DELCATH SYSTEMS INC
Form 10-K
March 06, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2011

o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission file number: 001-16133

DELCATH SYSTEMS, INC.

Delaware	06-1245881
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
810 Seventh Avenue, 35th Floor, New York, NY	10019
(Address of principal executive offices)	(Zip Code)

212-489-2100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act.
Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.
Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.
o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act).

Large accelerated filer o Accelerated filer x
Non-accelerated filer o (Do not check if smaller reporting company) Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes o No x

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based on the closing sale price on The NASDAQ Capital Market of $5.16 per share, was $217,100,199 as of June 30, 2011.

At March 2, 2012, the registrant had outstanding 48,502,902 shares of par value $0.01 Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2012 Annual Meeting of Stockholders are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Annual Report on Form 10-K. The definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

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DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the period ended December 31, 2011 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the period ending December 31, 2011 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Annual Report on Form 10-K for the fiscal year ended December 31, 2011 in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," our Quarterly Report on Form 10-Q for the period ended September 30, 2011 in Part II, Item 1A under "Risk Factors" as well as in Part I, Item 3 "Quantitative and Qualitative Disclosures About Market Risk" and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture and commercialize the Delcath chemosaturation system; and
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. 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 Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

Item 1. Business.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "Delcath", "Delcath Systems", "we", "our", and "us" refers to Delcath Systems, Inc., a Delaware corporation, incorporated in Augus 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 810 Seventh Avenue, 35th Floor, New York, New York 10019. Our telephone number is (212) 489-2100.

Company Overview

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

The Delcath chemosaturation system allows the administration of concentrated regional chemotherapy by isolating the circulatory system of the targeted organ. Once the organ is isolated, the Delcath chemosaturation system delivers high doses of chemotherapeutic agents directly to the liver, while limiting systemic exposure and the related side effects by

filtering the blood prior to returning it to the patient. The Delcath chemosaturation system involves a series of three catheter insertions, each of which is placed percutaneously through standard interventional radiology techniques. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs and the potential for concomitant cancer therapies. We believe that the Delcath chemosaturation system is a platform technology that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body.

On April 13, 2011, we obtained the right to affix the CE Mark to the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT System). The right to affix the CE mark allows us to market and sell the CHEMOSAT System in the European Economic Area (EEA). In the EEA, the CHEMOSAT System is regulated as a medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return. We have filed an application seeking CE Marking for Generation 2 of our CHEMOSAT System with melphalan as an amendment to the original CE Mark for the CHEMOSAT system and that application is currently under review with the Notified Body.

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We believe the CHEMOSAT system may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in the EEA. We intend to focus our initial efforts on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spain and Ireland. We believe these countries represent a majority of the total potential liver cancer market in EEA countries. We plan to use a combination of direct and indirect sales channels to market and distribute the CHEMOSAT system in the EEA. Our European commercialization strategy involves the establishment of clinical training and centers of excellence to educate and train physicians in these countries in order to develop key opinion thought leadership and foster initial market acceptance. To support our commercialization efforts in the EEA, we have established our European Headquarters in Galway, Ireland.

On November 21, 2011 we announced that we had entered into an initial training and marketing agreement with the European Institute of Oncology (IEO) in Milan, Italy. We have also entered into initial training and marketing agreements with the Frankfurt University Hospital in Frankfurt, Germany, as well as with University Medical Center Schleswig-Holstein in Kiel, Germany. In February 2012, we commenced our first European patient treatments with the CHEMOSAT system at IEO in Italy and Frankfurt University Hospital in Germany. The initial patients involved were treated for inoperable liver-dominant metastases from ocular melanoma, cutaneous melanoma, breast cancer and gastric cancer. We plan to add additional cancer centers in France, the United Kingdom, Netherlands, Spain and Ireland in the near future.

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

Advantages of the Delcath Chemosaturation System

Currently there are few effective treatment options for cancers in the liver and they are generally associated with significant side effects. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgically isolated perfusion and liver transplant. We believe the Delcath chemosaturation system may address the critical shortcomings of traditional liver cancer treatments based on the results of our Phase I, Phase II and Phase III trials:

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

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

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

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

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Strategy

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

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

Our strategy includes the following elements:

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

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

- Obtain FDA Approval for Use of the Delcath CHEMOSAT System in Combination with Melphalan to Treat Metastatic Melanoma in the Liver. Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission. Accordingly, we will continue with the preparation of our NDA submission as planned and expect to make the submission in the second quarter of 2012.

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

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

- Obtain Approval to Market the Delcath CHEMOSAT System in the United States for the Treatment of Other Cancers in addition to Metastatic Melanoma in the Liver. We concluded a multi-arm Phase II trial to evaluate the Delcath CHEMOSAT system for the treatment of other cancers in the liver, such as tumors of neuroendocrine and

colorectal adenocarcinoma and cholangiocarcinoma origin that have spread to the liver as well as primary liver cancer. Furthermore, we also intend to pursue pharmaceutical partners to co-develop and fund additional cancer indications for the Delcath CHEMOSAT system. Upon successful conclusion of the related clinical trials, we intend to apply for regulatory approval of additional indications.

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

At December 31, 2011, the Company had $30.8 million in cash, cash equivalents and certificates of deposit. Since our inception, the Company has raised approximately $149.1 million in aggregate funds (net of expenses). The Company has used approximately $81.8 million of those funds for research and development costs associated with development and testing of the Delcath chemosaturation system, and has cumulative net losses of approximately $145.4 million. For the years ended December 31, 2011, 2010, and 2009, we invested $25.2 million, $17.6 million, and $9.6 million, respectively on research and development activities.

