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 reac