.

We intend to disclose any restrictive covenants for any issuance or series of debt securities in the applicable prospectus supplement.

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DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements and in any related free writing prospectuses, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation and our Amended and Restated By-Laws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. We refer in this section to our Amended and Restated Certificate of Incorporation as our certificate of incorporation, and we refer to our Amended and Restated By-Laws as our by-laws. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 70,000,000 shares of our common stock, $0.01 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.01 par value per share. As of June 10, 2009, we had 25,383,354 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Voting

Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Other Rights and Restrictions

Our common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such stock. Our common stock is not subject to redemption by us. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the stockholder s shares of common stock. When we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

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Listing

Our common stock is listed on The NASDAQ Global Market under the symbol DCTH. On June 10, 2009, the last reported sale price for our common stock on The NASDAQ Global Market was $3.65 per share.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

Preferred Stock

Our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval, none of which are outstanding. Our board of directors may issue preferred stock in one or more series and has the authority to fix the rights, preferences, privileges and restrictions of this preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of a series, without further vote or action by the stockholders.[1] The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management.

If we decide to issue any preferred stock pursuant to this prospectus, we will describe in a prospectus supplement the terms of the preferred stock, including, if applicable, the following:

- the title of the series and stated value;
- the number of shares of the series of preferred stock offered, the liquidation preference per share, if applicable, and the offering price;
- the applicable dividend rate(s) or amount(s), period(s) and payment date(s) or method(s) of calculation thereof;
- the date from which dividends on the preferred stock will accumulate, if applicable;
- any procedures for auction and remarketing;
- any provisions for a sinking fund;
- any applicable provision for redemption and the price or prices, terms and conditions on which preferred stock may be redeemed;
- any securities exchange listing;
- any voting rights and powers;

whether interests in the preferred stock will be represented by depository shares;

the terms and conditions, if applicable, of conversion into shares of our common stock, including the conversion price or rate or manner of calculation thereof;

a discussion of any material U.S. federal income tax considerations;

the relative ranking and preference as to dividend rights and rights upon our liquidation, dissolution or the winding up of our affairs;

any limitations on issuance of any series of preferred stock ranking senior to or on a parity with such series of preferred stock as to dividend rights and rights upon our liquidation, dissolution or the winding up of our affairs; and

any other specific terms, preferences, rights, limitations or restrictions of such series of preferred stock.

[1] To consider conforming to charter.

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Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

Staggered Board of Directors

Our certificate of incorporation and by-laws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Stockholder Rights Plan;

On October 30, 2001, the Company entered into a Rights Agreement with American Stock Transfer & Trust Company (the Rights Agreement) in connection with the implementation of the Company s stockholder rights plan (the Rights Plan). The purposes of the Rights Plan are to deter, and protect the Company s shareholders from, certain coercive and otherwise unfair takeover tactics and to enable the board of directors to represent effectively the interests of shareholders in the event of a takeover attempt. The Rights Plan does not deter negotiated mergers or business combinations that the board of directors determines to be in the best interests of the Company and its shareholders. To implement the Rights Plan, the board of directors declared a dividend of one Common Stock purchase right (a Right) for each share of Common Stock of the Company, par value $0.01 per share (the Common Stock) outstanding at the close of business on November 14, 2001 (the Record Date) or issued by the Company on or after such date and prior to the earlier of the Distribution Date, the Redemption Date or the Final Expiration Date (as such terms are defined in the Rights Agreement). The rights expire October 30, 2011. Each Right entitles the registered holder, under specified circumstances, to purchase from the Company for $5.00, subject to adjustment (the Purchase Price), a number of shares determined by dividing the then applicable Purchase Price by 50% of the then current market price per share in the event that a person or group announces that it has acquired, or intends to acquire, 15% or more of the Company s outstanding Common Stock. On April 9, 2007 the Board of Directors voted to increase the threshold level to 20%.

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

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DESCRIPTION OF STOCK PURCHASE CONTRACTS

The following description, together with the additional information that we include in any applicable prospectus supplements and in any related free writing prospectuses, summarizes the material terms and provisions of the stock purchase contracts that we may offer under this prospectus. While the terms we have summarized below will apply generally to any stock purchase contracts that we may offer under this prospectus, we will describe the particular terms of any series of stock purchase contracts in more detail in the applicable prospectus supplement. The terms of any stock purchase contracts offered under a prospectus supplement may differ from the terms described below.