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The Cancer Treatment Landscape

Background

According to the American Cancer Society, cancer is the second leading cause of death in the United States, with an estimated 571,950 deaths and 1.6 million new cases diagnosed in 2011. Cancer is also the second leading cause of death worldwide, accounting for approximately 7.6 million deaths and 12.7 million new cases in 2008. The financial burden of cancer is enormous for patients, their families and society. The National Institutes of Health estimates the overall costs of cancer in the United States were $264 billion in 2010, including $103 billion for direct medical costs, $21 billion for indirect morbidity costs attributable to lost productivity due to illness and $140 billion for indirect mortality costs attributable to lost productivity due to premature death.

Liver Cancer—Incidence, Mortality and Cost

Liver cancer is one of the most prevalent and lethal forms of cancer. According to the American Cancer Society "Cancer Facts & Figures 2011," the five-year survival rate for liver cancer patients in the United States is approximately 14%, compared to 68% for all cancer combined. According to GLOBOCAN 2008, liver cancer is the second leading cause of cancer death in men and the sixth leading cause of cancer death among women worldwide. In 2008, there were estimated 748,300 new liver cancer cases worldwide and 695,900 people worldwide were projected to die from liver cancer.

There are two sources of liver cancer: primary and metastatic. Primary liver cancer (hepatocellular carcinoma or HCC) originates in the liver and is particularly prevalent in populations where the primary risk factors for the disease (hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants) are present. 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. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological function of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize in their liver. In the United States, metastatic liver cancer is more prevalent than primary liver cancer.

One of the cancer histologies with a high likelihood of metastasizing to the liver is melanoma of cutaneous and ocular origins. Once melanoma has spread to the liver, evidence suggests median overall survival for these patients is generally 3-6 months. According to the American Cancer Society, the annual incidence of cutaneous and ocular melanoma is approximately 70,230 and 2,570 cases per year, respectively. Currently there are limited approved treatment options for metastatic melanoma.

On April 13, 2011, we received CE mark approval for the Delcath Hepatic CHEMOSAT Delivery System as a Class III medical device for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver. We believe the approved label for CHEMOSAT in Europe permits broad use in liver cancers. During February 2012, five patients received CHEMOSAT treatments. Two patients were treated at the Johann Wolfgang Goethe University Hospital in Frankfurt Germany for inoperable, liver-dominant metastases, one from cutaneous melanoma and one from breast cancer. An additional three patients were treated at the European Institute of Oncology in Milan, Italy — two with liver metastasis stemming from ocular melanoma and one from gastric cancer. In the United States, we concluded a Phase III clinical trial for the CHEMOSAT system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver in 2010. The Company intends to seek FDA approval of chemosaturation system with melphalan as a combination product for an indication for the treatment of metastatic melanoma liver cancer.

Liver Cancer Treatment—Common Current Approaches

Traditional treatment options for liver cancer include surgery, chemotherapy, radiation therapy, ablation and chemoembolization and radioembolization, as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgical isolated hepatic perfusion and liver transplant. As is the case with treatment of many other cancer histologies, these options have limited efficacy and are associated with significant side effects. Some of the most frequently used treatments are:

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
External beam radiation therapy (XRT) 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. Radiation therapy using x-rays is rarely used for treating liver cancer due to toxicities that impact healthy tissue.

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Radioembolization

Selective Internal Radiation Therapy (SIRT) or radioembolization, is a focal therapy that involves the percutaneous, catheter delivery of tiny beads or microspheres that contain a radioactive isotope directly to the liver where they lodge in small vessels in order to deliver radiation to the tumor. The treatment is for specific tumors, not the entire region of the liver.

Resection

Resection— surgical removal of the diseased portion of the liver—offers the greatest chance of curative treatment for localized cancers and is the preferred method to treat liver cancer once detected. Frequently, symptoms of liver cancer do not appear until the tumors have spread broadly within the liver, making surgical resection impractical. As a consequence, only about 10%-20% of primary and metastatic liver tumors can be surgically removed. Additionally, recurrence of tumors is common, and in that event surgical resection typically cannot be repeated.

Chemoembolization

Chemoembolization or transarterial chemoembolization (TACE) 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 chemosaturation system. Furthermore, the treatment is for specific tumors, not the entire region of the liver.

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.

Isolated Hepatic Perfusion

Isolated Hepatic Perfusion (IHP) is a surgical procedure developed in the 1960s, whereby the venous and arterial vasculature of the liver are accessed through surgical incision of the abdomen. The liver is isolated from the general circulation, and high doses of chemotherapy, often melphalan or oxaliplatin, are perfused through the liver, saturating the entire organ. The procedure has shown significant tumor control rates. However, the procedure is associated with significant operation time and prolonged (2-3 week) hospital stay. Based on the invasiveness of the procedure and other factors, the therapy cannot be repeated.

Treatment with the Delcath Chemosaturation System

Chemosaturation, or percutaneous hepatic perfusion, evolved from IHP. The Delcath chemosaturation system is designed to be a minimally invasive, repeatable procedure that addresses many of the shortcomings of traditional treatments by permitting the delivery of much higher doses of chemotherapeutic drugs directly to the liver while minimizing the systemic exposure of such drugs. Unlike focal therapies that can only treat a limited number of visible tumors, the Delcath chemosaturation systems saturates the entire liver with concentrated doses of chemotherapeutic agents, thereby treating the whole liver, including both visible and invisible (micro-metastases) tumors. Unlike traditional systemic chemotherapy, our system concentrates the chemotherapy primarily on the liver and limits the exposure to healthy tissue in other areas of the body.

