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 Off