We may issue stock purchase contracts, including contracts obligating holders to purchase from us and us to sell to the holders, a specified number of shares of common stock or preferred stock at a future date or dates. Alternatively, the stock purchase contracts may obligate us to purchase from holders, and obligate holders to sell to us, a specified or varying number of shares of common stock or preferred stock. The consideration per share of common stock or preferred stock may be fixed at the time the stock purchase contracts are issued or may be determined by a specific reference to a formula set forth in the stock purchase contracts. The stock purchase contracts may provide for settlement by delivery by us or on our behalf of shares of the underlying security, or they may provide for settlement by reference or linkage to the value, performance or trading price of the underlying security. The stock purchase contracts may require us to make periodic payments to the holders of the certain of our securities or vice versa, and such payments may be unsecured or prefunded on some basis and may be paid on a current or on a deferred basis. The stock purchase contracts may require holders to secure their obligations thereunder in a specified manner and may provide for the prepayment of all or part of the consideration payable by holders in connection with the purchase of the underlying security or other property pursuant to the stock purchase contracts.

The securities related to the stock purchase contracts may be pledged to a collateral agent for our benefit pursuant to a pledge agreement to secure the obligations of holders of stock purchase contracts to purchase the underlying security or property under the related stock purchase contracts. The rights of holders of stock purchase contracts to the related pledged securities will be subject to our security interest therein created by the pledge agreement. No holder of stock purchase contracts will be permitted to withdraw the pledged securities related to such stock purchase contracts from the pledge arrangement.

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DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement, including a form of warrant certificate, that describes the terms of the particular warrants we are offering before the issuance of the related warrants. The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the warrants that we may offer under this prospectus, as well as any related free writing prospectuses, and the complete warrant agreements and warrant certificates that contain the terms of the warrants.

General

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock and preferred stock, and the warrants may be attached to or separate from these securities.

We may evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. We will indicate the name and address and other information regarding the warrant agent in the applicable prospectus supplement relating to a particular warrants.

If we decide to issue warrants pursuant to this prospectus, we will specify in a prospectus supplement the terms of the warrants, including, if applicable, the following:

- the offering price and aggregate number of warrants offered;
- the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase stock, the number of shares of stock purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreement and warrants may be modified;

a discussion of any material U.S. federal income tax considerations of holding or exercising the warrants;

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the terms of the securities issuable upon exercise of the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants may have no rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase shares of our stock at the exercise price that we describe in the applicable prospectus supplement. Holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. If we so indicate in the applicable prospectus supplement, the warrants may also provide that they may be exercised on a cashless or net basis. We will set forth on the reverse side of the warrant certificate, if applicable, and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to us or a warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at our offices, the corporate trust office of a warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the common stock or preferred stock purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender shares of common stock or preferred stock as all or part of the exercise price for warrants.

Enforceability of Rights by Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

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PLAN OF DISTRIBUTION

We may sell the securities in any one or more of the following ways:

- directly to investors, including through a specific bidding, auction or other process;
- to investors through agents;
- directly to agents;
- to or through brokers or dealers;
- to the public through underwriting syndicates led by one or more managing underwriters;
- to one or more underwriters acting alone for resale to investors or to the public; and
- through a combination of any such methods of sale.

The Company s common stock or preferred stock may be issued upon conversion of debt securities or preferred stock of the Company. Securities may also be issued upon exercise of warrants of the Company. The Company reserves the right to sell securities directly to investors on its own behalf in those jurisdictions where it is authorized to do so.

If we sell securities to a dealer acting as principal, the dealer may resell such securities at varying prices to be determined by such dealer in its discretion at the time of resale without consulting with us and such resale prices may not be disclosed in the applicable prospectus supplement.

Any underwritten offering may be on a best efforts or a firm commitment basis. We may also offer securities through subscription rights distributed to our stockholders on a pro rata basis, which may or may not be transferable. In any distribution of subscription rights to stockholders, if all of the underlying securities are not subscribed for, we may then sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers or agents, including standby underwriters, to sell the unsubscribed securities to third parties.

Sales of the securities may be effected from time to time in one or more transactions, including negotiated transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to prevailing market prices; or
- at negotiated prices.

Any of the prices may represent a discount from the then prevailing market prices.

In the sale of the securities, underwriters or agents may receive compensation from us in the form of underwriting discounts or commissions and may also receive compensation from purchasers of the securities, for whom they may act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Discounts, concessions and commissions may be changed from time to time. Dealers and agents that participate in the distribution of the securities may be deemed to be underwriters under the Securities Act, and any discounts, concessions or commissions they receive from us and any profit on the resale of securities they realize may be deemed to be underwriting compensation under applicable federal and state securities laws.