The most advanced application for which the Delcath chemosaturation system was evaluated is treatment of metastatic melanoma in the liver. The Delcath chemosaturation system isolates the liver from the patient's general circulatory system, allowing for the administration of high and concentrated doses of chemotherapeutic drugs directly to the isolated liver. The Delcath chemosaturation 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 the chemotherapeutic agents 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. During our clinical trials, the procedure typically took approximately two to three hours. Patients remained in the intensive care unit overnight for observation after undergoing treatment with the Delcath chemosaturation system. Treatment with Delcath's chemosaturation system is a repeatable procedure and during our clinical trials patients received an average of three procedures at approximately four to six week intervals. A new disposable Delcath chemosaturation system is used for each treatment.

The Company believes that the Delcath chemosaturation system allows for significantly higher doses of a chemotherapy agent, currently melphalan, to be delivered to the liver than what would otherwise be possible through conventional intravenous chemotherapy or chemoembolization. As a result, the Company believes that our clinical research will show the treatment effectively reduces the number of cancer cells in the liver and may help to control the disease in the liver, leading to better clinical outcomes. In some cases, the use of the Delcath chemosaturation system could potentially allow for therapies previously unavailable for certain patients. We believe that chemotherapy could also be administered through the Delcath chemosaturation system prior to or 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 in that organ.

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The side effects caused by the drug used in our clinical trials, melphalan, are similar to the side effects associated with delivery of melphalan by traditional methods.

The Delcath chemosaturation system includes the following disposable components:

- Infusion catheter—an arterial infusion catheter used to deliver chemotherapy to the liver.
- Isolation and aspiration catheter—a multi-lumen catheter containing two low-pressure occlusion balloons which are positioned to isolate and capture the blood flow from the liver.
- 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 chemosaturation system's filters and deliver the filtered blood back to the patient.
- Filters—external hemofiltration filters 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.
- In the United States, melphalan hydrochloride for injection will be included with the system.
- In Europe, the system will be sold separately and is intended to be used in conjunction with melphalan hydrochloride which is already commercially available from a third party.

Our Clinical Trials

Our Phase III trial and our multi-arm Phase II trial of the Delcath chemosaturation system with melphalan in patients with liver cancers are summarized below. The Phase III and Phase II clinical trials were subject to the terms and conditions of the Cooperative Research and Development Agreement (CRADA), between the Company and the National Cancer Institute (NCI). The Phase III trial was conducted under an FDA Special Protocol Assessment (SPA) and was conducted at centers throughout the United States. The Delcath chemosaturation system with melphalan was granted Fast Track designation by the FDA. The fast track programs of the FDA are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life threatening conditions and that demonstrate the potential to address unmet medical needs.

Phase III—Melanoma Metastases Trial

In February 2010, the Company concluded a randomized Phase III multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive treatments with melphalan using the Delcath chemosaturation system, or to a control group providing best alternative care. Patients assigned to the Delcath chemosaturation system were eligible to receive up to six cycles of treatment at approximately four to six week intervals. Patients randomized to the control arm were permitted to cross-over into the Delcath arm at radiographic documentation of hepatic disease progression. A majority of the control patients did in fact cross over to the treatment arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, the Company announced that our randomized Phase III clinical trial of the Delcath chemosaturation system with melphalan for patients with unresectable metastatic ocular and cutaneous melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival, or hPFS. An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization (ECCO) and the European Society of Medical Oncology (ESMO) in September, 2011. Comparing treatment with the chemosaturation system with melphalan (the treatment group) to best alternative care (the control group), based on investigator assessment, the statistical analysis revealed that patients in the treatment group had a statistically significant longer median hPFS of 8.0 months compared to 1.6 months in the best alternative care control group. This reflects a 5-fold increase of hPFS over that of the control arm, with less than

half the risk of progression and/or death in the Delcath chemosaturation system with melphalan group compared to the best alternative care control group.

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Phase II Trial

In addition to the Phase III metastatic melanoma clinical trial, the Company also concluded a separate multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), hepatocellular carcinoma (primary liver cancer or HCC), ocular or cutaneous melanoma (eye or skin cancer who have been previously treated with regional therapy using melphalan), and metastatic colorectal adenocarcinoma (mCRC). In the metastatic neuroendocrine (mNET) cohort (n=24), the objective tumor response rate was 70% based upon the investigator's assessment. In the primary liver cancer cohort, there were 9 patients with hepatobiliary origin (five HCC patients and four cholangiocarcimona patients) who received treatment with Delcath's chemosaturation system and the investigators noted positive efficacy signals. In the mCRC cohort, there was inconclusive efficacy due to very advanced disease status (e.g. 5th or 6th line) of the patients.

Other Clinical Trials

We intend to evaluate our CHEMOSAT system with melphalan for use in the treatment of metastatic colorectal cancer (mCRC) and hepatocellular carcinoma (HCC or primary liver cancer) in future clinical trials. In addition, we are currently developing a CHEMOSAT system with the chemotherapeutic agent doxorubicin and intend to evaluate the CHEMOSAT system with doxorubicin for use in the treatment of HCC in new clinical trials in Asia. We intend to initiate certain new clinical trials in these cancers in 2012. We also intend to evaluate a variety of chemotherapeutic agents for use with the Delcath chemosaturation system to treat other liver cancers, as well as other organs and body regions. The Company will need to conduct additional clinical trials in order to maximize the commercial opportunities of the chemosaturation system and, in certain markets including the United States, will need to seek additional approvals for each new indication for our system.

Strategic Alliances and Distribution Partners

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

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

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

Sales and Marketing

European Economic Area

Having obtained the right to affix the CE Mark in Europe, we plan to market and sell the Hepatic CHEMOSAT Delivery System in the EEA. The EEA consists of the 27 member countries of the European Union as well as Lichtenstein, Iceland, and Norway. We intend to focus our initial efforts on seven target markets including Germany, United Kingdom, France, the Netherlands, Italy, Spainand Ireland. We believe these countries represent a majority of the total potential liver cancer market in the EEA countries. We intend to pursue a two-pronged commercialization strategy under which we will directly and indirectly market the Delcath Hepatic CHEMOSAT Delivery System . To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals.. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors. We intend to engage a contract organization to provide Medical Science Liaisons (MSLs) to educate the medical oncologists in the seven target markets.

Under the regulatory scheme in the EEA, the Delcath Hepatic CHEMOSAT Delivery System has received authorization to affix the CE Mark as a device only and Physicians must separately obtain melphalan for use with the CHEMOSAT System. Our ability to market and promote the Delcath Hepatic CHEMOSAT Delivery System is limited to this approved indication. Melphalan is currently approved in 14 member states of the EEA, including the seven markets we are initially targeting.

However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use the Delcath Hepatic CHEMOSAT Delivery System must obtain and use melphalan independently at their discretion.

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United States

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

- surgical oncologists who administer the Delcath chemosaturation system;
- medical oncologists who have initial responsibility for cancer patients; and
- interventional radiologists who are physicians specialized in working with catheter-based systems and who will also administer the Delcath chemosaturation system.

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

Third-Party Reimbursement

In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis and we have engaged a third party to conduct a pricing cost benefit study which we intend to use to support our future filings for reimbursement. Medical devices are typically reimbursed under diagnosis related groups (DRG) as part of a procedure. Prior to obtaining permanent reimbursement codes, in certain jurisdictions, we intend to seek interim reimbursement from existing mechanism that include new technology payment programs as well as existing codes. In most EEA countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

After it is approved by the FDA, the Company will seek to have payors establish policy coverage and payment of the cost of the Delcath chemosaturation system and the associated procedures. In the United States, payors consist of government and private organizations, such as Medicare, Medicaid, private health insurance plans, managed care organizations and other similar entities. The elements necessary for reimbursement for any product are:

- Coding, the “why” and “what” to report when a procedure is performed;
- Coverage, the terms and conditions under which payors will or will not provide payment;
- Payment, the amount of monetary compensation allocated to providers who uses the technology.

It is Delcath’s intention to pursue specific codes that both describe and reflect the value provided by the Delcath chemosaturation system. The Company has retained experts in reimbursement to assist us in developing a strategy to maximize reimbursement for the Delcath chemosaturation system. The Company is compiling data comparing the Delcath chemosaturation system with alternative cancer treatments to prepare an analysis of the relative procedure costs and the expected therapeutic advantages of the Delcath chemosaturation system to support our efforts to secure coding, coverage and payment.

In the United States, following FDA approval the Company intends to apply for a Current Procedural Terminology (CPT) -Category I code. The Company also intends to apply for new ICD-10 (International Statistical Classification of Diseases and Related Health Problems) procedure codes to capture reimbursement for the full procedure of hepatic isolation and chemosaturation. Finally, the Company intends to request new Diagnosis Related Group (DRG) codes based on hospital costs above those of existing DRGs and clinical dissimilarity to other hepatic therapy related procedures in current DRGs. Government-sponsored initiatives to reform healthcare and reduce costs are ongoing in the United States, EEA and other countries. Third-party payors are also increasingly adjusting payment rates, often downwards, and challenging the prices charged for medical products and services. There can be no assurance that the

Delcath chemosaturation system will be covered by third-party payors, that reimbursement will be available, or, if available, that the coverage will be adequate.

Manufacturing and Quality Assurance

The Company assembles, sterilizes and packages the Delcath chemosaturation system at our facility in Queensbury, New York and has established our European headquarters and distribution facility in Galway, Ireland. Delcath currently utilizes contract manufacturers to manufacture some components of the Delcath chemosaturation system. The Delcath chemosaturation system and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and Delcath relies on third-party vendors to perform the sterilization process.

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The Company is committed to providing high quality products to our customers. To honor this commitment, Delcath has implemented updated quality systems and concepts throughout our organization. Delcath's quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. These systems are designed to enable us to satisfy the various international quality system regulations including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization (ISO) with respect to products sold in the EEA. The Company is required to maintain ISO 13485 certification for medical devices to be sold in the EEA, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. On February 17, 2011, the Company announced that it had achieved ISO 13485 certification for our Queensbury manufacturing facility. On December 28, 2011, the Company announced that it had achieved ISO 13485 certification for our Galway, Ireland facility.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. The Company believes that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. Delcath also believes that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors. The Company believes the current global economic conditions and potential healthcare reforms could put competitive pressure on us including reduced selling prices and potential reimbursement rates, overall procedure rates, and market sizes.

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

Regulatory Environment

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

European Regulation

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

In the EEA, the Delcath Hepatic CHEMOSAT Delivery System is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the European Union and Norway, Iceland and Liechtenstein. Under the EU

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

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

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The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments. For Class III medical devices, such as the Delcath chemosaturation system, before issuing a certification indicating compliance with the essential requirements, a Notified Body will typically audit a manufacturer's quality system for the design, manufacture, and final inspection of the medical devices, and examine the specific design dossier of the products covered by the conformity assessment. Based on this certification, manufacturers can complete an EC Declaration of Conformity which allows them to affix the CE mark to their products.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