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The applicable prospectus supplement will, where applicable:

- identify any such underwriter, dealer or agent;
- describe any compensation in the form of discounts, concessions, commissions or otherwise received from us by each such underwriter or agent and in the aggregate by all underwriters and agents;
- describe any discounts, concessions or commissions allowed by underwriters to participating dealers;
- identify the amounts underwritten; and
- identify the nature of the underwriter s or underwriters obligation to take the securities.

Unless otherwise specified in the related prospectus supplement, each series of securities will be a new issue with no established trading market, other than shares of common stock of the Company, which are listed on the NASDAQ Global Market. Any common stock sold pursuant to a prospectus supplement will be listed on the NASDAQ Global Market, subject to official notice of issuance. We may elect to list any warrants or series of debt securities or preferred stock on an exchange, but we are not obligated to do so. It is possible that one or more underwriters may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given as to the liquidity of, or the trading market for, any offered securities.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If disclosed in the applicable prospectus supplement, in connection with those derivative transactions third parties may sell securities covered by this prospectus and such prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or from others to settle those short sales or to close out any related open borrowings of securities, and may use securities received from us in settlement of those derivative transactions to close out any related open borrowings of securities. If the third party is or may be deemed to be an underwriter under the Securities Act, it will be identified in the applicable prospectus supplements.

Until the distribution of the securities is completed, rules of the SEC may limit the ability of any underwriters and selling group members to bid for and purchase the securities. As an exception to these rules, underwriters are permitted to engage in some transactions that stabilize the price of the securities. Such transactions consist of bids or purchases for the purpose of pegging, fixing or maintaining the price of the securities.

Underwriters may engage in overallotment. If any underwriters create a short position in the securities in an offering in which they sell more securities than are set forth on the cover page of the applicable prospectus supplement, the underwriters may reduce that short position by purchasing the securities in the open market.

The lead underwriters may also impose a penalty bid on other underwriters and selling group members participating in an offering. This means that if the lead underwriters purchase securities in the open market to reduce the underwriters short position or to stabilize the price of the securities, they may reclaim the amount of any selling concession from the underwriters and selling group members who sold those securities as part of the offering.

In general, purchases of a security for the purpose of stabilization or to reduce a short position could cause the price of the security to be higher than it might be in the absence of such purchases. The imposition of a penalty bid might also have an effect on the price of a security to the extent that it were to discourage resales of the security before the distribution is completed.

We do not make any representation or prediction as to the direction or magnitude of any effect that the transactions described above might have on the price of the securities. In addition, we do not make any representation that underwriters will engage in such transactions or that such transactions, once commenced, will not be discontinued without notice.

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Under agreements into which we may enter, underwriters, dealers and agents who participate in the distribution of the securities may be entitled to indemnification by us against or contribution towards certain civil liabilities, including liabilities under the applicable securities laws.

Underwriters, dealers and agents may engage in transactions with us, perform services for us or be our tenants in the ordinary course of business.

If indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by particular institutions to purchase securities from us at the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in such prospectus supplement. Each delayed delivery contract will be for an amount no less than, and the aggregate amounts of securities sold under delayed delivery contracts shall be not less nor more than, the respective amounts stated in the applicable prospectus supplement. Institutions with which such contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others, but will in all cases be subject to our approval. The obligations of any purchaser under any such contract will be subject to the conditions that (a) the purchase of the securities shall not at the time of delivery be prohibited under the laws of any jurisdiction in the United States to which the purchaser is subject, and (b) if the securities are being sold to underwriters, we shall have sold to the underwriters the total amount of the securities less the amount thereof covered by the contracts. The underwriters and such other agents will not have any responsibility in respect of the validity or performance of such contracts.

To comply with applicable state securities laws, the securities offered by this prospectus will be sold, if necessary, in such jurisdictions only through registered or licensed brokers or dealers. In addition, securities may not be sold in some states unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Underwriters, dealers or agents that participate in the offer of securities, or their affiliates or associates, may have engaged or engage in transactions with and perform services for, the Company in the ordinary course of business for which they may have received or receive customary fees and reimbursement of expenses.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon for us by Hughes Hubbard & Reed LLP, New York, New York.

EXPERTS

CCR LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2008, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on CCR LLP s report, given on their authority as experts in accounting and auditing.

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8,500,000 Shares

Delcath Systems, Inc.

Common Stock

PROSPECTUS SUPPLEMENT

Cowen and Company

Canaccord Adams

Wedbush PacGrow Life Sciences

Craig-Hallum Capital Group

November 12, 2009