On April 13, 2011, we obtained the required certification from Lloyd's Register Quality Assurance (LRQA), a UK notified body, for the Delcath Hepatic CHEMOSAT Delivery System with the following labeled indication: intra-arterial administration of the chemotherapeutic agent melphalan hydrochloride to the liver with additional extracorporeal flirtation of the venous blood return. Based on this certification, we can complete an EC Declaration of Conformity and affix the CE mark to the Delcath Hepatic CHEMOSAT Delivery System. We have filed an application seeking CE Marking for Generation 2 of the CHEMOSAT system as an amendment to the original approved CE Mark for CHEMOSAT system and the application is currently under review with LRQA. Although the Delcath Hepatic CHEMOSAT Delivery System is CE marked, the provisions of the EU Medical Devices Directive are implemented into the national laws of the Member States of the European Union, which may impose additional conditions on the commercialization of medical devices within their territory, including, for example, language used on the device's labeling. These Member State national laws are enforced by the respective competent authorities of each Member State, which may differ on the interpretation of the provisions of the EU Medical Device Directive as implemented into their national laws. Therefore, complying with the regulations of one Member State does not automatically ensure compliance in other Member States.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the European Union must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action (FSCA). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath Hepatic CHEMOSAT Delivery System and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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The European Commission is currently reviewing the medical devices legislative framework with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. These adopted or expected regulatory changes may adversely affect our business, financial condition and results of operations or restrict our operations.

Other International Regulations

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

United States Regulation

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act (FFDCA), and its implementing regulations. The Delcath chemosaturation system is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Delcath chemosaturation system, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research (CDER), has primary jurisdiction over its pre-market development and review. The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA,

unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials.

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Clinical Trials. For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase I Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- Phase II Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.
- Phase III Clinical Trials. These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- Phase IV Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase IV clinical trials.

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

New Drug Applications. The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which is may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy (REMS) that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

In December 2010, we submitted our NDA for the Delcath chemosaturation system under Section 505(b)(2) of the FFDCA seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products, such as melphalan. Melphalan, the drug we are initially seeking to have approved for use with the Delcath chemosaturation system, is a widely used chemotherapy agent that has already been approved by the FDA for use at a lower dose than we used in our Phase III clinical trial. The approved labeling for melphalan includes indications for use, method of action, dosing, side effects and contraindications. Because the Delcath chemosaturation system delivers the drug through a different mode of administration and at a dose strength that is substantially higher than that which is currently approved, we will be seeking a revised label of melphalan for use with the Delcath chemosaturation system through its Section 505(b)(2) NDA. The clinical trials were designed to provide the necessary clinical data to support this required labeling change.

In accordance with applicable regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission. The FDA will issue a Refusal to File letter, or RTF, if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue.

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In February 2011, we received an RTF from the FDA for the NDA. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. On January 12, 2012, we held a pre-NDA meeting with the FDA to discuss our NDA submission and provide an update on the items identified in the RTF. Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission. Accordingly, we will continue with the preparation of our NDA submission as planned and expect to make the submission in the second quarter of 2012.

Upon resubmission of our application, the FDA will again perform an initial review to assess whether the NDA is sufficiently complete to warrant a substantive review. If the FDA agrees to formally file the application, it will issue a Prescription Drug User Fee Act, or PDUFA, action date. If the drug is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs for the condition, the sponsor may be subject to a Fast Track designation. The Fast Track program is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Under the program, the sponsor of a new drug may request that the FDA designate the drug for a specific indication as a fast track product concurrent with or after the IND is filed for the product candidate, and the FDA must determine if the product qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The Delcath chemosaturation system has received a Fast Track designation. A drug that receives Fast Track designation may be eligible for more frequent meetings with FDA to discuss the drug's development; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials; eligibility for accelerated approval, i.e., approval of an effect on a surrogate, or substitute endpoint; and rolling review, meaning the sponsor may submit its NDA in sections rather than wait until the entire NDA is complete, among others. Most drugs with Fast Track designation are likely to be considered appropriate to receive a Priority Review. In 1992, under PDUFA, the FDA created a two-tiered system of review times – Standard Review and Priority Review. Standard Review is applied to a drug that offers at most, only minor improvement over existing marketed therapies with a goal of completing the FDA review of the NDA within a ten-month time frame. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a new drug application is reduced. The goal for completing a Priority Review is six months. We intend to request a Priority Review in our resubmitted NDA to the FDA. We cannot guarantee that our application for approval of the Delcath chemosaturation system will receive a Priority Review, or that if Priority Review is received, that the review or approval will be faster than conventional FDA procedures or that FDA will ultimately grant approval.

Orphan Drug Exclusivity. Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in

either a commercial or investigational setting. The FDA has granted Delcath four orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. If the Delcath chemosaturation system is approved for an indication different than the indications for which we have received orphan drug designations, we will not obtain orphan drug exclusivity.

Other Regulatory Requirements. Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. The Delcath chemosaturation system, if approved by the FDA, may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw approval of the NDA for that product.

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The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Thus, we may only market the Delcath chemosaturation system, if approved by the FDA, for its approved indications and we could be subject to enforcement action for any off-label marketing.

Intellectual Property and Other Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with bringing new products through the development and regulatory approval process, the health care industry places considerable emphasis on obtaining patent and trade secret protection for new technologies, products and processes. The Company holds seven United States patents, as well as ten foreign patents and four pending patent applications. When appropriate, the Company intends to seek protection of our products and proprietary information by means of U.S. and international patents and trademarks.

Delcath plans to enforce its intellectual property rights vigorously. In addition, the Company conducts searches and other activities relating to the protection of existing patents and the filing of new applications. Delcath seeks to patent improvements that we identify through research and development, manufacturing and clinical use of the Delcath chemosaturation system which allow us to expand the use of the Delcath chemosaturation system beyond the treatment of cancers in the liver. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

Certain of our United States and foreign patents have already expired and other patents relating to the Delcath chemosaturation system will expire in 2012 and 2016. In certain circumstances, United States patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. The Company intends to seek extension for one of our patents after FDA approval. Delcath also relies on trade secrets and proprietary technological experience. The Company relies, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

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

system in the United States.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against Delcath, the Company may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, Delcath may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

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Employees

As of December 31, 2011, the Company had 80 full-time employees. None of our employees is represented by a union and we believe relationships with our employees are good.

Available Information

Delcath maintains a website at www.delcath.com. The Company makes available, free of charge on our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after the Company electronically files those reports with, or furnishes them to, the Securities and Exchange Commission, or the SEC. The Company is not including the information contained at www.delcath.com or at any other internet address as part of, or incorporating by reference into, this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risks Related to Our Business and Financial Condition

If we are unable to develop the Delcath chemosaturation system, obtain regulatory approval outside the EEA or market and sell the system, we will not generate operating revenue or become profitable.

The Delcath chemosaturation 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, is our only product. Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of this product and currently we have only developed this system for the treatment of cancers in the liver with melphalan. If the Delcath chemosaturation system with melphalan fails as a commercial product, we have no other products to sell. In addition, since the Delcath Hepatic CHEMOSAT Delivery System is currently only authorized for marketing in the EEA, if we are unsuccessful in commercializing the product in the EEA and the Delcath chemosaturation system is not approved in the United States and elsewhere, we will have no other means of generating revenue.

Continuing losses may exhaust our capital resources.

As of December 31, 2011, we had $30.8 million in cash, cash equivalents and certificates of deposit. We have had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow. We expect to continue to incur losses while generating minimal revenues over the next year. From our inception on August 5, 1988 through December 31, 2011, we have incurred cumulative net losses of approximately $145.4 million. For the years ended December 31, 2011, 2010, and 2009, we incurred net losses of approximately $30.9 million, $46.7 million, and $22.1 million, respectively, with these amounts being effected by derivative accounting related to warrants as described in our Annual Reports on Form 10-K for the years ended December 31, 2011, 2010, and 2009. To date, we have funded our operations through a combination of private placements and public offerings of our securities. 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, regulatory approval process and commercialization of the Delcath chemosaturation system with melphalan or any other versions of the system.

If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to commercialize the Delcath chemosaturation system, resubmit our NDA to the FDA or conduct future development and clinical trials.

We may require additional financing to commercialize our product in the EEA and any other markets where we receive approval for our system, to resubmit our NDA seeking U.S. marketing approval or seek other approvals and to conduct future development and clinical trials. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to able to commercialize the Delcath chemosaturation system commercially, obtain regulatory approvals or complete our

development projects or our clinical trials.

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 U.S. and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution 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.

Insufficient funds may require us to curtail or stop our commercialization activities, submissions for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

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Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

The Delcath chemosaturation system is subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath chemosaturation system is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Delcath chemosaturation system, the primary mode of action is attributable to the drug component of the product, which means that the CDER has primary jurisdiction over its pre-market development and review.

We are not permitted to market the Delcath chemosaturation system in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is ten months for a standard application and six months for a priority review application. The FDA's review goals are subject to change and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA's

review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted to FDA around the same time period. The development and approval process may take many years, require substantial resources and may never lead to the approval of a product. Failure to obtain or delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current Delcath chemosaturation system or any products that we develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have obtained the right to affix the CE Mark for the Delcath Hepatic CHEMOSAT Delivery System as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with the Delcath Hepatic CHEMOSAT Delivery System , our ability to commercialize the Delcath Hepatic CHEMOSAT Delivery System in the EEA will be significantly limited.

In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. To the extent that our promotion of the Delcath chemosaturation system is found to be outside the scope of our approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize the Delcath chemosaturation system in the EEA.

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Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable melphalan label with respect to some indications in some Member States of the EEA where the drug is authorized for marketing. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath CHEMOSAT system and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from our product and/or to prescribe the use of melphalan independently, our sales opportunities in the EEA will be significantly impaired.

While we have obtained the right to affix the CE Mark, we will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where we receive marketing authorization or approval. In April 2011, we obtained the required certification from our European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Delcath Hepatic CHEMOSAT Delivery System. In order to maintain the right to affix the CE Mark in the EEA, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we will be subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Delcath Hepatic CHEMOSAT Delivery System m may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that the Delcath chemosaturation system is approved by the FDA or any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where we obtain approval. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that we conduct post-approval. In addition, post-marketing requirements for the Delcath chemosaturation system may include implementation of a REMS to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;

- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States may take many years, require substantial resources and may never lead to the approval of the Delcath chemosaturation system by the FDA for use in the United States.

We cannot sell or market the Delcath chemosaturation system with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for the Delcath chemosaturation system. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agent used in our system. We are seeking approval of the Delcath chemosaturation system for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for the Delcath chemosaturation system with melphalan and every other chemotherapeutic agent or other compound used with our system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of the Delcath chemosaturation system with melphalan or any other chemotherapeutic agent or compound we use in our system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of melphalan or other chemotherapeutic agents, the value of our company and our results of operations will be harmed.

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In December 2010, we submitted our Section 505(b)(2) NDA to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. An NDA submitted under Section 505(b)(2) of the FFDCA permits the application to incorporate information required for approval from studies not conducted by or for the application and for which the applicant has not obtained a right of reference. Our Section 505(b)(2) application cited the safety information for melphalan submitted by prior NDA applicants for this drug. In February 2011, we received an RTF from the FDA for the NDA. In accordance with applicable regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission. The FDA will issue an RTF if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. On January 12, 2012, we held a pre-NDA meeting with the FDA to discuss our NDA submission and provide an update on the items identified in the RTF. Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission. Accordingly, we will continue with the preparation of our NDA submission as planned and expect to make the submission in the second quarter of 2012. If we are unable to properly address the issues raised in the RTF to the FDA's satisfaction, we may be unable to resubmit our NDA to the FDA. Further, if we resubmit the NDA and subsequently receive a second RTF from the FDA, or, if it is accepted for filing and the FDA fails to approve the application after a substantive review, we will not be able to commercialize the Delcath chemosaturation system in the United States and our value and our results of operations will be harmed.

Even if we obtain regulatory approval for the Delcath chemosaturation system in the United States, our ability to market the Delcath chemosaturation system would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. In the United States, we intend to seek approval for use of the Delcath chemosaturation system with melphalan in the treatment of ocular and cutaneous melanoma that has metastasized to the liver. If the FDA approves this application, our ability to market and promote the Delcath chemosaturation system would be limited to this indication for use only with melphalan in treating that specific disease, so even with FDA approval, the Delcath chemosaturation system may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, including oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market the Delcath chemosaturation system, if approved by the FDA, for its approved indication and we could be subject to enforcement action for off-label marketing.

Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

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If we do not obtain required approvals in the United States and in the countries outside of the EEA in which we aim to market the Delcath chemosaturation system, we may not be able to export or sell the Delcath chemosaturation system in those markets, which will limit our sales opportunities.

We intend to leverage our CE Mark to obtain required regulatory approvals for the Delcath Hepatic CHEMOSAT Delivery System in other parts of the world, including Asia. However, our lack of experience conducting clinical trials outside the United States may negatively impact the approval process in foreign countries where we intend to seek approval for the Delcath chemosaturation system. We have not previously conducted multi-national clinical trials, and, particularly in countries where melphalan has not yet been approved, obtaining approval for the Delcath chemosaturation system may be challenging.

If we are unable to obtain and maintain required approval from one or more foreign countries outside of the EEA where we would like to sell the Delcath chemosaturation system, we will be unable to market our product as intended, our international market opportunity will be limited and the value of our company and our results of operations will be harmed.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market the Delcath chemosaturation system for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, we concluded a Phase III clinical trial of the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic melanoma stratified into four arms. We currently have no clinical trials on any other major forms of liver cancer.

We intend to conduct clinical trials for other indications, and it may take several years to complete the testing of the Delcath chemosaturation system with melphalan, doxorubicin or other chemotherapeutic agents for use in the treatment of the indications we wish to obtain approval of, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase III trial, relating to our NDA submissions;
- the FDA or foreign regulatory authorities may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an application for marketing approval or cause us to cease the development of the Delcath chemosaturation system for other indications. If we are unable to develop the Delcath chemosaturation system for other indications the future growth of our business could be negatively impacted.

While we have received approval of our clinical trial protocol from the FDA under a SPA, our failure to execute the clinical trial according to the agreed upon trial protocol may result in loss of FDA approval and invalidation of our clinical trials.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the design, execution, and analysis under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. Pursuant to the FDA's guidance on SPAs, a SPA is documented in a SPA letter and/or the minutes of a Type A meeting. We conducted our Phase III trial under a SPA. The SPA may be invalidated for a number of reasons including our failure to execute the clinical trial according to the agreed upon trial protocol. While we believe our SPA is currently valid, our failure to execute the clinical trial according to the agreed upon trial procedures, or the FDA's identification of a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins, may lead to the invalidation of the SPA, and as a result, the trial itself may not be sufficient to serve as the primary basis of an effectiveness claim.

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We rely on third parties to conduct certain of the clinical trials for the Delcath chemosaturation system, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for the Delcath chemosaturation system, but we rely on academic institutions, corporate partners, contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. In particular, we relied on a third party to conduct monitoring of our Phase II and Phase III clinical trials and collect the data for our planned resubmission of an NDA. We intend to rely upon third parties to conduct monitoring and data collection of our future clinical trials. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements, and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and we may fail to obtain regulatory approval for the Delcath chemosaturation system if these requirements are not met.

Purchasers of the Delcath Hepatic CHEMOSAT Delivery System in the EEA may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, we may not be able to successfully commercialize the Delcath Hepatic CHEMOSAT Delivery System in the EEA. We have obtained the right to affix the CE Mark for the Delcath Hepatic CHEMOSAT Delivery System , and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell the Delcath CHEMOSAT. Until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that we will qualify for such funding. Even if we do qualify, the amount and the duration of this funding may be limited. There are also no assurances that third-party payors or government health agencies of members states of the EEA will reimburse the product's use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase the Delcath CHEMOSAT System if they do not receive substantial reimbursement for the cost of using our product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

As the Delcath chemosaturation system is not currently approved by the FDA or other regulatory bodies outside the EEA, Australia or New Zealand, third-party payors in the United States and elsewhere will not reimburse the use of our product. Even if approval is obtained, inadequate reimbursement may harm results of operations.

The Delcath chemosaturation system is currently not approved by the FDA or any other regulatory body outside the EEA, Australia or New Zealand. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the Delcath chemosaturation system's use since the product is currently not approved outside the EEA, Australia or New Zealand. We will seek reimbursement by third-party payors of the cost of the Delcath chemosaturation system after its use is approved, but there are no assurances that third-party payors in the United States or other countries will agree to cover the cost of procedures using the Delcath chemosaturation system at all or at rates that are adequate to cover the actual costs. Further, third-party payors may deny reimbursement if they

determine that the Delcath chemosaturation system is not used in accordance with established payor protocols regarding cost effective treatment methods or is used outside its approved indication or for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals and other health care providers will be less likely to purchase the Delcath chemosaturation system, thereby harming our results of operations.

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

There is only one approved third-party manufacturer of melphalan in the EEA. If this manufacturer fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the EEA.

Under the regulatory scheme in the EEA, the Delcath Hepatic CHEMOSAT Delivery System is approved for marketing as a device only, and doctors will separately obtain melphalan for use with the Delcath CHEMOSAT system. Although melphalan has been approved in the EEA for over a decade, we are aware that there is currently only one approved manufacturer of melphalan in the EEA, with whom we have no supply arrangements or other affiliation, and therefore we will not have any control over the quality, availability, price or labeling of melphalan in that market. As a result, there may not be sufficient supply of melphalan for use with our system, and any adverse change in the sole manufacturer’s commercial operations or regulatory approval status may seriously impair our sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where we intend to market the Delcath CHEMOSAT system. If supply of melphalan remains limited or unavailable, we will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

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We purchase components for the Delcath chemosaturation system from third parties, some of which are sole-source suppliers.

The components of the Delcath system, including catheters, filters, introducers and chemotherapy agents, must be manufactured and assembled in accordance with approved manufacturing and predetermined performance specifications and must meet cGMP and quality systems requirements. Some states also have similar regulations. Many of the components of the Delcath chemosaturation system are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If Delcath or any of our suppliers fails 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 chemosaturation system, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply the Delcath chemosaturation system to the market.

All of the manufacturers of the components for the Delcath chemosaturation system must comply with a number of FDA and International Organization for Standardization, or ISO, and foreign regulatory agency requirements and regulations. If we or one of our suppliers fails to meet such requirements, we may need to change suppliers. If we are unable to successfully change suppliers, the successful completion of some of our future clinical trials and/or commercialization of the Delcath chemosaturation system could be jeopardized.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize the Delcath system in the United States.

We have entered into a manufacturing and supply agreement with Synerx Pharma, LLC, or Synerx, and Bioniche Teoranta, or Bioniche, an affiliate of Mylan, Inc., for the supply of our branded melphalan for injection. The agreement with Synerx and Bioniche currently represents our sole source of branded melphalan in the United States. We intend to pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that we will use in the future for the commercialization of the Delcath chemosaturation system, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. To manufacture melphalan or other chemotherapeutic agents on our own, we would first have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture the Delcath chemosaturation system, our ability to develop and commercialize the system would be impaired.

We will manufacture the Delcath chemosaturation system for distribution in the EEA in our Queensbury, NY facility. We have a limited manufacturing history and we may not be able to manufacture the system in commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver the Delcath chemosaturation system to purchasers.

In addition to limiting sales opportunities, delays in manufacturing the Delcath chemosaturation system may adversely affect our ability to obtain regulatory approval in other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture the Delcath chemosaturation system in a timely manner, we may not be able to conduct the

clinical trials required to obtain regulatory approval and commercialize our product.

If our Queensbury, NY facility fails to maintain compliance with ISO 13485, a comprehensive management system for the design and manufacture of medical devices, and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble the Delcath chemosaturation system in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

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We do not have written contracts with all of our suppliers for the manufacture of components for the Delcath chemosaturation system.

We do not have written contracts with all our suppliers for the manufacture of components for the Delcath chemosaturation system. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture the system in commercial quantities or in a cost-effective manner, and commercialization of the Delcath chemosaturation system in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of the Delcath chemosaturation 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 or other regulatory agency approval of that supplier, commercialization of the Delcath chemosaturation system may be delayed.

We have limited experience in marketing and commercializing our products, and as a result, we may not be successful in commercializing the Delcath CHEMOSAT System in the EEA.

We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly and indirectly market the Delcath Hepatic CHEMOSAT Delivery System. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize a contract sales organization to provide MSLs to educate the medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors. However, we have not previously sold, marketed or distributed any products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors. Even though we have obtained the right to affix the CE Mark, we currently have limited sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue our strategy to commercialize the Delcath CHEMOSAT system in the EEA, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. 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 CHEMOSAT system, our ability to generate revenues in the EEA 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. Further, since our marketing strategy in the EEA includes establishing a network of third-party distributors, we must enter into collaborative arrangements with these third-party distributors. We may not be able to enter into such arrangements on reasonable terms or at all.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing the Delcath chemosaturation system in markets outside the EEA, because of inadequate infrastructure or an ineffective commercialization strategy.

Outside the EEA, even if we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize the Delcath chemosaturation system may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. In the United States, we intend to develop and train our own sales force to market our products, and in foreign countries other than in the EEA, we intend to market our products primarily through strategic partners and distributors. If we are unable to develop this infrastructure in the United States or to collaborate with an alliance partner to market our products in foreign countries, particularly in Asia, our efforts to commercialize the Delcath chemosaturation system or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing the Delcath chemosaturation system in the EEA, we may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so our EEA strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market the Delcath Hepatic CHEMOSAT Delivery System in each of our target markets may fail in any or all of those markets.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell the Delcath chemosaturation system may not be successful.

We have entered into a collaborative agreement with Chi Fu Trading Company for the country of Taiwan and intend to enter into one or more strategic alliances to further address markets outside the United States, particularly in Asia, and to help fund the development of additional indications or for use with additional chemotherapy agents within the United States. We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in our search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all.

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Our collaborative relationships may never result in the successful development or commercialization of the Delcath chemosaturation system or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration 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 or our collaborators may breach their agreements with us. 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 are not 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 the Delcath chemosaturation system or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Currently we have only received authorization to market the Delcath Hepatic CHEMOSAT Delivery System in the EEA, Australia and New Zealand, and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of our products to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to fulfill foreign regulatory requirements to market our products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;